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CLINICAL RESEARCH ARTICLE

Electrocardiogram for heart rate evaluation during preterm resuscitation at birth: a randomized trial

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BACKGROUND: Although electrocardiogram (ECG) can detect heart rate (HR) faster compared to pulse oximetry, it remains unknown if routine use of ECG for delivery room (DR) resuscitation reduces the time to stabilization in preterm infants.
METHODS: Neonates <31 weeks' gestation were randomized to either an ECG-displayed or an ECG-blinded HR assessment in the DR. HR, oxygen saturation, resuscitation interventions, and clinical outcomes were compared.
RESULTS: During the study period, 51 neonates were enrolled. The mean gestational age in both groups was 28 ± 2 weeks. The time to stabilization, defined as the time from birth to achieve HR ≥100 b.p.m., as well as oxygen saturation within goal range, was not different between the ECG-displayed and the ECG-blinded groups [360 (269, 435) vs 345 (240, 475) s, $p = 1.00$]. There was also no difference in the time to HR ≥100 b.p.m. [100 (75, 228) vs 138 (88, 220) s, $p = 0.40$] or duration of positive pressure ventilation (PPV) [345 (120, 558) vs 196 (150, 273) s, $p = 0.36$]. Clinical outcomes were also similar between groups.
CONCLUSIONS: Although feasible and safe, the use of ECG in the DR during preterm resuscitation did not reduce time to stabilization.

Pediatric Research (2022) 91:1445–1451; https://doi.org/10.1038/s41390-021-01731-z

IMPACT:

- Although feasible and apparently safe, routine use of the ECG in the DR did not decrease time to HR >100 b.p.m., time to stabilization, or use of resuscitation interventions such as PPV for preterm infants <31 weeks' gestational age.
- This article adds to the limited randomized controlled trial evidence regarding the impact of routine use of ECG during preterm resuscitation on DR clinical outcomes.
- Such evidence is important when considering recommendations for routine use of the ECG in the DR worldwide as such a recommendation comes with a significant cost burden.

INTRODUCTION

At birth, a newborn undergoes multiple anatomical and physiological changes to adapt to the extrauterine environment. The majority of preterm infants <31 weeks' gestational age (GA) require some assistance with this transition including support of breathing after birth. Many are bradycardic at birth and require delivery room (DR) resuscitation.[1–4]

The persistence of bradycardia despite the initial steps of stabilization requires positive pressure ventilation (PPV).[5,6] Delay in initiating PPV may result in adverse clinical outcomes. A rising heart rate (HR) is the most important indicator of effective PPV in initially bradycardic newborns.[3] Accurate estimation of HR is essential as it is used throughout neonatal resuscitation to make decisions and determine the effectiveness of the resuscitation efforts.[7] Underestimating HR can lead to interventions when not indicated, such as PPV, intubation, chest compressions, or epinephrine, and may cause harm. On the other hand, overestimation of HR may result in a delay of necessary critical interventions such as PPV, may increase the duration of true bradycardia, and potentially contribute to adverse outcomes. Multiple studies have shown that the intensity of DR resuscitation is associated with adverse neonatal outcomes.[8–10] Therefore, rapid, continuous, reliable, and accurate HR assessment is critical in the DR.

Traditionally, auscultation in conjunction with pulse oximetry (PO) has been the preferred method for HR assessment during DR resuscitation.[4,11,12] However, clinical assessment of HR by auscultation and/or palpation of umbilical cord pulsations can be variable and inaccurate.[13–16] Several observational studies have shown that PO is slow to pick up a reliable HR and underestimates HR in the first few minutes of life.[17–21] In comparison, recent evidence suggests that three lead electrocardiogram (ECG) is much faster and accurate in measuring HR in the DR.[14,18–20,22–25]

ECG is the gold standard for HR assessment in the neonatal intensive care unit (NICU), but its routine use during all DR resuscitations is not mandatory. Current International Liaison Committee on Resuscitation recommendations suggest using ECG

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Received: 30 April 2021 Revised: 18 August 2021 Accepted: 24 August 2021
Published online: 13 October 2021

for HR assessment if available during DR resuscitation and strongly recommend it if a newborn needs chest compressions.[3] Multiple knowledge gaps exist regarding the routine use of ECG during preterm resuscitation in the DR. The majority of studies comparing PO with ECG for HR assessment during DR resuscitation are observational and focused on term infants who did not need significant resuscitation in the DR.[17–20] Concern has been raised that routine use of ECG for HR determination during preterm resuscitation may not be feasible, as the leads may not properly stick to the fragile preterm skin. In addition, if the plastic wrap used for thermoregulation is being repeatedly undone to reposition the ECG leads, the risk of hypothermia can increase. Furthermore, if there is a poor signal or erroneous ECG signal, the resuscitation team may get distracted and inadvertently delay necessary interventions. On the other hand, transient bradycardia right after birth may be reflective of the timing of cord clamping, and it remains unclear if acting on this information will increase interventions such as PPV in the DR.[7] A recent observational study showed that ECG used in the DR was associated with lower rates of endotracheal intubations and increased use of chest compressions in the DR without any change in mortality or other neonatal morbidities.[11] However, it can be hypothesized that appropriate use of the ECG during preterm resuscitation can result in prevention of delay in necessary interventions such as PPV by early and accurate recognition of bradycardia. This, in turn, may result in the decreased duration of bradycardia and time to stabilization (HR ≥ 100 b.p.m. and oxygen saturation (SpO_2) within the target range) in preterm infants. There is an urgent need for more robust clinical randomized controlled trial evidence of the impact of routine use of ECG on resuscitation interventions and outcomes in preterm infants.

The objectives of the current study were to test the feasibility and effectiveness of using ECG for HR assessment in high-risk preterm infants who require resuscitation. Our primary hypothesis was that the routine DR use of the ECG in preterm infants <31 weeks' gestation would decrease the time to stabilization in these neonates by 30%.

METHODS

Study population

This study was a prospective randomized controlled trial conducted from June 2017 and March 2018 at Parkland Hospital, Dallas, Texas. The study was approved by the University of Texas Southwestern Medical Center institutional review board. This trial has been registered with ClinicalTrials.gov (Identifier: NCT03133663). Because the DR interventions in both treatment arms were consistent with the 2015 Neonatal Resuscitation Program (NRP) guidelines[3] and because there was an equipoise regarding the two treatment arms, the International Review Board permitted the trial to proceed without antenatal consent as long as parental informed consent was subsequently obtained postnatally as soon as feasible.

All inborn neonates of obstetrical GA 23 0/7 to 30 6/7 weeks for whom the high-risk resuscitation team was present at birth and who required active resuscitation were included. Active resuscitation was defined as continuous positive airway pressure (CPAP) or PPV. Neonates were excluded for nonviability or if no active resuscitation was required. Multiple gestations were assigned randomly according to the individual neonate.

Randomization

A non-investigator used permuted design in blocks of six to determine the randomization sequence. Allocation was concealed via serially numbered, sealed, opaque envelopes that were opened sequentially by the resuscitation team when the need for resuscitation was recognized. Infants were randomized into either an ECG-displayed arm or an ECG-blinded arm.

The ECG-blinded and the ECG-displayed arms

Before delivery of the infant, the neonatal nurse connected three ECG lead wires (Red Dot, 3M, St. Paul, MN) to the Philips Intellivue MX700 monitor (Philips, Amsterdam, Netherlands). Radical oximeters (Masimo Corporation, Irvine, CA) were set to maximal sensitivity and 2 s averaging. The cord was immediately clamped after delivery and the infant was brought to radiant warmer, in accordance with the Parkland Hospital policy at that time. The infant was placed in a polyurethane bag. The bag was briefly moved to wipe the chest. A resuscitation nurse placed three ECG leads as soon as possible over the infant's chest. PO sensor was applied to the right wrist/hand before it was connected to the PO. The research protocol recommended having the ECG leads and the PO sensors applied as soon as possible after birth. In the ECG-displayed arm, HR monitors and auscultation were available for HR assessment. In the ECG-blinded arm (control arm), an opaque cover was placed over the ECG monitor, and the sound was muted. Only auscultation in conjunction with PO was used to assess HR in the control arm as an ECG signal was not available to the clinical team. The PO was used to monitor SpO_2 in both groups.

Resuscitation management

Apart from the randomized strategy for the assessment of HR, resuscitation followed 2015 NRP guidelines.[3] Resuscitation of all newborns started with 21% oxygen and a fraction of inspired oxygen was adjusted every 30 s to meet NRP recommended goal SpO_2. If chest compressions were needed, the plan was to remove the cover over the ECG monitor as ECG is recommended for HR assessment in newborns requiring chest compressions as per the NRP guidelines.

Data collection

Baseline maternal and infant characteristics, resuscitation details, and morbidity and mortality data were collected. Data were obtained from the electronic medical records, the Parkland Neonatal Resuscitation Registry, and the Parkland NICU database, which collects data on all neonates admitted to the NICU prospectively. HR from the ECG (HR_{ECG}) was downloaded from Philips MX700 monitors. The monitor calculates the HR by averaging the 12 most recent RR intervals. The HR from the PO (HR_{PO}) SpO_2 and perfusion index (PI) were downloaded as per the PO manufacturer's instructions. Resuscitation interventions and physiologic responses were manually recorded in real-time by a nurse as per the routine practice at Parkland Hospital. The time of birth and the time to warmer were recorded. The time it took to apply ECG leads and PO sensor and the time when the first HR was visible were also recorded. After NICU admission, all care decisions were at the discretion of the primary clinical team receiving the infant. The resuscitation details were reviewed throughout the study period for adherence to the study protocols and the NRP guidelines. The resuscitation nurses were asked to record if they encountered any difficulty with the ECG leads in the DR.

Outcomes

The primary outcome was time to stabilization, which was defined as the time it takes from birth for HR to be >100 b.p.m. and SpO_2 to be in the goal range. To calculate the time from birth to achieve goal SpO_2, an infant had to achieve a pre-ductal SpO_2 value that was within the goal range as defined by the NRP guidelines and had to stay within the goal for > 1 min. Secondary outcomes defined a priori included the time to HR > 100 b.p.m., the time to first reliable visible HR, use of PPV, and duration of PPV. The time to ECG lead placement, the time to PO sensor placement, and the time to first visible HR were calculated from the time infant was placed in the resuscitation warmer. All other outcomes were timed from birth. The resuscitation outcomes, short-term clinical outcomes, and in-hospital mortality were compared between the two arms. The integrated excessive inspired O_2 for the first 10 min of life was calculated using the formula $\Sigma[F_iO_2 - 0.21] \times$ time [min] as previously described.[26] The Eunice Kennedy Shriver National Institute of Child Health and Human Development expert panel definition for chorioamnionitis was used.[27] Antenatal magnesium is given for neuroprotection to all neonates born preterm at <28 weeks GA. Intrauterine growth retardation was defined by Ponderal index <10th percentile for GA. Respiratory distress syndrome was recorded if the clinician documented this morbidity in the infant's electronic medical record. Bronchopulmonary dysplasia was defined as the need for supplemental oxygen at 36 weeks' postmenstrual age.[28,29] Intraventricular hemorrhage was defined as grade III or greater on any ultrasound scans of the head unilaterally or bilaterally as per the Papile criteria.[30] Severe retinopathy of prematurity was defined as stage 3 or greater based on the international classification.[31] Necrotizing enterocolitis was defined as ≥stage 2 based on the modified Bell criteria.[32]

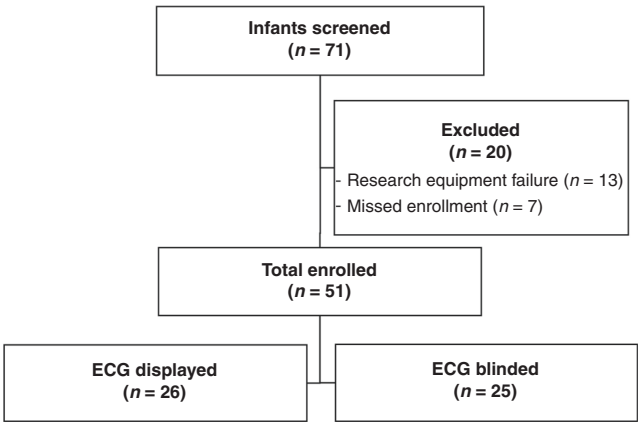

Fig. 1 Flow diagram. Study flow diagram shows screening of eligible infants, enrollment, and randomization.

Table 1. Maternal and infant characteristics.

Characteristics	ECG displayed (*N* = 26)	Control (*N* = 25)	*P* value
Maternal			
Age, mean ± SD, years	30 ± 7	27 ± 8	NS
Antenatal steroids	21 (81)	23 (92)	NS
Chorioamnionitis	3 (12)	1 (4)	NS
Gestational diabetes	5 (19)	1 (4)	NS
Pregnancy-induced hypertension	13 (50)	12 (48)	NS
Antenatal magnesium	18 (69)	15 (60)	NS
Multiple gestations	6 (23)	8 (32)	NS
Non-reassuring fetal heart tones	4 (15)	7 (28)	NS
Abruption	3 (12)	4 (16)	NS
Cesarean section	19 (73)	21 (84)	NS
Emergent cesarean section	4 (21)	6 (29)	NS
Infant			
Gestational age (weeks), mean ± SD	28 ± 2	28 ± 2	NS
Birth weight (g), mean ± SD	1184 ± 353	1071 ± 337	NS
Female	11 (42)	18 (72)	0.03
Intrauterine growth retardation	1 (4)	1 (4)	NS
Cord pH, median (25th quartile, 75th quartile)	7.27 (7.25, 7.28)	7.24 (7.20, 7.31)	NS
Cord BE, median (25th quartile, 75th quartile)	−5.1 (−6.0, −4.2)	−5.9 (−9.5, −3.0)	NS

Unless otherwise noted, data are presented as *n* (%).
NS not significant, which is $p > 0.05$.

To compare the accuracy of HR assessment by PO during preterm resuscitation in the DR, paired data of HR_{PO} and HR_{ECG} were analyzed for each infant irrespective of group assignment, strictly as secondary analysis.

Statistical analysis

Statistical analyses were conducted by using SAS version 9.2 (SAS Institute, Cary, NC). Demographics, antenatal and perinatal variables of interest, resuscitation characteristics, and short-term clinical outcomes were compared between the ECG-displayed and the ECG-blinded groups. Normally distributed variables were compared by using Student's *t* test. Nonparametric variables were compared using Mann–Whitney rank-sum tests. The HR data were compared at every 24 s interval using linear mixed-model repeated-measures analysis, which included factors to assess group, time, and group-by-time interaction. The relationship between HR_{PO} and HR_{ECG} was evaluated using the Bland–Altman bias analysis. The difference between the measurements was plotted against their average. Two standard deviations around the mean difference represented the upper and lower limits of the agreement.

Preliminary data obtained from the Parkland Neonatal Resuscitation Registry showed that the mean time to stabilization in infants <31 weeks gestation was 360 ± 128 s. Based on this preliminary data, to detect a 30% change in the time to stabilization, 24 infants were needed for each arm using a two-sided α level of 0.05 and power of 0.8. To accommodate a 5% loss of subjects, the plan was to enroll 25 infants in each group.

RESULTS

Eligible neonates, comprising those enrolled and randomized to ECG-displayed ($n = 26$) and ECG-blinded arms ($n = 25$), are shown in Fig. 1. In the ECG-displayed arm, 11 infants were <28 weeks' GA and 15 infants ≥28 weeks' GA. In the ECG-blinded arm, 10 infants were <28 weeks' GA and 15 infants ≥28 weeks' GA. Neonates in both arms had similar maternal and baseline neonatal characteristics, except the ECG-blinded group had more female newborns (Table 1). Mean GA for neonates in both arms was 28 weeks.

DR HR and SpO_2 (Table 2)

Neonates in both groups were brought to the radiant warmer after birth at a similar time. The time to place the ECG leads and the PO sensors were similar as well. There was no reported difficulty with the application of ECG leads to the preterm newborn. Time to first visible HR and time to HR ≥100 b.p.m. were not different between groups. When analyzed for only those infants who were bradycardic at birth, time to HR ≥100 b.p.m. remained similar between groups. There was no difference between the median HR_{ECG} and HR_{PO} for the first 10 min of life (Fig. 2 online). Similarly, the time to goal SpO_2, the time spent outside the goal SpO_2 range, and the number of infants with SpO_2 < 80% at 5 min were not different between groups (Fig. 3 online) For the primary outcome of the study, time to stabilization was not different between the ECG-displayed and ECG-blinded groups [360 (269, 435) vs 345 (240, 475), $p > 0.05$].

DR resuscitation interventions (Table 2)

Both groups had similar integrated excessive inspired O_2 for the first 10 min. A similar number of neonates received PPV, CPAP, and intubation in both groups. The time to start PPV and the total duration of PPV were similar as well. One infant in the ECG-displayed group and three infants in the ECG-blinded group experienced a delay of 30 s in the initiation of PPV. None of the neonates enrolled in the trial required chest compressions or epinephrine in the DR. None of the infants in the ECG-blinded group required removal of the cover over the ECG monitor during DR resuscitation.

Clinical outcomes (Table 3)

There was no difference in the rectal temperature after stabilization. Admission blood gas parameters and the ventilator support were similar between groups. ECG-displayed and control arm neonates had similar rates of respiratory distress syndrome and bronchopulmonary dysplasia. Days on a ventilator, CPAP levels, and oxygen were similar between both the groups. Rates of intraventricular hemorrhage, necrotizing enterocolitis, severe retinopathy of prematurity, and in-hospital mortality were similar as well. Neonates in the ECG-displayed and the ECG-blinded groups had similar lengths of NICU stay.

Table 2. Resuscitation and delivery room characteristics.

Characteristics	ECG displayed ($N = 26$)	Control ($N = 25$)	P value
HR during resuscitation			
Time to warmer	22 (17, 25)	18 (16, 23)	0.67
Time to ECG lead placed[‡]	37 (20, 56)	37 (16, 72)	0.54
Time to PO sensor placed[‡]	29 (17, 37)	31 (17, 51)	0.88
Time to first visible HR[‡]	64 (52, 85) (ECG)	75 (56, 134) (PO)	0.13
Time to ECG HR ≥ 100	100 (75, 228)	138 (88, 220)	0.40
Number of infants with bradycardia at birth, *n* (%)	14 (54)	13 (52)	0.88
Time to ECG HR ≥ 100 in bradycardic neonates, mean ± SD	210 ± 104	211 ± 107	0.98
SpO_2 during resuscitation			
Time to goal SpO_2 from birth	355 (269, 435)	345 (240, 475)	0.97
Time spent below goal SpO_2	360 (258, 435)	270 (225, 350)	0.07
Time spent above goal SpO_2	65 (0, 120)	82 (35, 198)	0.15
SpO_2 < 80% at 5 min, *n* (%)	11 (42)	10 (40)	0.91
Time to stabilization from birth	360 (269, 435)	345 (240, 475)	1.00
Resuscitation interventions			
Integrated excessive inspired O_2	2.2 (0.8, 3.9)	1.7 (0.8, 3.1)	0.47
Positive pressure ventilation (PPV), *n* (%)	17 (65)	19 (76)	0.60
Time to start PPV	36 (25, 45)	38 (23, 78)	0.54
Total duration of PPV	345 (120, 558)	196 (150, 273)	0.37
Delayed PPV, *n* (%)	1 (4)	3 (12)	0.57
Continuous positive airway pressure only, *n* (%)	9 (35)	6 (24)	0.60
Intubation, *n* (%)	9 (35)	5 (20)	0.39
Chest compressions, *n* (%)	0 (0)	0 (0)	NS
Rectal temperature after stabilization, mean ± SD	37 ± 0.6	36.8 ± 0.7	0.87
Rectal temperature 36–36.5, *n* (%)	0 (0)	5 (20)	NS
Rectal temperature <36, *n* (%)	2 (8)	0 (0)	NS

Unless otherwise noted, data are presented as median (25th quartile, 75th quartile). All times are presented in seconds. All times are calculated from birth, except the time to ECG leads placed; the time to PO sensor placed is calculated from the placement of infant in warmer.

Comparison of HRPO with HRECG to compare the accuracy of HR estimation during preterm resuscitation in the DR

A secondary analysis was conducted to compare HR estimation by the PO vs the ECG in all enrolled infants irrespective of the randomized group assignment. The mean difference ($HR_{PO} - HR_{ECG}$) was −2 b.p.m., and the 95% limit of agreement was 46 b.p.m., which is more than four times the accepted manufacturer's level of agreement (Fig. 4a online). There was a good linear correlation between the HR_{PO} and the HR_{ECG} (Fig. 4b online). For detecting HR <100 b.p.m., the PO had a positive predictive value of 62% (57–66%) and a negative predictive value of 96% (96–98%). In 27 (53%) infants, in the first few minutes after birth, HR_{PO} was <100 b.p.m., while HR_{ECG} was >100 b.p.m. PI was also analyzed as a possible reason for the underestimation of HR by PO by conducting a paired data analysis of all observations when HR_{PO} was <100 b.p.m. The paired data analysis revealed that the PI was lower when HR_{PO} was falsely positive for bradycardia compared to when the PO and the ECG both identified bradycardia [1.7 (1.3, 2.3) vs 1.9 (1.2, 3.1), $p = 0.03$].

DISCUSSION

In preterm infants <31 weeks' GA, use of the ECG in the DR did not decrease time to stabilization. In addition, routine use of ECG for preterm resuscitation did not decrease the use of resuscitation interventions such as PPV in the DR. Routine use of ECG for preterm resuscitation did not increase the rate of hypothermia or chest compressions in the DR. There were no difficulties in the application or obtaining a useful ECG signal in preterm infants during the first few minutes of life, suggesting that the routine use of the ECG during preterm resuscitation in the DR is feasible and apparently safe.

Katheria et al. published a randomized trial of ECG use in preterm infants ≤32 weeks and found that use of ECG made the visible HR available faster, but did not influence the timing of any clinical interventions in the DR.[23] In our trial, use of ECG did not make the visible HR available faster. Similar to their trial, our study did not find any difference in the timing of any clinical intervention in the DR. In addition, we did not find any difference in the duration of bradycardia or the time to stabilization. Compared to the study by Katheria et al., where ≤32 weeks' GA preterm infants were randomized, in the current study eligible infants were ≤30 weeks' GA. In addition, the current study was powered to detect a difference in the time to stabilization in the DR and also had more infants with bradycardia at birth requiring PPV. Another recent study by Murphy et al. reported in low-risk term infants that the ECG picked up HR faster, but showed more bradycardia episodes in the ECG + PO group.[25] The current study did not show more episodes of bradycardia in the ECG arm.

The NRP currently suggests using ECG for preterm resuscitation if available and strongly recommends using ECG if the newborn requires chest compressions.[3] In the absence of evidence of a clinical benefit and due to associated cost, routine use of the ECG in the DR has not been strongly recommended by the NRP for newborns not requiring chest compressions.[4] Although the current study confirmed feasibility, its routine use did not result in faster stabilization of preterm infants. It did not decrease inappropriate use of PPV or prevent unnecessary delay in initiating

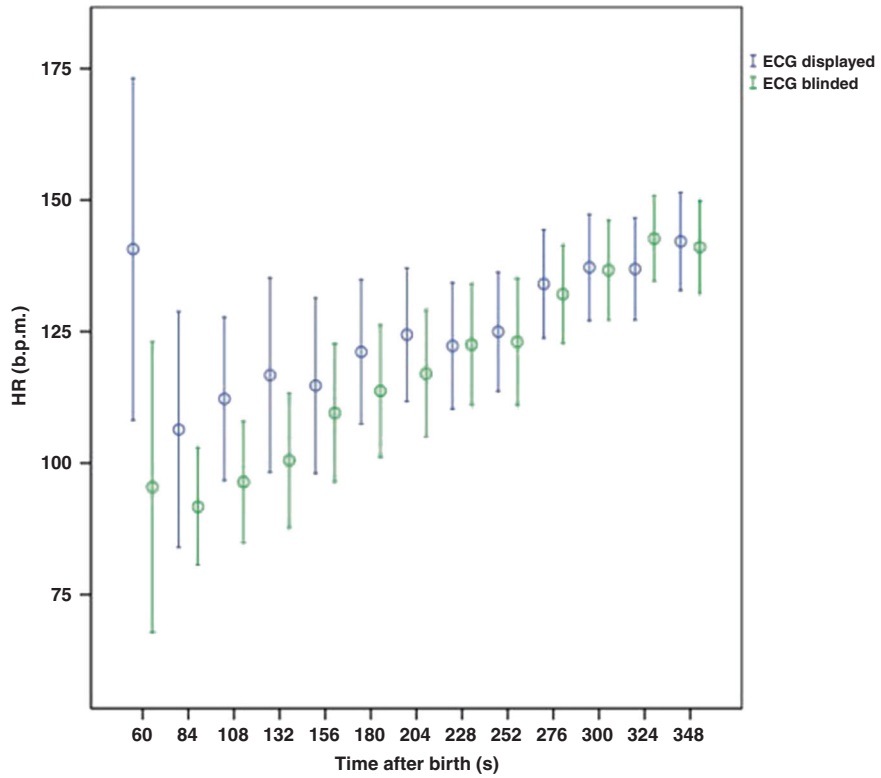

Fig. 2 Heart rate changes in the first few minutes after birth measured by ECG and PO. ANOVA for the difference between ECG and PO within patient *P* value: 0.54.

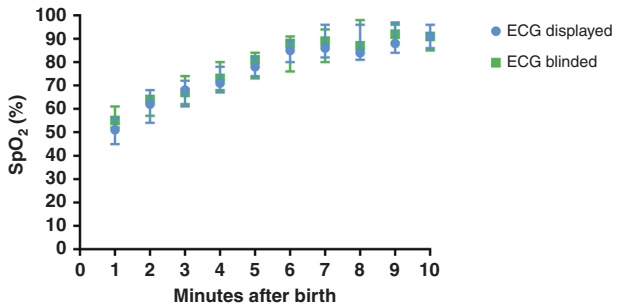

Fig. 3 SpO_2 changes in the first few minutes after birth in the ECG-displayed and ECG-blinded groups. There was no difference between SpO_2 changes in the first 10 minutes after birth between two groups.

PPV. This could be due to concurrent use of auscultation to confirm HR even in the absence of availability of HR_{ECG}. It is possible that HR may not be the predominant trigger for clinical interventions in these situations. In the majority of infants, where PO underestimated the HR, PPV was still an appropriate response as those infants were apneic or breathing ineffectively. The study was not powered to detect a difference in the duration of bradycardia or inappropriate use of PPV between the two groups; a larger study is needed to answer these questions. Concern has been raised that by adding another monitor, such as an ECG monitor, human performance will worsen as it may further direct the visual attention of providers toward monitors and away from the infant.[4,25] Although we did not see any adverse effect of routine ECG use during DR resuscitation, future studies should evaluate the resuscitation team performance and the quality of resuscitation systematically.

Interestingly, when analyzed using Bland–Altman plot and a correlation graph between HR_{PO} and HR_{ECG}, the current study confirmed the findings of previous observational studies that PO is inaccurate and often underestimates HR during the first few minutes of neonatal resuscitation.[18–20,23,33] In addition, we found that the PI is slightly lower when the PO underestimates the HR in the first few minutes of life. PI is calculated as the ratio between the pulsatile and nonpulsatile components of the photoelectric plethysmographic signal of transcutaneous PO.[34] As the PI is a noninvasive real-time measure of peripheral circulation, it can be speculated that the PO underestimates the HR during the time that peripheral perfusion is somewhat compromised. The difference in PI between the two groups is very small and likely clinically irrelevant. As an infant is undergoing complex hemodynamic changes for adaptation to the extrauterine existence, the PI can be difficult to interpret in the first few minutes of life.[34]

Given that the PO can be inaccurate in the first few minutes of life, the current NRP recommendation of using ECG for preterm resuscitation if available remains a reasonable suggestion even in the absence of a difference in time to stabilization. None of the infants in the study required chest compressions. As ECG is recommended for the HR assessment in a newborn who requires chest compression in the DR, it should be readily available if not used routinely. The impact of the substantial inaccuracy of HR_{PO} in the first few minutes of life on resuscitation team performance should be considered in future studies. Given the significant cost associated with making an ECG available for routine use for neonatal resuscitation in all DRs,[4] larger adequately powered trials, which show improvement in clinical outcomes, are needed before such a recommendation can be made. An inexpensive, but still an accurate novel device that measures HR_{ECG} in the DR may be a reasonable solution.

This study had several limitations. We did not have the ability to video record the DR interventions, and we did not use respiratory function monitors or oxygen analyzers in the DR during the study. However, a nurse whose sole responsibility was to maintain such records diligently recorded the DR interventions. There was around a 30 s delay between placing the infant in a resuscitation

Table 3. Admission characteristics and short-term outcomes.

Characteristics	ECG displayed ($N = 26$)	Control ($N = 25$)	*P* value
Status on admission to NICU			
Admission pH, median (25th quartile, 75th quartile)	7.25 (7.21, 7.31)	7.28 (7.18, 7.32)	0.58
Admission BE, median (25th quartile, 75th quartile)	−5.0 (−7.0, −4.3)	−5.5 (−10.0, −3.0)	0.77
Ventilator support on admission	8 (31)	5 (20)	0.57
Outcomes			
Respiratory distress syndrome	25 (96)	24 (96)	0.49
Surfactant administration	15 (58)	13 (52)	0.90
Bronchopulmonary dysplasia (O_2 at 36 weeks)	11 (42)	7 (28)	0.44
Days on ventilator, median (25th quartile, 75th quartile)	3.0 (0.5, 20.5)	0.6 (0.4, 1.5)	0.09
Days on continuous positive airway pressure, median (25th quartile, 75th quartile)	26 (8, 41)	19 (10, 33)	0.53
Days on O_2, median (25th quartile, 75th quartile)	15 (1, 62)	6 (2, 25)	0.56
Intraventricular hemorrhage grade III or IV	1 (4)	1 (4)	0.49
Surgical necrotizing enterocolitis	2 (8)	0 (0)	NS
Retinopathy of prematurity stage III or higher	0 (0)	1 (4)	NS
Length of hospitalization, median (25th quartile, 75th quartile)	74 (48, 106)	67 (52, 89)	0.81
Death before discharge	2 (8)	2 (8)	0.63

Unless otherwise noted, data are presented as *n* (%).
NS not significant.

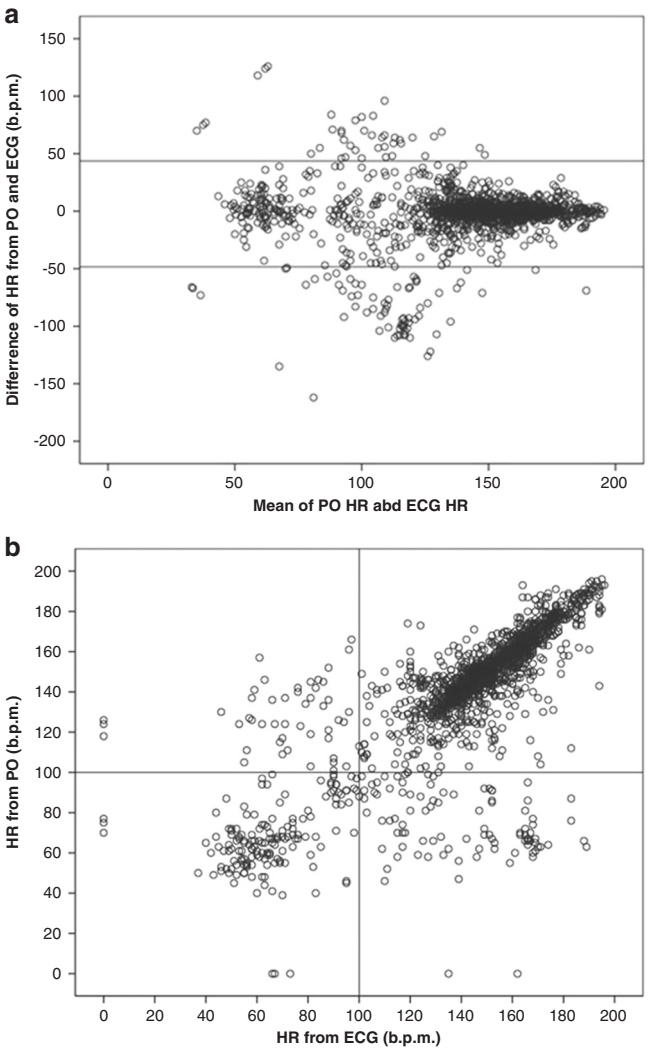

Fig. 4 Accuracy of PO heart rate compared to the gold standard ECG heart rate. a Bland–Altman plot analysis of PO heart rate and ECG heart rate. **b** Scatterplot of paired data points from ECG heart rate and PO heart rate. Each circle represents one data pair.

warmer and placement of the ECG and the PO leads. On review of the resuscitation records, it was discovered that the resuscitation nurse auscultated for the HR assessment before attempting to place the ECG leads or the PO sensor. This likely resulted in a delay in the placement of the ECG leads and the PO sensor. This short delay should be improved upon in future randomized control trials so that the ECG and the PO signal potentially can be available sooner. The time from birth to achieve SpO_2 in the goal range depends on various factors. The use of time to stabilization as a primary outcome may not truly reflect the effect of the HR assessment method. Future randomized controlled trials should consider the duration of bradycardia as a primary outcome in place of time to stabilization to remove the confounding effect of time to achieve goal SpO_2. In addition, a smaller effect size should be used to power the future randomized control trial as a 30% difference in the primary outcome, as the magnitude of the effect may be too high. In addition, a small sample size remains a limitation of the study. Sex differences in preterm morbidity and mortality have been well documented.[35] It is unclear if a higher proportion of females in the control group resulted in differences in resuscitation characteristics or clinical outcomes. During the study period, routine practice at Parkland Hospital was to clamp the umbilical cord immediately after birth for all preterm infants. Studies have shown that transient bradycardia right after birth is common with immediate cord clamping.[36]

One of the strengths of this study is that it is a randomized trial of infants born <31 weeks' GA with a blinded control arm. There is a paucity of randomized controlled trial data to evaluate whether ECG should be used routinely during preterm resuscitation in the DR.[23] The current study was powered to determine if routine use of the ECG would decrease the time to stabilization during preterm resuscitation. Unlike previous studies, we did report short-term clinical outcomes to assess the impact of routine ECG use in the DR beyond the quality of resuscitation. The study was not powered for any short-term clinical morbidities, but it does provide preliminary data for future larger trials. In addition, while other studies have focused on a late preterm population,[17,19,20,25] by focusing on more immature infants, the current study was able to demonstrate the feasibility of using ECG leads in this population. Furthermore, the lack of research personnel assigned to attach the ECG leads after birth or to make real-time HR assessments allowed the current study to examine the effects of routine use of ECG on the human performance in a real-world setting.

In conclusion, although ECG use is feasible in preterm infants during resuscitation in the DR, it does not decrease the time to stabilization. HR assessment in the DR by PO can be inaccurate. For that reason, ECG may be used routinely during the resuscitation of preterm infants if resources are available. Future trials should be powered for the duration of bradycardia or the need for PPV and should include a cost-value analysis of routine use of the ECG in the DR.

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AUTHOR CONTRIBUTIONS

All authors made substantial contributions to conception and design, acquisition of data, analysis and interpretation of data, and critical revisions for important intellectual content. N.V.A. wrote the first draft of the manuscript. All authors approved the final version of the manuscript as submitted.

FUNDING

V.K. acknowledges support by K23HD083511 grant from the NIH.

COMPETING INTERESTS

The authors declare no competing interests.

CONSENT STATEMENT

Parental informed consent was obtained postnatally.

ADDITIONAL INFORMATION

Supplementary information The online version contains supplementary material available at https://doi.org/10.1038/s41390-021-01731-z.

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