Trends in pulse oximetery derived heart rate variations in healthy newborns in the first few days of life

Heart rate (HR) forms an important aspect of newborn assessment, intensive care monitoring and early warning scores for babies in the postnatal ward and those who are transferred to the neonatal unit.[1] Because term babies who are born healthy do not routinely undergo HR monitoring, there is a lack of knowledge regarding the normal values and variations in their heart rate.

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Key points

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1. Heart rate is an important vital sign in newborn assessment and is an integral part of newborn early warning score.
2. Limited knowledge exists with regards to normative values and variations in heart rate in the first few days of life.

Previous studies have reported HR immediately after birth[2,3] and over a wide age range (zero to three months).[1,4] The UK National Institute for Health and Care Excellence (NIHCE) reports normal HR as 100-160 beats per minute (bpm)[5] and the World Health Organisation (WHO) reports HR more than 180bpm as abnormal.[6] These reported values are not based on strong evidence, however.[7] Newborn Early Warning Trigger and Tracking (NEWTT), an early warning tool endorsed by the British Association of Perinatal Medicine and commonly used in the UK,[8] defines normal HR as 100-160bpm. Assuming certain values of HR as abnormal could potentially introduce a bias and lead to many babies being wrongly classified as 'unhealthy'. With an increase in term infants being admitted to neonatal units and an increasing focus on transitional care, where the infants are cared for at their mother's side,[9] it is essential to report evidence-based normative HR values.

Although electrocardiogram (ECG) is the gold standard for accurate estimation of HR, pulse oximeters that provide a pulse rate (PR) are commonly used in clinical practice.[4] In this study we used PR recordings from the pulse oximeter to describe the normal reference range for HR, HR variations with clinically important variables and incidence of bradycardia with varying thresholds for healthy infants more than 37 weeks' gestation in the first few days after birth.

We also wanted to determine the proportion of babies with HR data from our study cohort that were plotting outside the normative range, as described in the literature.

Methods

This study is part of a prospective, observational study conducted at three separate hospitals in the city of Calgary, Alberta, Canada (March 2014 to September 2015). The main objective of the primary study was to report longitudinal trends in oxygen saturation, which will be reported elsewhere. We analyse and present only PR measurements reported here as HR measurements.

We included all newborns from the postnatal ward with the following characteristics: more than 37 weeks' gestation at birth, age between six to 24 hours at enrolment and normal cardiorespiratory examination, as defined by ACoRN Neonatal.[10] Neonates with an antenatal or postnatal diagnosis of congenital cardiopulmonary disease, major congenital abnormality, those at risk of neonatal abstinence syndrome, or admission to a NICU were excluded.

We identified potential subjects from hospital electronic health records and enrolled within 24 hours of birth. Parental written informed consent was obtained prior to enrolment. This study was registered with clinicaltrials.gov (NCT 02095041) and local research ethics board approval was obtained.

HR of all the enrolled infants were measured using a pulse oximeter (Masimo Radical-7, Irvine California) chosen due to its resistance to movement artefacts and good performance in states of low perfusion.[11,12] The pulse oximeter was set to normal sensitivity with two second averaging times. HR data were recorded every two seconds by the oximeter. We obscured the pulse oximeter readings by fastening a custom-made opaque cover over the oximeter's display. The perfusion index and wave forms were left visible so that the investigator could ensure a good quality signal was present. The beat-to-beat tone function was turned off and all the alarms were silenced. In this manner, the investigators, staff and families were blinded to the HR readings.

One pulse oximeter probe was placed on the right wrist (pre-ductal) and the other probe was placed on either foot (post-ductal) to take continuous measurements for 10 minutes, starting from the point of good plethysmographic wave forms. This initial phase of recording occurred under the direct supervision of one of the investigators. Following the 10-minute period, we returned the infant to the mother with one pulse oximeter probe still attached to the right wrist for the completion of the 90-minute recording period. During this 80-minute period, we recorded only pre-ductal HR, to avoid the inconvenience for the mother of having two probes attached to the infant, and to carry out routine newborn care (eg feeding). Oximetry recordings were performed every 12-24 hours prior to discharge during regular working hours, with the first recording occurring between six and 24 hours after birth, to allow completion of normal transition to the extra-uterine environment.[13] All the recruited infants were followed until eight weeks of age, by reviewing their electronic health record to identify those who died, required readmission to hospital or visited the emergency department. Those infants who were found to have a diagnosis that could interfere with the creation of healthy HR data were excluded from the primary outcome analysis.

Bradycardia definition: Each episode is defined as a period of more than 15 seconds, during which HR values are below a specified threshold (eg 120, 100, 80/minute).[14] Dynamic bradycardia is defined as being when the HR falls below the second or third of the median HR for the infant,[14] (for example, for an infant with a median HR of 120bpm, we defined the dynamic bradycardia to be when the HR is less than 80bpm for 15 contiguous seconds).

NEWTT chart: HR above 160bpm and below 100bpm are traditionally classified as Amber category, which warrants senior review within 30 minutes. We plotted each HR measurement every two seconds and plotted against the NEWTT chart. We plotted median and various centiles for 10 divided bins between six hours and 50 hours of infant's age. We also calculated median and inter-quartile range (IQR) for the entire population.

Data management and cleaning: Oximeter data were downloaded using Trendcom software. Non-identifying study data were collected and managed using Research Electronic Data Capture (REDCap), a secure online research database.[15] Manual and automated SpO_2 data cleaning was performed to remove data of questionable validity. PR less than 10bpm were removed, as were any data points with 'zero' values.

Data analysis: We aimed at recruiting a convenient sample of 300 infants. We used descriptive statistics for population characteristics. Categorical variables were presented as proportions, while numerical variables were presented as mean with standard deviation (SD) or median with IQR as appropriate.

All the analysis has been performed using Python 3.6.9. In particular, we choose to exploit the advantage of an object-oriented programming language (OOP) and create the class "baby" in order to collect the properties and the measurements of each baby in a single object. The software created (available on request), was specifically designed for the features of this sample and is able to create simple plots of the HR of the baby simply by inputting the anonymised identity for each baby. Moreover, it includes an algorithm to identify, count and measure the duration of events of bradycardia and hypoxia.

We used non-parametric tests and applied a significance level 'alpha' of 0.05 for all statistical testing. We used the Strengthening the Reporting of Observational Studies in Epidemiology statement (STROBE) guidelines for reporting of the study.[16]

		Full cohort (n= 268)
Female sex – n (%)		123 (45.9%)
Birth weight – mean (SD)		3,348 (503) grams
Gestational age – mean (SD)		39.55 (1.15) weeks
Ethnicity	Caucasian	161 (60.07 %)
	African American	12 (4.48 %)
	East Indian	31 (11.57 %)
	Asian	27 (10.07 %)
	Hispanic	15 (5.6 %)
	Other	17 (6.34 %)
	Unknown	2 (0.75 %)
	Native	3 (1.12 %)
Maternal age – mean (SD)		31.87 (4.54)
Caesarean delivery – n (%)		76 (28.4 %)
Maternal pre-eclampsia – n (%)		12 (4.48 %)
Maternal gestational diabetes – n (%)		26 (9.70 %)
Smoking – n (%)		12 (4.48 %)
Meconium-stained liquor – n (%)		36 (13.43 %)
Apgar 5min - mean (SD)		8.96 (0.33)
Age in hours at first recording – median (IQR)		16.48 (11.3 to 20.6)

TABLE 1 Demographics. Key: SD – standard deviation; IQR – inter-quartile range.

	Wrist	Foot
Age<24hrs	N=233	N=245
5th centile	106.0	104.3
25th centile	115.2	113.7
50th centile	121.9	121.5
75th centile	128.9	129.4
90th centile	135.4	137.1
95th centile	142.2	143.0
Age 24hrs-72hrs	N=42	N=43
5th centile	111.8	109.7
25th centile	117.3	117.3
50th centile	124.9	131.4
75th centile	135.9	139.0
90th centile	140.0	145.6
95th centile	142.3	152.0

TABLE 2 Percentiles of HR.

Results

Demographics

Out of a total of 294 babies recruited (after excluding babies with invalid data) we had 268 (91%) babies in the final analysis. Thirty-seven (14%) infants had a second recording and three (1.1%) had a third recording before hospital discharge. Due to the hospital's early discharge policy, we had a smaller number of newborns on days two and three. Demographic data are provided in **TABLE 1**. Most babies received routine care and 3% received some form of minor resuscitation at the time of birth.

There are a total of 1,016,801 (equivalent to 564.89 hours = 23.54 days) data points and after cleaning we had 992,678 (97.62%) valid data points. For the wrist recordings, the number of infants with one recording, two recordings and three recordings each were 151, 105 and five respectively. For the foot recordings, the number of infants with one recording, two recordings and three recordings each were 152, 109 and six respectively.

Of the recruited infants, 45 (17%) required acute medical care during the eight-week follow-up period and 11 (4%) infants were subsequently admitted to hospital. Based on the investigator's discretion, we excluded four infants' data from the original study.

HR percentiles (TABLE 2)

In the first 24 hours of life, median wrist HR was 121.9bpm (IQR 115, 129) which

	Mean	SD	Mean	SD	Mean diff (95% CI)	Statistics
Gestation	<40 weeks		≥40 weeks			p-value
Wrist	124.87 (n=139, 52%)	10.65	120.66 (n=113, 42%)	10.44	4.21 [2.96,5.46]	0.00077
Foot	124.65 (n=146, 54%)	13.02	121.32 (n=117, 44%)	11.95	3.33 [1.89,4.77]	0.0163
Type of delivery	Vaginal		Caesarean			
Wrist	122.56 (n=179, 67%)	10.73	124.03 (n=73, 27%)	10.78	1.47 [0.15,2.80]	0.2360
Foot	122.25 (n=187, 70%)	12.07	125.10 (n=76, 28%)	13.57	2.86 [1.28,4.43]	0.0622
Sex	Male		Female			
Wrist	121.05 (n=135, 50%)	9.77	125.43 (n=117, 44%)	11.37	4.38 [3.13,5.64]	0.00218
Foot	121.60 (n=141, 53%)	10.48	125.16 (n=122, 46%)	14.63	3.56 [2.08,5.04]	0.0643
Timing	<24hrs		24-72hrs			
Wrist	122.38 (n=233, 87%)	10.52	126.58 (n=42, 16%)	11.31	4.20 [2.43, 5.97]	0.01732
Foot	122.06 (n=245, 91%)	11.87	129.45 (n=43, 16%)	14.94	7.39 [5.13,9.65]	0.0004077

TABLE 3 Pulse rate variations with gestational age, type of delivery, sex and time. Key: CI – confidence interval.

was similar to the median foot HR of 121.5bpm (IQR 114, 130; p 0.29). Similarly, median wrist HR was 124.9bpm (IQR 117, 136) and median foot HR was 131.4bpm (IQR 117, 139: p 0.17) for infants age 24 hours to 72 hours of life.

HR variations

HR variations with gestational age, sex, type of delivery and time of life are provided in **TABLE 3.** Babies with birth gestational age of more than 40 weeks had significantly lower HR. This trend is seen for both wrist and foot. The HR in females is higher than in male infants, with mean difference of approximately four beats per minute. Similarly, HR tends to be higher for babies who are more than 24 hours old, although the sample size is smaller in this cohort. There was no difference in HR for infants born by caesarean and vaginal delivery.

Trends in bradycardia

In total there were 475 episodes of HR less than 120bpm, bradycardia with 183 episodes of HR less than 100bpm, 91 episodes of HR less than 80bpm and 89 episodes with HR less than the second or

third median HR. All these episodes lasted for at least 15 seconds duration (**TABLE 4**). Durations of bradycardia were similar among all the thresholds. Transient bradycardia (less than 15 seconds) is more common than bradycardia of 15 seconds duration. In general, bradycardia events (lasting for at least 15 seconds) in healthy term infants were rare, with a frequency of approximately one episode every two hours and lasting for approximately 30 seconds.

HR plotting against NEWTT chart

FIGURE 1 shows HR plotted against infant (in hours). The normative HR range prescribed in the NEWTT chart (HR 100-160bpm) is also shown. The majority of the data points fall between a HR of 100 and 160bpm, with their median (25th-75th centile) HR for the entire population within the normative range. Similar findings were noted when the median and the IQR were plotted for individual bins for infants' age after birth. Creating 1st-99th centile with data points for the same bins, shows multiple HR data points were plotted outside the normative range. We had 43787 (6%) HR data points less

than or equal to 100bpm and 13,812 (2%) HR data points greater than or equal to 160bpm.

Impact of HR measurements with shorter recording time

We identified infants with median HR of less than 100bpm and more than 160bpm. We then examined infants in these groups with a significant difference in the median HR between the wrist and foot measurements. Six infants with HR less than 100bpm and three infants with HR greater than 160bpm had different median HR between the foot and wrist measurements. Since we recorded foot measurements only for a short period (10 minutes), we compared the foot measurements with wrist measurements over a similar duration (ie the first 10 minutes of wrist measurement). This comparison showed similar median HR between the two measurements, indicating the impact of the shorter period of recording and the variations in HR. Whether this is due to any underlying physiological variations or technical limitations is unknown.

Discussion

Our study provides a better understanding of normative values of HR and its variability with various factors in the first few days of life. We have shown that bradycardia events of HR less than 80bpm, or HR less than two or three of the baseline, are rare and short lasting in the first few days of life. Any infant with bradycardia episodes is worth monitoring.

We argue that a dynamic definition of the HR threshold for bradycardia, based on the median HR of an individual, is more accurate than the currently used global definition given the large variation we find in the median HR in healthy infants. We have shown that spot check HR measurements could lead to false labelling, as we have shown in **FIGURE 1**. Trends in HR over a short period of time would provide the true estimate of HR, rather than a spot check. We noted minor variations between foot and wrist measurements, which does not reflect actual physiology, but instead may result from technical limitations of pulse oximetry related to the quality of the pulse waveform encountered in the upper versus lower limbs.

In a recently published study with many infants, reference ranges for HR were obtained by auscultation in the first 24

	Number of bradycardia episodes per hour[1] mean (SD)		Duration of bradycardia episodes in seconds[2] median (IQR)		Percentage of time with bradycardia[3] mean (SD)		Number bradycardia per hour any duration[4] mean (SD)	
	Wrist	Foot	Wrist	Foot	Wrist	Foot	Wrist	Foot
HR <2/3 of median	0.388 (1.167)	0.389 (1.510)	34 [24,66]	34 [22,57]	0.0089 (0.0322)	0.0072 (0.0324)	0.689 (1.606)	0.977 (3.107)
HR <120	16.025 (10.758)	17.387 (16.129)	36 [27,54]	41 [26,95]	0.421 (0.299)	0.432 (0.357)	35.117 (21.423)	38.022 (31.368)
HR<100	2.238 (5.279)	2.489 (6.874)	27 [20,39]	27 [20,49]	0.0463 (0.108)	0.0466 (0.121)	6.986 (12.594)	8.600 (17.651)
HR <80	0.418 (1.309)	0.436 (1.560)	36 [24,62]	29 [20,59]	0.00943 (0.0341)	0.00756 (0.0338)	0.785 (1.810)	1.0173 (3.173)

TABLE 4 Episodes of bradycardia.
[1]A bradycardia episode is defined as a period of ≥15 contiguous seconds during which HR values are below the specified threshold (eg 120, 100, 80). [2]Duration of bradycardias includes only infants with at least one bradycardia episode lasting ≥15 seconds and refers to the median duration of each bradycardia episode. [3]Percentage of time with bradycardias denotes the ratio of total time with bradycardias of any duration (ie not just for episodes lasting ≥15 seconds). [4]Bradycardias per hour refers to the number of bradycardia episodes of any duration per hour.
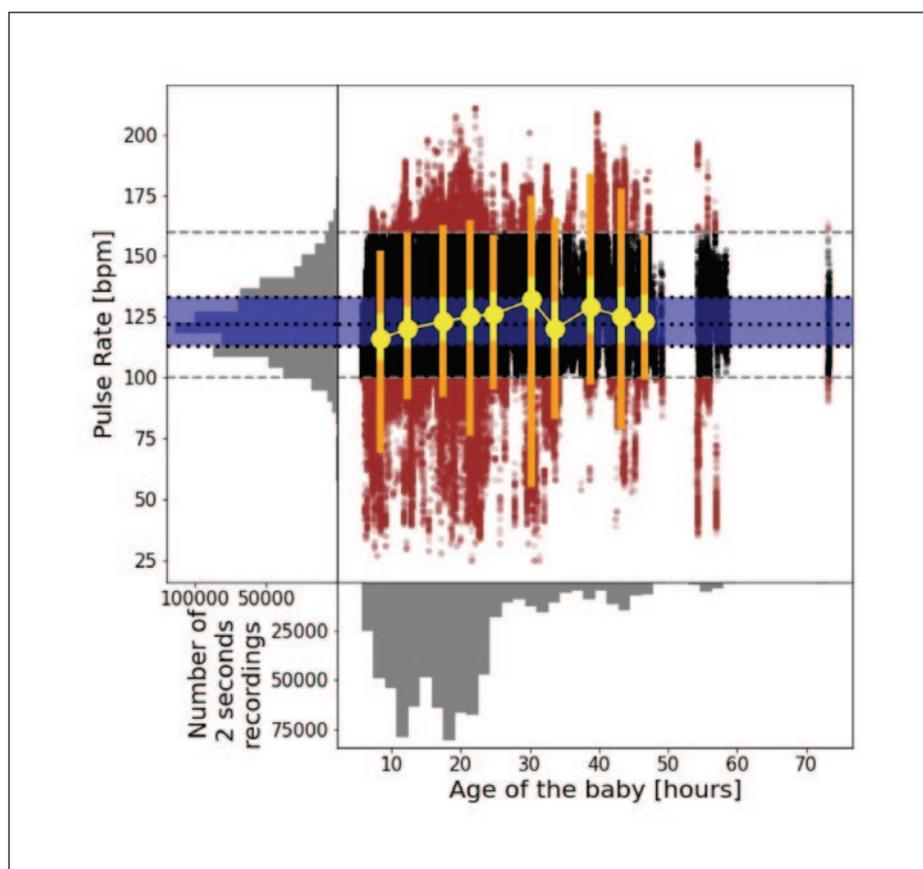

FIGURE 1 HR versus age of the infant in hours plotted against the normal range (HR 100-160bpm). The black circles show HR measurements at two second intervals, that fall within the traditional normative range of 100-160bpm. Brown circles show HR recordings outside of this range. The symbols and bars show the median, 25-75 (yellow) and 1-99 (orange) percentile ranges, for measurements in each bin. Histograms on the side show the distribution of the number of two second recordings for the baby's age (x-axis) and pulse rate (y-axis). The horizontal dotted line shows the global median, and the blue shading indicates the global 25-75 percentile range.

hours of life.[7] Auscultation findings of HR were validated against ECG recordings. In this study, median HR reported a higher HR in girls compared to boys. The findings of our own study were similar. In another large systematic review, with 69 studies reporting normal range of HR from birth until 18 years of age, the median HR at birth was 127bpm, which is similar to our own results.[1] In this review, settings in which measurements were made and methods to collect HR data were variable.

A pulse oximeter can provide reliable results equivalent to ECG when there is a good signal and no rhythm disturbances.[3] A systematic review comparing the performance of ECG and pulse oximeter concluded both devices provided precise results as compared to clinical assessments alone.[4] A pulse oximeter can underestimate the HR compared with an ECG in the first few minutes of life. In this review, all the studies included were conducted at the time of birth in resuscitation settings. The differences between ECG and pulse oximeter are systematic to the technology, which may affect the precise HR values and should not affect our study conclusions.

Our study has a few advantages. We collected all data prospectively, with relatively long periods of recording. We collected data from wrist and foot recordings using similar monitors. We classified infants in our study as healthy after a follow-up period of eight weeks of life. We followed a detailed process of data cleaning. We also defined clinically significant bradycardias as HR <80/min and HR <2nd/3rd median. There are a few limitations we should mention. We did not use ECG monitors, which are the gold standard for HR measurements. Although we collected data on neonatal state, we did not analyse the influence of the neonatal state on HR. In routine clinical practice we do not assess neonatal state, hence our data could be more clinically relevant; this is left

to a future study with this dataset.

Although our study was conducted at moderately high altitude (1,045m), variations of HR with altitude have not been previously reported. Hence, we believe this normative HR data and their variations would be applicable to all clinical settings.

What this study adds

This study found that infants with a gestational age of over 40 weeks, as compared to infants with gestational age less than 40 weeks, had higher heart rates. Females as compared to male infants and infants with age of 24-72hrs as compared to infants in the first 24 hours, also had higher mean HR.

Severe bradycardia events were found to be rare (one episode within two hours) and short lasting (less than or equal to 30 seconds). The study showed that a higher number of HR data points are outside the previously adopted normative range (100-160bpm).

Conclusion

In this large prospective dataset from healthy term infants, we have provided normative values of heart rate and its variation with gestational age, sex, mode of delivery and age of life. In this population, bradycardia events were rare with an approximate frequency of one episode every two hours and are short lasting. Significant HR data points were outside the previously described normative range.

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