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**ORIGINAL ARTICLE** 

# Arterial oxygen saturation and heart rate in term newborn in the first hour after birth\*

Saturación arterial de oxígeno y frecuencia cardíaca en recién nacidos de término sanos durante la primera hora post nacimiento

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#### **Abstract**

The pulse oximeter has been useful in the cardiorespiratory evaluation of the newborn. **Objective:** To assess arterial oxygen saturation (SpO<sub>2</sub>) and heart rate (HR) in newborns in the first 60 minutes after birth. **Patients and Method:** Prospective observational study in healthy term newborns, delivered vaginally or by cesarean section, with maternal bonding, carried out at sea level. A continuous post-ductal SpO<sub>2</sub> and HR record were obtained from minute 1 to 10 after birth, and then at 15, 30 and 60 minutes. The SpO<sub>2</sub> and HR were measured with a Nellcor pulse oximeter. The software Stata v.14 was used for the statistical analysis. **Results:** 324 healthy term newborns that met the inclusion criteria were included, of which 160 born vaginally and 164 by cesarean section. The SpO<sub>2</sub> increased progressively from minute 1 (58.7%) to minute 10 (94.5%). Newborns delivered vaginally had a significantly higher SpO<sub>2</sub> until minute 10 after birth than those born by cesarean section (p < 0.001). In newborns delivered vaginally, HR was significantly higher in the first two minutes after birth, and then from minute 10 to 60 (p < 0.003). There were no differences by gender in SpO<sub>2</sub> and HR. **Conclusion:** In term newborns, the SpO<sub>2</sub> increases progressively, being higher in the first 10 minutes in those born vaginally. In newborns delivered vaginally, a higher HR was also observed in the first and last minutes evaluated.

Keywords:
Oxygen saturation;
pulse oximetry;
heart rate;
term newborn

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#### Introduction

In the newborn (NB), the function of the placenta ends after the cord ligation, initiating a transitional period in which oxygenation increases progressively during the first few minutes after birth. This progression can be measured using the pulse oximeter<sup>1</sup>. The physiological processes that occur during the immediate postnatal period, especially arterial oxygen saturation (SpO<sub>2</sub>) and heart rate (HR) have been studied in recent years<sup>2</sup>.

Based on oxygen saturation studies in healthy term newborns in the first minutes of life after birth<sup>2,5,7,8</sup>, the American Academy of Pediatrics (AAP) and the American Heart Association (AHA)<sup>3</sup> in 2010 determined the SpO<sub>2</sub> objectives during the first 10 minutes of postnatal life, thus establishing arterial oxygen saturation that a newborn must present in the first minutes of postnatal life<sup>3</sup>. The SpO<sub>2</sub> objectives table has been crucial in assessing the resuscitation effectiveness and in avoiding unnecessary oxygen administration in the first postnatal minutes in healthy newborns<sup>3</sup>.

Pulse oximetry is a simple, painless, non-invasive, easy-to-use, low-cost procedure for continuous, objective monitoring of arterial oxygen saturation and heart rate<sup>4</sup>. The pulse oximeter sensibly measures cardiopulmonary changes that occur during the adaptation of the newborn in the postnatal period and in other clinical situations, becoming a useful tool in the evaluation of NB in the delivery room and in Neonatal Units<sup>5</sup>.

The cardiopulmonary transition experienced by the fetus when it turns into a newborn is a complex process that requires a few minutes to achieve stabilization<sup>6,7</sup>. After clamping the umbilical cord, several physiological changes occur, producing a progressive increase of SpO<sub>2</sub> in a few minutes to definitive values<sup>7</sup>. Several factors may influence oxygen saturation in the first postnatal minutes such as place of birth, birth at sea level or high altitude, type of delivery (vaginal or cesarean), or the vitality level of the NB<sup>8-12</sup>.

The objective of this study was to assess arterial oxygen saturation and heart rate in term infants in the first 60 minutes after birth.

#### Patients and Method

Quantitative and observational study of prospective cohort carried out in healthy term infants, born vaginally or by cesarean section, who did not require resuscitation or additional oxygen.

The study was conducted in the neonatal immediate care unit of the Guillermo Grant Benavente Hospital in Concepción (HGGB), between July and December

2012. This health center is located at sea level (atmospheric pressure 760 mmHg).

Neonates included were those whose mothers agreed to participate in the study and to the extent that a member of the research team was available to record the SpO<sub>2</sub> and HR measurements. The research team did not participate in the care of the NBs in the delivery room. The evaluated SpO<sub>2</sub> was post-ductal in order not to interfere with the maternal attachment carried out in the delivery room. All newborns received attachment according to the protocol established in our hospital; 30 minutes for those born vaginally and 10 minutes for those born by cesarean section.

351 healthy term NBs were enrolled, of which 27 were excluded due to technical difficulties in obtaining the saturation and heart rate signal within two minutes postpartum. The final sample under study was 324 NB who did not require any type of intervention and were selected using non-probability sampling for convenience.

The inclusion criteria in the study were: healthy single birth, gestational age > 37 weeks, adequate weight for gestational age, no evidence of hypoxia or history of maternal morbidity or complication, and good pulse oximeter signal within two minutes after umbilical cord clamping.

#### **Exclusion criteria**

All births ending in emergency cesarean section were excluded; those babies whose father or mother did not agree to participate in the study, and babies whose mothers received oxygen, morphine and/or steroids during labor.

Umbilical cord clamping was in most NBs after the first cry, which occurred between 30 and 60 seconds after birth. The sensor was placed in the anterior region of the right foot (dorsalis pedis artery), corresponding to post-ductal SpO2, as soon as possible and a continuous record of SpO<sub>2</sub> and HR was obtained from minute 1 to 10 after delivery. SpO<sub>2</sub> and HR were subsequently recorded at 15, 30 and 60 minutes without removing the pulse oximeter. The times were measured with a stopwatch that started after the umbilical cord ligation. SpO2 and HR were measured with a Nellcor N-600 OxiMax pulse oximeter (Mansfield, MA, USA). The sensor was connected to the oximetry cable before being applied to the newborn, as it increases the reliability and speeds up the display of the analyzed parameter<sup>13</sup>.

Routine oronasopharyngeal suction was not performed in the NBs according to HGGB Neonatology Service protocol, according to local experience, and as published by Gungor et al<sup>14</sup>. The Apgar score was assigned by the pediatricians or midwives on duty who take care of NBs at the time of delivery.

Table 1. Demographic characteristics of 324 newborns				
	Cesarean delivery (n = 164)	Vaginal delivery (n = 160)	p value	
Gestational age, weeks (mean, range)	38.6 (37 - 40)	38.7 (37 - 41)	0.41	
Birth weight, g (mean, range)	3624 (2230-4930)	3415 (2460 - 4330)	0.0001	
**1st minute Apgar (median, range)	9 (8 - 9)	9 (7 - 10)	0.80	
5th minute Apgar (median, range)	9 (9 - 10)	9 (8 - 10)	0.90	
Female gender n, %	64 (63.4)	37 (36.6)		
Male gender n, %	64 (64.6)	35 (35.4)	0.85	

Mothers who underwent a cesarean section received epidural anesthesia, while only local anesthesia was used for vaginal deliveries.

The temperature of the delivery room and the immediate care room ranged between 24°C and 26°C and the NBs were placed in a radiant warmer with servo-controlled temperature. The axillary temperature of the NB ranged between 36.5°C and 37°C during the studied period.

This study was approved by the Scientific Ethics Committee of the Concepción Health Service and informed consent was obtained from one of the parents before childbirth.

The researchers who recorded SpO<sub>2</sub> and HR data were independent of NB aftercare.

#### Statistical analysis

For the information storage, a database was created in Microsoft Excel, which was later analyzed with the Stata V. 14 statistical software.

Table 2.  $SpO_2$  and HR during the first 60 minutes after birth in 324 newborns

Time	SpO <sub>2</sub> (%)	HR (bpm)
(minutes)	Mean (range)	Median (range)
1	58.7 (29-88)	150 (76-199)
2	64.6 (32-90)	159 (75-198)
3	71.3 (36-96)	165 (75-198)
4	77.8 (38-99)	163 (82-204)
5	83.0 (46-100)	163 (96-200)
6	86.9 (46-100)	162 (98-198)
7	89.5 (64-100)	160 (98-194)
8	91.4 (60-100)	158 (100-194)
9	92.8 (64-100)	157 (100-200)
10	94.5 (78-100)	156 (115-192)
15	96.1 (86-100)	152 (120-193)
30	97.7 (90-100)	147 (125-190)
60	98.3 (89-100)	143 (125-189)
h h		:- +

bpm: beats per minute. SpO<sub>2</sub>: Oxygen arterial saturation. HR: Heart rate.

In the univariate analysis, absolute frequency and percentage relative frequency were calculated for qualitative variables, while quantitative variables are presented in mean, standard deviation, minimum and maximum.

Bivariate analysis was used to determine if there were differences between SpO<sub>2</sub> and HR, according to the type of delivery and gender of the newborn, and Student's T-Test or Mann-Whitney test were used according to data distribution and Chi-square. The significance level used was 0.05.

#### Results

When comparing gestational age, Apgar at 1 and 5 minutes, and NB gender, no statistically significant differences were found by type of delivery. Only significant differences were found regarding birth weight, with a significantly lower average weight observed in NBs vaginally born (Table 1).

#### SpO<sub>2</sub> and heart rate measurement

The average and standard deviation of  $\mathrm{SpO_2}$  of the analyzed group was  $58.7\% \pm 11.6\%$  (range: 29-88%), for the first minute, gradually increasing to 83% at 5 minutes (46 to 100%) and then above 90% at 8 minutes postpartum (60 to 100%). Regarding to the HR of the studied group, the average and standard deviation at 1 minute was  $150 \pm 24.5$  bpm (range:76-199 bpm), reaching its highest average value at 3 minutes  $165 \mathrm{pm}$  (75-198 bpm), and then gradually descending to  $143 \mathrm{pm}$  on average at 60 minutes (95-  $189 \mathrm{pm}$ ) (Table 2).

When comparing  $SpO_2$  according to the type of delivery, significant differences were found up to 10 minutes after birth, with significantly higher mean values (p<0.05) observed in vaginal births compared to cesarean births. Subsequently, for minutes 15, 30 and 60 no significant differences were found (Table 3).

Regarding HR, statistically significant differences were found in the first two minutes postpartum, with higher average values observed in vaginal deliveries

Time (min)	Oxygen arterial saturation (%)		p value	Heart rate (HR)		p value
	Vaginal delivery Mean (range)	Cesarean delivery Mean (range)		Vaginal delivery Mean (range)	Cesarean delivery Mean (range)	
1	62.4 (29-88)	54.9 (32-80)	< 0.0001	155 (86-199)	144 (76-190)	< 0.01
2	69.0 (32-90)	60.0 (32-87)	< 0.0001	162 (90-198)	156 (75-198)	0.01
3	75.5 (40-96)	67.1 (36-90)	< 0.0001	166 (94-198)	164 (75-197)	0.26
4	81.6 (50-99)	74.1 (38-95)	< 0.0001	164 (98-204)	163 (82-198)	0.47
5	86.0 (58-100)	80.0 (46-96)	< 0.0001	164 (99-200)	162 (96-195)	0.23
6	88.8 (57-100)	85.0 (46-99)	< 0.0001	163 (112-198)	160 (98-196)	0.28
7	91.0 (64-100)	88.0 (65-100)	< 0.0001	161 (118-194)	159 (98-194)	0.7
8	92.2 (60-100)	90.6 (64-100)	0.02	160 (117-194)	157 (100-191)	0.63
9	93.6 (76-100)	92.0 (64-100)	0.02	159 (127-190)	156 (100-200)	0.25
10	95.1 (80-100)	93.9 (78-100)	0.01	158 (126-190)	154 (115-192)	0.02
15	96.2 (86-100)	96.0 (86-100)	0.63	154 (120-193)	150 (120-189)	0.02
30	97.7 (90-100)	97.5 (90-100)	0.26	149 (95-190)	145 (110-184)	< 0.0
60	98.3 (89-100)	98.2 (92-100)	0.62	143 (95-170)	142 (115-189)	0.04

compared to cesarean deliveries. The same results were obtained in minutes 10, 15, 30 and 60, which were significantly higher in vaginal deliveries (Table 3).

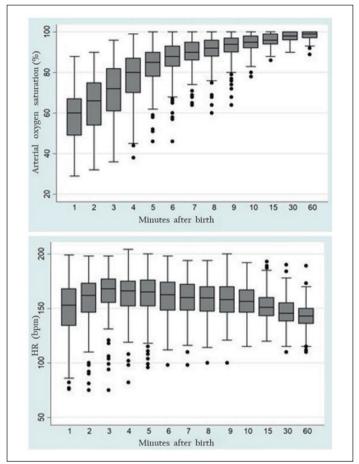
When SpO<sub>2</sub> and HR were compared according to NB gender, no statistically significant differences were found in any of the minutes evaluated in this study (Table 4).

Figure 1 shows that the oxygen saturation gradually increases minute by minute until it reaches a

value higher than 90% at minute 8. There are some newborns who still have a low SpO<sub>2</sub> lower than 60% at 5 and 6 minutes postpartum, and two NB who had a SpO<sub>2</sub> lower than or equal to 80% at 10 minutes postpartum. With respect to HR, neonates with values below 100 bpm up to 7 minutes postpartum are observed. However, from minute 8 to 60 minutes postpartum, the HR is equal to or higher than 100 bpm.

Time (min)	Oxygen arterial saturation (%)		p value	Heart rate (bpm)		p value
	Femenine Mean (range)	Masculine Mean (range)		Femenine Mean (range)	Masculine Mean (range)	
1	57.23 (29-80)	58.53 (36-88)	0.44	144.99 (76-188)	147.59 (77-189)	0.43
2	63.43 (32-90)	63.69 (38-89)	0.94	157.87 (98-194)	156.91 (75-190)	0.86
3	70.79 (47-95)	70.52 (40-95)	0.98	165.97 (104-195)	162.54 (75-194)	0.19
4	77.49 (48-96)	77.79 (56-99)	0.91	163.92 (108-194)	161.13 (82-196)	0.25
5	82.9 (51-98)	82.7 (59-100)	0.74	163.68 (111-191)	160.86 (96-199)	0.25
6	86.91 (67-98)	87.22 (68-100)	0.74	163.1 (122-193)	158.74 (98-196)	0.08
7	89.37 (65-100)	89.72 (68-100)	0.91	161.68 (118-191)	157.29 (98-194)	0.07
8	91.39 (68-100)	91.85 (69-100)	0.73	159.41 (117-191)	157.2 (100-194)	0.35
9	93.01 (72-100)	92.77 (64-100)	0.77	157.76 (123-189)	155.51 (100-192)	0.32
10	94.47 (78-100)	94.45 (78-100)	0.59	157.28 (126-190)	153.74 (115-190)	0.10
15	96.42 (89-100)	96 (86-100)	0.25	152.91 (120-193)	150.81 (120-185)	0.29
30	97.5 (90-100)	97.63 (90-100)	0.61	147.51 (110-184)	145.71 (120-190)	0.33
60	98.3 (89-100)	98.22 (93-100)	0.77	144.45 (110-189)	141.8 (118-170)	0.13

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**Figure 1.** SpO<sub>2</sub> and HR during the first 60 minutes after birth in 324 newborns. The boxes represents the 25th and 75th percentiles and the line inside the boxes is the median. The upper and lower lines outside the boxes correspond to the dispersion, obtained by the interquartile range. The circles represent the outliers.

#### **Discussion**

In the NB evaluation, continuous monitoring of oxygenation and heart rate allows the evaluation of neonatal well-being, which is particularly useful in the first minutes after birth<sup>2,4</sup>.

SpO<sub>2</sub> and HR were measured in all infants from birth, both those born vaginally and by cesarean section, and who met the inclusion criteria. Data recording was carried out up to the first 60 minutes post-birth. The results of this study confirm, as other authors<sup>7,8,15-18</sup>, that postnatal oxygenation requires an adaptation period of a few minutes after childbirth in order to achieve oxygenation levels within the normal range. The initial low postnatal oxygen saturation would be due to the persistence of the right-to-left shunt caused by the ductus arteriosus and the patent foramen ovale. The SpO<sub>2</sub> increases after 15 to 30 minutes to definitive values would correspond to the functional closing of the shunts at ductal and atrial level<sup>8,16</sup>.

In our study, SpO<sub>2</sub> showed a progressive increase from 58.7% the first minute after birth to reach 83% at 5 minutes and surpassed the 90% threshold at 8 minutes and then above 95% at 15 minutes after birth which was similar to that reported by other authors<sup>7,8,15,16</sup>. It should be noted that the group of studied neonates presented an average SpO<sub>2</sub> lower than 80% in the first 4 minutes of postnatal life, demonstrating that an oxygen saturation lower than 80% can be associated with cyanosis due to hypoxemia (PaO<sub>2</sub> < 50 mmHg), and with the changes that occur in the oxygen-hemoglobin dissociation curve<sup>3,19</sup>. Consequently, it is physiologically feasible to expect some degree of cyanosis in the first postnatal minutes of the NB<sup>20</sup>.

Large variability in the visualization of cyanosis in neonates has also been observed, along with poor correlation between cyanosis and SpO<sub>2</sub><sup>20,21</sup>. According to the AAP and the AHA consensus<sup>3</sup>, NBs who are breathing spontaneously, with normal HR, and good muscle tone in the first postnatal minutes, if they present cyanosis, oxygen supplementation is unnecessary, especially due to the potential medium- and long-term toxic effects secondary to hyperoxygenation<sup>22</sup>.

In this research, as well as the studies by Kamlin et al.<sup>7</sup>, Harris et al.<sup>9</sup>, Rabi et al.<sup>15</sup>, Dawson et al.<sup>23</sup>, Zubarioglu et al.<sup>24</sup>, and Zanardo et al.<sup>25</sup>, NBs born by cesarean section showed a significantly lower SpO<sub>2</sub> than those born vaginally in the first minutes after birth.

The lower SpO<sub>2</sub> in those born by cesarean section could be due to the increase of lung fluid due to lack of compression of the fetal thorax in the birth canal, generating a ventilation-perfusion mismatch and therefore lower oxygenation<sup>9</sup>. According to this study and others<sup>9,15</sup>, total or partial reabsorption of lung fluid is a rapid and transient mechanism, since SpO<sub>2</sub> is usually equal at 10 minutes in neonates born vaginally or by cesarean section. In the studies by Dawson et al.<sup>23</sup>, Harris et al.<sup>9</sup>, and Rabi et al.<sup>15</sup>, the mean SpO<sub>2</sub> values in NBs delivered vaginally or by cesarean section were equaled at 6, 7, and 8 postnatal minutes, respectively.

In the study by Kamlin et al.<sup>7</sup>, it is not known at which point SpO<sub>2</sub> values are equaled between NBs born vaginally or those by cesarean section since saturation values were only recorded up to 5 minutes postbirth, at which time SpO<sub>2</sub> was significantly higher in neonates born vaginally.

In our study, as described by other authors<sup>15,23</sup>, the average SpO<sub>2</sub> was higher than 90% at 8 minutes postnatal. The difference between our experience and that of Rabi et al.<sup>15</sup> is that in the latter, SpO<sub>2</sub> was measured pre-ductal and at 1000 meters above sea level (atmospheric pressure 660 mmHg) and the measurement of our study was post-ductal and at sea level. The study by Mariani et al.<sup>17</sup> revealed a pre-ductal SpO<sub>2</sub> value of 90% at 5 minutes and a post-ductal value higher than

90% at 10 minutes post-birth. However, other authors have reported longer times to achieve an average post-ductal SpO<sub>2</sub> over 90%<sup>8</sup>.

The pulse oximeters along with the constant evaluation of SpO<sub>2</sub> also simultaneously measure the heart rate. However, several publications<sup>7-9,15-17</sup>, which evaluated SpO<sub>2</sub> from birth, did not report HR, despite it is considered one of the most reliable, accurate, and useful vital signs for determining newborn vitality and evaluating response to resuscitation if necessary<sup>26</sup>. It is important to highlight the importance of HR measurement by a pulse oximeter since it has been shown that HR measurement by clinical parameters, such as auscultation or palpation, can be underestimated by as much as 17 bpm<sup>26</sup>.

The average HR in our case was 150 bpm at the first post-natal minute with a range between 76 and 199 bpm, which increased to 159 bpm at the two post-natal minutes, similar to what Toth et al.8 reported from 157 bpm at 2 minutes and Meier-Stauss et al.27 from 155 bpm at 3 postnatal minutes. The study carried out by Brady et al.<sup>28</sup> on heart rate, more than 50 years ago, showed an HR of 152 bpm at 1 minute post-birth, with a decrease to 140 bpm at 60 minutes post-natal. This was consistent with our experience, which showed an HR of 143 bpm at 60 minutes post-birth in the studied group. However, these findings differ from the study by Dawson et al.23 in a population of 468 preterm and term NB, with a gestational age between 25 and 42 weeks that showed an average HR of 97 bpm at the first post-natal minute, of which 50% presented lower than 100 bpm, increasing to 139 bpm at the second post-natal minute. This heart rate was lower than that reported by Toth et al.<sup>8</sup> and the one observed in our study.

The HR values of our study are consistent with those of Toth et al.<sup>8</sup> and Meier-Stauss<sup>27</sup> which reported an increase in HR in the first 4 minutes after birth with values of 168 bpm and 160 bpm respectively, and then stabilized at 10 minutes. It should be noted that in the study by Dawson et al.<sup>23</sup>, HR in preterm NB was lower than in term NB, the latter showing HR values similar to ours from the third post-natal minute. However, in the same study, HR in vaginally born NB was significantly higher than those born by cesarean section. This was similar to our observation, in which NB born vaginally presented a higher HR in the first 2 post-natal minutes and later from minute 10 to 60, compared to NB born by cesarean section.

We also share other similarities with what was reported by Dawson et al.<sup>23</sup>, since we also recorded some NB with HR lower than 100 bpm at the first minute after birth, which recovered quickly spontaneously, without medical action.

In this study, the report of HR lower than 100 bpm in healthy NB at the first post-natal minute, as repor-

ted in a significant percentage of neonates by Dawson et al.  $^{23}$ , is an interesting finding that needs further study; since, according to the AAP-AHA resuscitation algorithm<sup>3</sup>, when the NB presented an HR < 100 bpm at the first post-natal minute, it would be an indication to perform positive-pressure ventilation, an intervention that was not necessary for the work of Dawson et al.  $^{23}$  or in ours.

It should be noted that in our series the umbilical cord was clamped mostly after the first breath of the newborn, avoiding the depressor reflex, which could have contributed to registering a higher HR in the first 3 minutes post-natal.

In our investigation, the highest HR values of the total group, compared to what was reported by Dawson et al.<sup>23</sup>, could be due to the fact that this last study included premature NB, the use of anesthetics, or to the fact that the cord clamping was perhaps performed before the first breath of the NB (unrecorded event), situations that alone or together could have depressed the HR of the NB in the first post-partum minutes. In our case, mothers who underwent a cesarean section only received regional anesthesia.

The HR measurement by pulse oximeter is a safe and more accurate measurement than simple auscultation<sup>26</sup>, therefore, it is unlikely to assume any error in the measurement reported by Dawson et al.<sup>23</sup>. It should be noted that our SpO2 and HR data were analyzed only if they had an adequate plethysmographic waveform and a quality numerical signal; therefore, they are unlikely to have been altered by artifacts. The NBs in this study did not receive any additional oxygen and/or respiratory support during the first 60 postnatal minutes.

The measurements of SpO<sub>2</sub> and HR made by the pulse oximeter (Nellcor OxiMax N-600) used in our study present a reliability very similar to the equipment that has signal extraction technology (Masimo)<sup>29</sup>.

Although several cardiorespiratory pathologies are more prevalent in boys<sup>30,31</sup>, most of the studies that have evaluated SpO<sub>2</sub> pre- and post-ductal in the first post-natal minutes have not reported what happen with SpO<sub>2</sub> regarding to the gender of NB<sup>7-9,15-18</sup>, except as published by the group of authors from Turkey<sup>24,32</sup> which did not demonstrate gender differences in oxygen saturation in both term and preterm NB. This observation is consistent with what was found in this work, where no significant differences were demonstrated for both SpO<sub>2</sub> and HR.

Unlike previous studies<sup>7,15,17</sup>, we recorded SpO<sub>2</sub> and HR measurements during the first 60 minutes postpartum and not only in the first 10 minutes postpartum, as in most studies<sup>5,28,32-34</sup> or until saturation was higher than 95%<sup>15,27</sup>.

One of the possible limitations of our study is that

post-ductal saturation was measured in order to favor attachment. The strengths include significant sample size and the fact that it was carried out in a single health center, which allowed for an adequate study standardization.

This study, like previous studies<sup>7-9,15-17,28,32-34</sup>, showed the feasibility of using the pulse oximeter immediately after birth in order to rapidly, timely, and accurately monitor arterial oxygen saturation and the heart rate of the neonate.

In conclusion, in healthy term NB, SpO<sub>2</sub> increases progressively during the first 10 minutes post-natal, being higher in the first 7 minutes in children born vaginally. In NB vaginally delivered, a higher HR was observed in the first 2 post-natal minutes and then from 10 to 60 minutes.

#### **Ethical Responsibilities**

**Human Beings and animals protection:** Disclosure the authors state that the procedures were followed according to the Declaration of Helsinki and the World

Medical Association regarding human experimentation developed for the medical community.

**Data confidentiality:** The authors state that they have followed the protocols of their Center and Local regulations on the publication of patient data.

**Rights to privacy and informed consent:** The authors have obtained the informed consent of the patients and/or subjects referred to in the article. This document is in the possession of the correspondence author.

#### **Financial Disclosure**

Authors state that no economic support has been associated with the present study.

#### **Conflicts of Interest**

Authors declare no conflict of interest regarding the present study.

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