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## Clinical Paper

# Pedi-cap color change precedes a significant increase in heart rate during neonatal resuscitation\*



Doug Blank<sup>a,\*</sup>, Wade Rich<sup>a</sup>, Tina Leone<sup>b</sup>, Donna Garey<sup>a</sup>, Neil Finer<sup>a</sup>

- <sup>a</sup> Division of Neonatology, UCSD Medical Center, University of California, San Diego, CA, USA
- <sup>b</sup> Division of Neonatology, Columbia University, New York, NY, USA

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#### ABSTRACT

Introduction: Heart rate is the most important indicator of infant well-being during neonatal resuscitation. The Nellcor Pedi-Cap turns gold when exposed to exhaled gas with  $CO_2 > 15$  mmHg. The aim of this study was to determine if Pedi-Cap gold color change during neonatal resuscitation precedes an increase in heart rate in babies with bradycardia receiving mask ventilation.

Methods: This was a single-center retrospective review of video recordings and physiologic data of newborns with bradycardia receiving mask positive pressure ventilation during neonatal resuscitation. Subjects were included if the baby's HR < 100 BPM within the first 90 s of resuscitation. The primary outcome was the change in HR prior to Pedi-Cap gold color change compared to the HR after Pedi-Cap gold color change.

Results: Forty-one newborns during the study period had HR < 100 BPM and received mask positive pressure ventilation with a Pedi-Cap. The median heart rate 10 s prior to Pedi-Cap gold color change was 75 BPM (IQR 62–85) and increased to 136 BPM (IQR 113–158) 30 s after gold color change (p < 0.001). SpO<sub>2</sub> increased from  $45 \pm 17\%$  prior to Pedi-Cap gold color change to  $52 \pm 17\%$  30 s after gold color change (p = 0.001).

Conclusions: Colorimetric  $CO_2$  detection during mask positive pressure ventilation in neonatal resuscitation precedes a significant increase in heart rate and  $SpO_2$ . The Pedi-Cap can be easily applied during resuscitation, requires no electricity, provides immediate feedback and may be a useful, simple tool early in resuscitation and may be especially useful in resource limited settings.

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#### 1. Introduction

Heart rate is the most important indicator of infant well-being during neonatal resuscitation. The American Academy of Pediatrics Neonatal Resuscitation Program guidelines recommends adequate ventilation as the key intervention during neonatal resuscitation to improve cardiac output and stimulate breathing. Inflating the neonatal lung establishes functional residual capacity, stimulates pulmonary blood flow and improves heart rate.<sup>1–3</sup>

The Pedi-Cap® (Nellcor Puritan Bennett, Pleasanton, CA) is an example of a semi-quantitative, single-use colorimetric carbon dioxide detector. The Pedi-Cap contains a pH-sensitive chemical indicator that undergoes cyclical color change with each

E-mail address: blankdouglas@gmail.com (D. Blank).

inspiration and expiration when it is placed in an infant's breathing circuit. During effective ventilation, the Pedi-Cap will "cycle" between purple and gold with each delivered breath. Disposable colorimetric  $\mathrm{CO}_2$  detectors are recommended to confirm successful endotracheal tube placement during neonatal resuscitation and can also be used to qualify airway patency during mask positive pressure ventilation.  $^{1,2,4-8}$ 

At UCSD Medical Center all babies that are at risk for requiring extensive resuscitation at birth are evaluated in a designated resuscitation suite outfitted with high definition audio/video monitoring along with multi-channel analog data capture. 9-11 In an ongoing quality improvement review of the recorded resuscitations, we observed that large increases in HR were associated with Pedi-Cap gold color change (PGC). CO<sub>2</sub> detection may be the first signal that there is adequate lung inflation, pulmonary blood flow and gas exchange. Several studies have demonstrated that assessment of HR via auscultation and palpation is inaccurate during neonatal resuscitation. 12-14 An additional method of determining an increase in HR during neonatal resuscitation may helpful, especially in resource limited settings where resuscitation is often performed

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<sup>\*</sup> Corresponding author at: Division of Neonatology, UCSD Medical Center, 402 Dickinson Street, MPF 1-140 #8774, USA.

by single providers without the availability of pulse oximetry. <sup>15–17</sup> We hypothesized that PGC during mask ventilation would precede an increasing heart rate during neonatal resuscitation.

#### 2. Methods

This is a retrospective review of data obtained during neonatal resuscitations conducted at the UCSD Medical Center, a 49 bed regional neonatal intensive care unit with a high-risk perinatal service averaging 3500 deliveries per year. The team attending each delivery consisted at minimum of a neonatal fellow or neonatal nurse practitioner, a respiratory therapist and a neonatal nurse.

#### 2.1. Inclusion criteria

All available real-time physiologic data and high definition video and audio recordings between April 2012 and November 2012 were obtained using our previously described data acquisition system. 9-11 Data was analyzed and included if the baby's HR was <100 BPM within the first 90 s of resuscitation and the baby received mask positive pressure (PPV) during the first 2 min of resuscitation, the team used a Pedi-Cap with the initial mask ventilation and the baby was resuscitated on a warming bed with the data acquisition system available.

#### 2.2. Pedi-Cap

There are 3 ranges of color which indicate different ranges of exhaled carbon dioxide (eFigure): purple indicates <4 mmHg (or <0.5%), tan indicates 4–15 mmHg (or 0.5–2%) and gold indicates >15 mmHg (>2%). <sup>18</sup> The time at which PGC occurred was determined by reviewing the video recording of the resuscitation and recorded in seconds from the time that the baby was placed on the warming bed.

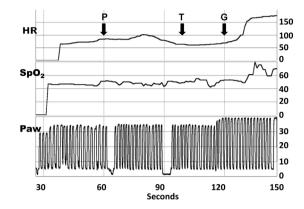
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## 2.3. Data collection

ECG was used to evaluate heart rate using previously described techniques because ECG electrodes can pick up a continuous HR in less than 30 s, significantly faster than pulse oximetry. 9,10,19 ECG readings were obtained from defibrillator analog output of a HR monitor (M3046A Phillips Medical Systems, Andover, MA). The HR produced from the ECG tracing was considered reliable if the QRS waveform was visually identifiable on the tracing during data analysis. If not, HR was obtained from the pulse oximetry tracing if available.

A pulse oximeter sensor was applied to the baby's right palm or wrist immediately after the baby was placed on the warming bed, then connected to the oximeter. A Radical 7 (Masimo, Irvine CA) oximeter was used to determine SpO<sub>2</sub> and pulse rate if ECG was not reliably detecting heart rate. The analog output was 1 sample/s and was set to a 2 s averaging interval and maximum sensitivity. Data were considered reliable when the tracing showed a steady pulse rate signal. The time to obtain a reliable HR via ECG and pulse oximetry was recorded.

During the study period, our practice was to initiate mask PPV using a t-piece resuscitator (Neopuff, Fisher & Paykel, Auckland, NZ) with starting peak inflation pressures of  $30 \, \text{cmH}_2\text{O}$  and PEEP of  $5 \, \text{cmH}_2\text{O}$ . A flow-inflating bag was set up and available for use at the discretion of the team, but only used on one occasion during the period of analysis. A Pedi-Cap was attached to the t-piece or anesthesia bag prior to the start of any high risk delivery in order



**Fig. 1.** Example of a tracing, HR in BPM, SpO<sub>2</sub>, inflation pressures via PPV (cmH<sub>2</sub>O) over time in seconds. P=Pedicap is purple. T=Pedi-Cap turns tan, indicating some exhaled CO<sub>2</sub>. After PGC (G), HR increases >100 BPM and SpO<sub>2</sub> increases >20%.

to detect airway obstruction during mask PPV. The data acquisition system recorded the pressure of each manual inflation delivered.

The need to intubate was determined by the clinical team. If the baby did not require intubation as part of the resuscitation (i.e. did not need intubation for bradycardia, did not receive chest compressions or require epinephrine), our practice was to consider intubation in the delivery room if the baby required more than 0.4  $FiO_2$  to maintain  $SpO_2$  in targeted ranges recommended by NRP or was still requiring mask PPV for treatment of apnea prior to transport to the NICU.

All physiologic data captured from the monitors was converted to digital form using a data acquisition system (MP 150 [Biopac Systems, Inc., Goleta, CA]) and integrated with the digital video signal using previously described methods.  $^{9-11}$  The standard data captured includes pulse and saturation values from an oximeter, airway pressure,  $\rm FiO_2$  and heart rate from ECG (Fig. 1). We recorded the HR and  $\rm SpO_2$  for each baby every 30 s for the first 5 min of the resuscitation. To analyze the HR and  $\rm SpO_2$  during PGC, we recorded the HR and  $\rm SpO_2$  in 10 s intervals from 30 s prior to PGC to 30 s after PGC.

Interventions performed by the team to stabilize the baby as well as patient demographic characteristics and clinical outcomes were recorded. Resuscitations were reviewed as part of an ongoing quality improvement project. Data for each delivery was obtained from our quality improvement database. The institutional review board of UCSD approved a waiver of consent for this study.

#### 2.4. Statistics

Comparisons of HR and SpO<sub>2</sub>, at single time points, before and after PGC were analyzed using repeated measures analysis of variance (ANOVA) for normally distributed data and the Friedman test for non-parametric data. Post hoc analysis was conducted using a Bonferroni adjustment. A paired T-Test was used to compare normally distributed data and a Wilcoxon signed-rank test was used to compare non-parametric data. Means with SD are reported for normally distributed continuous variables and medians with 25-75% interquartile ranges are reported when the distribution was skewed. Demographic data are presented as numbers and proportions for categorical variables. The sensitivity, specificity, positive predictive value, negative predictive value and accuracy of PGC to indicate a HR > 100 BPM was measured every 30 s for the first 5 min of the resuscitation. We assigned a true positive if the Pedi-Cap was gold and the HR was >100 BPM and a true negative if the Pedi-Cap was purple and the HR < 100 BPM.

To test inter-rater reliability of when Pedi-Cap gold color change occurs, three clinicians independently watched 15

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