Building Evidence for Practice: A Pilot Study of Newborn Bulb Suctioning at Birth

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The purpose of the study was to examine the effects of bulb suctioning on healthy, term newborns and the feasibility of conducting a large-scale study of this practice. In a randomized, controlled two-group design pilot study, 10 newborns received oronasopharyngeal bulb suctioning at birth and 10 did not. Differences in Apgar scores, heart rates, and oxygen saturation levels were determined. Infants were randomized to groups before delivery. The participants were 20 term, healthy newborns of uncomplicated pregnancies. Apgar scores, heart rates, and oxygen saturation levels in the first 20 minutes of life were the main outcome variables. There were no statistically significant differences in Apgar scores between groups. Apgar scores at 5 and 10 minutes were 9 or 10 for all newborns. Newborns receiving bulb suctioning showed a statistically significant, lower heart rate ($P = .042$) during the first 20 minutes and a significantly higher SpO_2 level ($P = .005$) by 15 minutes of age. Although statistically significant, these findings were not considered clinically significant because values remained within normal parameters. J Midwifery Womens Health 2004;49:32–38 © 2004 by the American College of Nurse-Midwives.

keywords: delivery, infant, newborn, pulse oximetry suction

INTRODUCTION

Bulb suctioning of the mouth and nose has been a routine part of the initial management of the normal term newborn for many years, whether delivered vaginally or by cesarean section.[1,2] Reasons given for performing brief suctioning of the mouth and nose at birth have been to 1) remove pulmonary fluid expelled from the trachea, 2) clear the small air passages to facilitate air entry, 3) prevent aspiration of mucous and blood with the establishment of respirations, and 4) provide tactile stimulation to assist in the initiation of respirations in the infant.[3,4]

McCartney[4] summarized common issues raised by a diverse group of midwives and perinatal nurses in an electronic forum on mother-baby care. A frequent comment based on clinical observation was that bulb suctioning seemed irrelevant to the status of the healthy newborn. Concerns of this group included 1) possible harmful effects of deep pharyngeal bulb suctioning, which may cause vagal-induced bradycardia or apnea; 2) irritation to mucus membranes causing increased mucus production and rebound nasal congestion that can interfere with subsequent breastfeeding; 3) tissue trauma caused by aggressive suctioning practices that can occur with lack of knowledge of proper technique; and 4) concerns about increased risk for infection with prolonged use of the same bulb syringe. McCartney asked the question that others have raised recently, "Is it time to reexamine this practice?"[4]

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LITERATURE REVIEW

A literature search on MEDLINE, CINAHL, and the Cochrane Collaboration Library was performed from 1966 to present by using the following keywords that appear in the National Library of Medicine's Medical Subject Headings: Suction, Newborn, Delivery. Only three studies addressed suctioning the normal term newborn at birth,[5–7] and these addressed the use of suction catheters rather than bulb syringes.

In a randomly assigned, control study of 40 normal term vaginally born infants, Estol and colleagues[7] found no significant differences in respiratory functions between the group of newborns who received catheter suctioning immediately after birth and the control group not suctioned. An additional finding was that the volume of lung fluid withdrawn during the suction procedure was miniscule and did not appear to affect mechanical adaptation of the lung in any way. These investigators concluded that the volume of fluid eliminated by the suction procedure is only a minimal fraction of that contained in the respiratory system at birth; in the normal newborn, all of this fluid is totally and rapidly disposed of shortly after birth by physiological mechanisms.

In a more recent study, Carrasco and associates[5] examined the effects of oronasopharyngeal catheter suctioning immediately after birth on arterial oxygen saturation in a randomized study of 30 vaginally born normal term newborns. Newborns who received suctioning compared with the control group had significantly lower oxygen saturation levels through the first 6 minutes of life and took longer to reach a normal range of 86% to 92% saturation ($P < .05$). These investigators concluded that a gradual increase of oxygen saturation occurs after birth until it becomes stabilized at 12 to 13 minutes of life and that oronasopharyngeal suction in this study showed no benefit in oxygenation of

the newborn. They also pointed out that oxygen saturation levels remaining less than 85%, even briefly may cause or prolong pulmonary vasoconstriction and possibly trigger pulmonary artery hypertension. Therefore, it may be important for oxygen saturation levels to be greater than 85% as soon as possible after birth.

Current guidelines state there is no evidence to support the value of the practice of routine bulb suctioning of the newborn.[8] In addition, the current Neonatal Resuscitation Program (NRP) guidelines[9] no longer include bulb suctioning in the initial resuscitation management of the normal term newborn. As noted by McCartney,[4] these guidelines recommend mechanical suctioning of the mouth and nasopharynx on the perineum when meconium is present in the amniotic fluid.

In summary, studies investigating the practice of routine suctioning of normal term infants at birth have looked at the role of suction catheters in removing lung liquid, mucus, and secretions and facilitating entry of air.[5,7] These studies fail to show a benefit in oxygenation with the use of catheter suctioning and have recommended that the routine and indiscriminate use of oronasopharyngeal catheter suctioning at birth be curtailed. These recommendations do not address the more routine procedure of bulb suctioning at birth. The bulb syringe generates less suction pressure and is not inserted as deeply as the catheter. This raises questions about its usefulness in improving oxygenation through removing secretions from air passages and facilitating air entry.

Nurses have expressed concern that bulb suctioning can produce harmful and undesirable responses in the newborn. Corderro and Hon[6] reported this same concern 30 years ago in one of the few studies on oronasopharyngeal suction at birth. They noted that apnea, bradycardia, and lowered arterial oxygen saturation levels have been reported to occur with deep, prolonged oronasopharyngeal catheter suctioning of newborns at birth but have not been studied with bulb suctioning.[5,6] The vagus nerves supply the soft palate, pharynx, and larynx, and when stimulated, will cause the heart rate to decrease because of the inhibitory effect that parasympathetic stimulation of acetylcholine has on heart function.[10] Gastric suctioning has been associated with slight elevation in mean arterial pressure, retching, and

disruption in sequence of prefeeding behaviors (i.e., sucking, rooting, and hand to mouth movements).[11] It is possible that improperly performed deep and prolonged bulb suctioning could stimulate the vagus nerves of the posterior pharynx and induce bradycardia and lower the arterial oxygen saturation level. Multiple or prolonged suctioning can also delay initiation of necessary and beneficial resuscitation measures in a compromised infant at birth.[9]

At term, approximately 20 mL/kg of lung fluid is present in the respiratory tract of the newborn. It is thought that mechanical chest compression during birth squeezes out most of this lung fluid through the trachea and oronasopharynx and creates negative pulmonary pressure in preparation for inspiration.[1] Bulb suctioning of the mouth and nose is thought to aid in the removal of pulmonary fluid and facilitate the entrance of air. However, studies on fetal animals indicate that pulmonary fluid secretions begin to decline toward the end of gestation, and pulmonary microcirculation is primarily responsible for the absorption of lung fluid after birth.[12] These findings raise questions about the value of bulb suctioning in removal of lung fluid.

Airway obstruction, caused by excessive fluid and mucus, can compromise air entry, oxygen delivery, and a decreased amount of oxygen to bind with hemoglobin. This results in decreased oxygen saturation levels.[13] Measurement of oxygen saturation by pulse oximetry is a noninvasive form of oxygen monitoring. It reflects oxygen saturation accurately and very rarely results in complications.[14] Since its introduction in the 1980s, pulse oximetry has become a standard method for monitoring arterial oxygen saturation levels. Oxygen saturation represents the percent of hemoglobin that is saturated with oxygen. Because the transport of oxygen in the blood is achieved almost entirely by hemoglobin, oxygen saturation can be a measure of the oxygen load in the bloodstream. The amount of oxygen in the blood depends on the transport of oxygen from the environment to the lungs and the adequacy of gas exchange within the lungs.

Pulse oximetry values have been reported to change over time in healthy term newborns. Reddy, Holzman, and Wedgwood[15] found that pulse oximetry values in term newborns were lower in the first 20 minutes of life (range 91%–100%), compared to the second hour (range 96%–100%), and that babies during the first 6 hours of life spent a majority of time with saturations >97% to 100%. Dimich and associates[16] demonstrated that oxygen saturation, measured by pulse oximetry, did not differ between neonates delivered vaginally or by cesarean section and that oxygen saturations obtained from the right hand is a better index of neonatal oxygenation than that obtained from the heel. Limitations in the use of pulse oximetry are that false estimates can occur if the pulse oximeter probe is applied incorrectly or if motion of the patient or probe occurs, resulting in poor signal or an optical shunt.[14]

The purpose of this pilot study was to examine the bulb

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Inclusion Criteria	Exclusion Criteria
Singleton gestation	Any contradictions to vaginal delivery
Term pregnancy (37–42 wk)	Significant non-remedial variable or
Cephalic presentation	late decelerations
Vaginal delivery	Prolonged rupture of membranes
Ruptured membranes < 18 h	Meconium-stained amniotic fluid
Clear amniotic fluid	Suspected maternal chorioamnionitis
No known fetal or maternal	Any delivery emergency (i.e., shoulder
morbidity	dystocia, etc.)
Uncomplicated labor course	

suctioning procedure in healthy newborns and systematically acquire data on the effects of bulb suctioning in the care of healthy term newborns at birth. A second goal was to determine the feasibility of conducting a large-scale study of bulb suctioning.

HYPOTHESES

1) There is no significant difference in 1-, 5-, and 10-minute overall Apgar scores between newborns who receive bulb suctioning at birth and those who do not. 2) There is no significant difference in heart rates in the first 20 minutes of life as measured by non-invasive continuous cardiac electrode monitoring system between newborns who receive bulb suctioning at birth and those who do not. 3) There is no significant difference in arterial oxygen saturation in the first 20 minutes of life as measured by the pulse oximeter between newborns who receive bulb suctioning at birth and those who do not.

METHODS

A randomized controlled trial with a two-group design was used in this pilot study to determine differences in Apgar scores, heart rates, and arterial oxygen saturation (SpO_2) levels between healthy term infants who received bulb suctioning at birth and those who did not.

The study was conducted at a southeastern medical center over 4 months. Approval by the institutional review board was obtained prior to initiating the study. Pregnant women admitted to the labor and delivery unit were evaluated for inclusion in the study (Table 1).

Women who met the selection criteria were approached soon after admission to the labor and delivery unit and while they were in the early stages of labor to obtain written informed consent for participation of their newborn in the study. In every case, these women were approached only when they were comfortable and able to attend to the explanation of the study. Twenty-five eligible women consented to the study, and five of these were later withdrawn. Reasons for withdrawal included delivery by cesarean section (n = 3) and rupture of membranes greater than 18 hours (n = 2).

Prior to initiation of the study, the principal investigator met with resident physicians and nursery nurses who would be attending the deliveries to provide instruction and training in the study protocols. Throughout the study the on-call resident physician was notified whenever a participant was enrolled in the study. Shortly before delivery, the principal investigator or member of the research team randomly assigned the unborn infant to either the suction group or the no suction group and notified the attending resident physician of the prescribed protocol to follow. The prescribed protocol was followed in every case and was verified by the principal investigator or a member of the research team who attended all study deliveries.

Instruments

A standard sterile, 2-ounce soft rubber bulb syringe, also known as an ear/ulcer syringe, was used to suction the mouth and nares of each infant in the suction group. A reusable neonatal saturation sensor (Hewlett Packard (HP) M1193A) connected to a pulse oximeter with digital reading and recording (HP M1175A) was used to provide continuous non-invasive oxygen saturation and heart rate monitoring. Electrodes for simultaneous heart rate recording (ConMed – Neotrode II) were also applied to verify the accuracy of measurements obtained by the saturation sensor. The neonatal sensor has a reported accuracy of ±3% SpO_2 for the range $70\% < SpO_2 < 100\%$ based on the clinical data from neonates.[17] The same reusable sensor was used for all SpO_2 measurements. The reusable saturation sensor was tested for reliability against a standard disposable neonatal SpO_2 sensor prior to data collection. The sensor demonstrated similar readings when compared with simultaneous disposable sensor readings.

Procedures

At birth, infants randomly assigned to the suction group received oronasopharyngeal bulb suctioning by the attending obstetric resident when the head was delivered. First the mouth and then the nares were suctioned with a bulb syringe, one time each. The mouth was suctioned first because stimulation of the nares can cause reflex inspiration and possible inhalation of oropharyngeal contents. The bulb was compressed to squeeze out the air, and then the tip was gently placed in the mouth, approximately 1.5 inches deep, and finger pressure was slowly released, allowing mucus and fluid to be drawn into the bulb syringe. Following this, the compressed bulb syringe was placed in each naris approximately 0.5 inches. Infants in the no suction group did not receive bulb suctioning. All infants had their mouth and nose wiped with a towel if any visible matter was present. In the suction group, this was done prior to bulb suctioning. The only intervention in the no suction group was to wipe away any visible matter. Infants were then placed under the radiant warmer, dried thoroughly, and received standard care according to the NRP guidelines.[9]

Table 2. Maternal Demographics

Variable	Suction Mean (SD) Range	No Suction Mean (SD) Range	P^*
Maternal age	23 (4.9) 16–31	20 (2.4) 16–24	.1291
Gestational age (wk)	39.2 (1.2) 37–41	38.8 (1.5) 37–42	.4491
Hours from ruptured membranes to delivery	5.36 (2.71) 4–11 h	7.68 (4.50) 3–15.5 h	.248

* Based on Mann-Whitney U test.

The nursery nurse attending the delivery scored the Apgar and provided all newborn care. After drying the infant's face and head, the nursery nurse positioned the infant in the warmer, and a single-pass bulb suctioning of the mouth and nose was again performed on infants in the suction group. All deliveries were attended by routine labor and delivery staff, who along with a member of the research team served as independent observers of this study protocol.

Within the first minute of life, the newborn was placed on the infant warmer. An oxygen saturation sensor was applied to the hand, and electrodes were attached to the chest and left thigh to provide continuous digital readings and recordings. Minute-by-minute SpO_2 and heart rate recordings were obtained during the first 20 minutes of life. The time frame selected was based on previous studies that reported stabilization of SpO_2 levels by 12 to 13 minutes of life.[5,7] Secondarily, investigators chose to limit the observation period because of concerns about keeping the newborn away from the mother, thereby delaying maternal-infant bonding. Reading stabilization took between 2 and 3 minutes, and first readings were obtained between 2 and 5 minutes of age.

Statistical Analysis

A t test or a Mann-Whitney test for continuous outcomes and a Fisher's exact test for categorical responses were used to determine differences in the maternal and fetal demographic variables. Data from the Apgar scores were analyzed by using Fisher's exact for group differences. Heart rate and pulse oximetry sensor readings of the two groups were compared using repeated-measures linear regression model.

Changes in SpO_2 levels over time were analyzed using repeated-measures regression models to account for the correlation between observations taken on the same subject. Repeated-measures covariate models were used to determine the effect of the perfusion index (numeric measurement of the quality of the signal being used to calculate SpO_2) and its relationship to movement quantified by the difference between oximetry and electrode heart rates on SpO_2 readings.

Statistical analysis was performed using SAS and SPSS

Table 3. Intrapartum Characteristics

Variable	Suction (%)	No Suction (%)	P^*
Gravida 1	40	40	.152
Labor induction	20	20	1.000
Labor augmentation	100	100	1.000
Medication			
$MgSO_4$	10	0	1.000
Stadol	40	70	.370
Anesthesia			
Spinal	10	10	1.000
Pudendal	10	10	1.000
Epidural	80	100	.472
Spontaneous delivery	50	70	.650
Infant gender			
Male	60	50	1.000

* Based on Fisher's exact test.

statistical software packages with a P value of .05 as the level of significance.

RESULTS

Twenty term newborns of mothers meeting the maternal inclusion criteria were enrolled in the study. The two groups were similar in maternal demographics, intrapartum characteristics, and birthweight (Tables 2–4). Infants in the no suction group had a slightly higher, statistically significant umbilical cord pCO_2 at birth ($P = .035$) prior to any intervention (Table 4).

One infant in the no suction group, born at 37 weeks' gestation, developed mild respiratory distress and was treated with supplemental oxygen via oxyhood for approximately 24 hours. These findings were believed to be unrelated to the lack of bulb suctioning at birth, but more likely related to the lower gestational age and the fact that oronasopharyngeal suctioning removes fluid from the upper
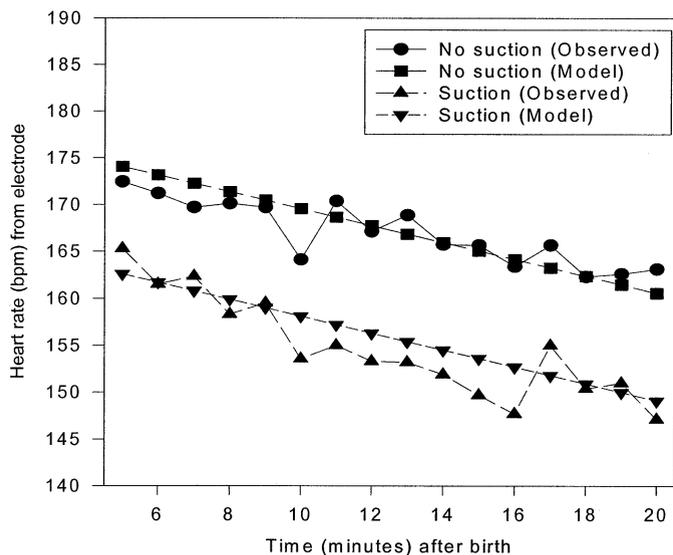
Table 4. Newborn Outcomes

Variable	Suction (N = 10)	No Suction (N = 10)	P^*
Birth weight (g)	3,272 ± 460	3,147 ± 464	.554
Apgar score			
< 9 at 1 min	0	1[†]	
< 9 at 5 min	0	0	
< 9 at 10 min	0	0	
Cord gases			
pH	7.26 (0.06)	7.22 (0.07)	.213
CO_2 (mm Hg)	37 (9)	48 (12)	.035[‡]
O_2 (mm Hg)	23 (7)	18 (8)	.212

* Based on t test.

† One infant in the non-suction group had an Apgar score of 8 at 1 min.

‡ $P < .05$.

Figure 1. Average changes in heart rate over time (5–20 minutes after birth).

Figure 2. Average changes in SpO$_2$ over time (5–20 minutes after birth).

nasopharyngeal area and not from the lung. However, a larger study will provide more evidence.
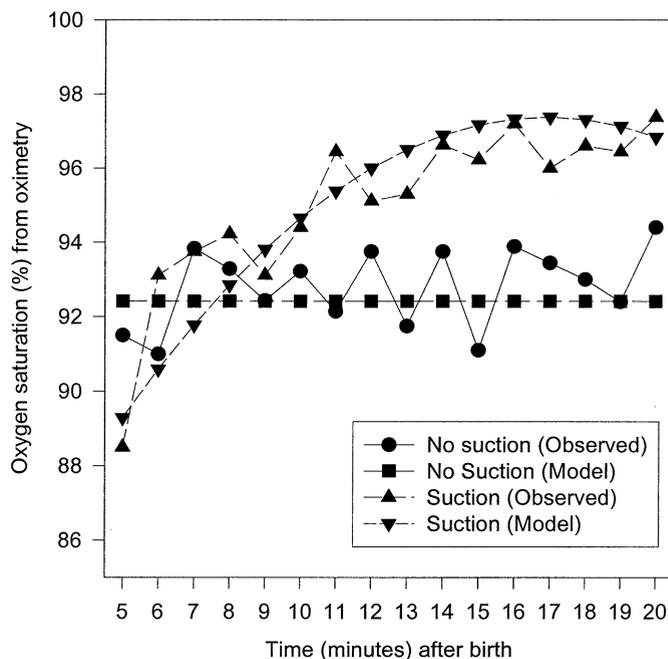
Apgar Scores

There were no statistically significant differences ($P = .303$) in Apgar scores between the suction and no suction groups. The mean at 1 minute was 8.95 (SD = .22); at 5 minutes the mean was 9 (SD = 0) in all infants. At 10 minutes of age, the mean was 9.40 (SD = .44). Table 4 shows the range of Apgar scores for the suction and no suction groups at 1, 5, and 10 minutes.

Newborn Heart Rate

There was a significant and constant difference in the heart rates for the two groups, mean 160.84 (SD = 7.65). Figure 1 illustrates the changes in heart rate over time as measured by the electrode recordings. The fitted linear model shows that infants in the suction group had a consistently lower heart rate of 11 ± 5.2 beats per minute (bpm) ($P = .042$), as indicated by the parallel slopes in Figure 1. There is a significant decrease in heart rate of -0.9 ± 0.3 bpm ($P = .005$) for both groups, suggesting that for each minute of observation, one would expect the heart rate to drop by approximately 1 bpm until stabilization, regardless of whether suction was used or not. Heart rates for both groups remained within normal range (suction group 150–166; no suction group 166–173). Normal heart rate during the first 30 minutes of life is 120 to 160 but may vary from 100 to 180 with sleep or crying.[1]

Oxygen Saturation

Due to differences over time, it is not possible to make a global statement of statistical significance, so differences at

specific points in time during the first 20 minutes of life were investigated. Artifacts produced by neonatal movements unfortunately resulted in sparse usable data in the first 5 minutes. Therefore, only those oxygen saturation measurements recorded from 5 to 20 minutes were used in the analysis. The average perfusion index measurements for all SpO$_2$ recordings after 5 minutes of age were between 0.6 and 1.5, indicating acceptable arterial pulses identified for reliable readings. A standard method of dealing with the issue of motion is averaging over subsequent measures, and the regression models accomplish a similar goal so that high and low values are somewhat attenuated.

Figure 2 illustrates the relationship of oxygen saturation levels over time for both groups from 5 to 20 minutes of age. There is a difference in the regression model that explains the trends in the data for the suction and no suction groups. Based on the final model, for the no suction group, oxygen saturation levels did not appear to change significantly over time and remained constant at approximately 92%.

Oronasopharyngeal bulb suctioning may alter oxygen saturation levels as time progresses as evidenced by a component of the regression that approached statistical significance ($P = .057$). The newborn group who received bulb suctioning had a slightly lower, although nonsignificant, oxygen saturation level at 5 minutes of age ($-3\% \pm 2.3\%$). However, 10 minutes after birth, this trend had reversed, and this group had a slightly higher oxygen saturation level by approximately 2.2% ± 2.1%. At 15 minutes of life, oxygen saturation levels for the suction group were significantly higher by 4.8% ± 1.7% ($P = .005$), and this trend seemed to continue. At the end of the

first 20 minutes of life, SpO_2 levels were approximately 97% for those in the suction group and 92% for those in the no suction group.

DISCUSSION

The purposes of this pilot study were to examine the effects of bulb suctioning at birth of healthy, term newborns and to determine the feasibility for conducting a large-scale study of this practice in the clinical setting of a busy labor and delivery unit. The results of this initial pilot study suggest that a larger study is feasible and warranted. The statistical parameters (mean and standard deviation) from the pilot data are used in the power analysis to determine the sample size needed to obtain a statistically significant result in a larger study.

Feasibility

Additional questions addressed in the pilot study were as follows:

1. The ability to enroll a sufficient sample size in a larger study.
2. The ability to obtain accurate and reliable data on heart rate and SpO_2 levels soon after birth.
3. Identification of other study limitations related to the clinical setting.

Obtaining informed consent of women in labor and delivery had clear drawbacks. Many women who met the study criteria were not approached because of active labor or patient care activities that were occurring at the bedside. An alternate approach would be to make the initial contact with potential participants during a routine prenatal visit to discuss the study, answer questions, and obtain preliminary consent. Later, when the woman is admitted to the unit for delivery, signed, informed consent could be obtained. This would allow time for a relationship to develop and questions to be answered before the day of delivery, as well as time for mothers to discuss the study with significant others prior to enrolling as a participant.

The study also demonstrated difficulty in obtaining accurate heart rate and SpO_2 readings before 2 to 3 minutes of age because of the time required to dry the infant's trunk and extremities and apply the electrodes and oximetry sensor. Repeated practice to increase efficiency with this procedure are required for consistency in obtaining accurate recordings as soon as possible after birth.

Another limitation was the use of different residents and nursery nurses rather than one individual attending the deliveries, which could have resulted in variations in timing and techniques. However, this could be viewed as a strength because even with several different residents attending the deliveries, there was no clinically significant difference in the two groups.

Finally, other problems encountered included changes in the status of the mother or fetus requiring cesarean section. Space in the delivery room was also a challenge. Equipment had to be set up and checked before the mother was brought to the delivery room.

Outcomes

The results of this study indicate that SpO_2 levels gradually stabilize after birth at 92% to 97%. Similar to findings obtained by Carrasco and colleagues,[5] the suction group initially had lower SpO_2 levels and took longer to reach 92%. However, by 10 minutes of life, this trend had reversed, and the suction group showed a higher SpO_2 level, which persisted through the data collection period of the first 20 minutes of life

The lower heart rate in the suction group may have resulted from a transient decrease in heart rate as a vagal response to stimulation of the posterior pharynx with the bulb suction. Even so, all heart rates remained within normal range throughout the observation period.

The findings of the pilot study do not support the claim that bulb suctioning is beneficial. Although the power to detect statistically significant differences is low due to the small sample size, comparison of the clinical morbidity measures reveals that the two groups are similar in most respects. There were statistically significant differences in heart rate and SpO_2 levels between the two groups, but these were not considered clinically relevant because they remained inside normal parameters.

Conducting this pilot study proved to be a valuable experience. Potential problems in subject recruitment, data collection, and control of the environment were identified and provided valuable insight for future study designs. In addition, the results of the study indicate that additional study of the bulb suctioning practice is warranted. Plans are underway to conduct a large-scale study incorporating the findings from this pilot study.

Childbirth is a normal, natural process that over the years has become fraught with interventions that are not evidence based. Our purpose is to examine these interventions systematically and scientifically to promote practices that foster optimum health for mother and infant.

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