UNIVERSITÀ DEGLI STUDI DI PADOVA

DIPARTIMENTO DI SALUTE DELLA DONNA E DEL BAMBINO

CORSO DI LAUREA IN OSTETRICIA

Presidente Prof.ssa Alessandra Andrisani

TESI DI LAUREA:

A randomized controlled trial for neonatal suctioning in a low-resource setting delivery room: a comparison between penguin and catheter

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A tutte le mamme di Wolisso e ai loro bambini

"Se la salute è un diritto, l'accesso ai servizi
sanitari non può essere un privilegio.
Se la salute è un diritto, battersi per il suo
rispetto universale è un dovere"

Motto di Medici con l'Africa Cuamm

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RIASSUNTO

Background: molta è la letteratura scientifica a supporto dell'offerta di aspirazione a tutti i neonati con difficoltà respiratorie da evidente ostruzione delle vie aeree o con necessità di ventilazione a pressione positiva. In questi casi, le linee guida internazionali raccomandano l'aspirazione manuale con pinguino o elettrica con catetere senza però specificare eventuali differenze cliniche tra i due metodi.

Scopo dello studio: lo studio si propone di rilevare l'esistenza di differenze tra aspirazione manuale con pinguino ed elettrica con catetere in una popolazione di neonati che necessitavano dell'intervento di aspirazione. L'outcome primario dello studio era la determinazione dei valori di saturazione di ossigeno nei primi 10 minuti di vita.

Materiali e metodi: lo studio è stato condotto da agosto ad ottobre 2021 e da giugno 2022 a settembre 2022 al St. Luke Catholic Hospital, Wolisso (Ethiopia), un ospedale di riferimento, non profit, privato e di terzo livello che conta circa 3600 parti l'anno. Si tratta di un trial monocentrico, prospettico, randomizzato, controllato il cui obiettivo è stato quello di comparare due diversi metodi di aspirazione. I criteri di inclusione comprendevano: neonati di qualsiasi età gestazionale, la necessità di aspirazione oro nasofaringea alla nascita e il consenso dei genitori. Immediatamente dopo la nascita, in modo randomizzato, a tutti i neonati eligibili, è stato assegnato uno dei due interventi di aspirazione: pinguino per l'aspirazione manuale o catetere per l'aspirazione elettrica. Tutte le procedure di rianimazione neonatale sono state eseguite seguendo l'Helping Babies Breathe Algorithm (versione 2). Un osservatore esterno, non coinvolto nella rianimazione neonatale, era responsabile del posizionamento della sonda del saturimetro e della raccolta dati, quali, innanzitutto la saturazione di ossigeno e la frequenza cardiaca.

Risultati: 61 pazienti sono stati reclutati per l'analisi (31 nel gruppo dell'aspirazione elettrica e 30 in quello dell'aspirazione manuale). La saturazione di ossigeno è incrementata in entrambi i gruppi ($p < 0.0001$) con uguale pendenza ($p = 0.7728$). Anche la frequenza cardiaca è aumentata nei due gruppi ($p < 0.0001$) con uguale pendenza ($p = 0.0989$). Il ricovero in terapia intensiva neonatale è risultato più frequente nel gruppo dell'aspirazione elettrica con catetere (61% vs. 33%, $p = 0.0288$).

Conclusioni: dallo studio emerge che i due metodi di aspirazione si equivalgono in termini di ossigenazione e frequenza cardiaca nei primi 10 minuti di vita. Questo risultato potrebbe orientare, soprattutto in paesi a basse risorse, verso la scelta del pinguino, che a differenza del catetere, può essere riutilizzato dopo adeguato lavaggio e disinfezione ottimizzando, così, le risorse.
Per l'impossibilità di condurre lo studio in cieco rispetto alla pratica stessa e per un'espressione di preferenza e maggiore preparazione da parte del personale locale nell'effettuare l'aspirazione manuale rispetto a quella elettrica, questi risultati preliminari dovranno essere riconfermati da ulteriori studi.

Registrazione: ClinicalTrials.gov con identificativo: NCT05472155.

ABSTRACT

Background: evidence from literature showed that suctioning should be offered to newborn infants who have obvious obstruction to spontaneous breathing or who require positive pressure ventilation. In these cases, international guidelines recommend the use of a penguin suction device or a suction catheter in newborn infants needing suctioning at birth, but they do not provide any information on clinical differences between the two procedures.

Objectives: this trial aims to compare two different methods of oropharyngeal suctioning (with penguin suction device or suction catheter) in newborn infants needing suctioning at birth. The primary outcome measure was oxygen saturation during the first 10 minutes of life.

Materials and methods: the study was conducted from August to October 2021 and from June to September 2022 at the St. Luke Catholic Hospital, Wolisso (Ethiopia), a non profit, referral, private, level III hospital with around 3,600 deliveries per year. This was a single center, prospective, randomized clinical trial comparing two different methods of oropharyngeal suctioning (with bulb syringe/penguin or suction catheter). Sixty-one neonates, term and preterm, were enrolled. Inclusion criteria included neonates of any gestational age, need for oronasopharyngeal suctioning and parental consent. Immediately after birth, all infants needing suctioning were randomized to receive suctioning with bulb syringe/penguin or suction catheter. All resuscitative procedures were performed following the Help Babies Breathe algorithm. An external observer, not involved in the care of the newborn, was responsible of the positioning of the pulse oximeter probe and the data collection, first among all oxygen saturation and heart rate.

Results: 61 patients were enrolled in the trial (31 in electrical arm and 30 in the manual arm). The oxygen saturation increases over time in both arms ($p < 0.0001$), with the same slope ($p = 0.7728$). The heart rate increases over time in both arms

($p < 0.0001$), with no different slope ($p = 0.0989$). Admission to special care unit is more frequent in electrical vs. manual arm (61% vs. 33%, $p = 0.0288$).

Conclusions: there was no difference between the two methods. This could lead to choose the manual suction in a low-resource setting in order to optimize the resources available.
Since the midwives could not be masked to the study intervention and since they were more trained in performing manual suction, further studies should be conducted in order to confirm the results.

Trial registration: ClinicalTrials.gov with identifier: NCT05472155.

Premessa

Questo elaborato ha avuto origine dalla mia esperienza in Etiopia, svoltasi nel periodo compreso tra luglio e ottobre 2021, resa possibile grazie alla Borsa di Studio "Michele Mega".

Il progetto Borsa di Studio "Michele Mega" permette a due studenti del corso di Laurea (CdL) in Ostetricia dell'Università degli studi di Padova di trascorrere tre mesi di formazione in Africa, in uno degli ospedali in cui opera Medici con l'Africa Cuamm. Questa opportunità è possibile grazie all'impegno e alla lungimiranza di Carolina Mega Cacciavillani che, in ricordo del padre, il prof Michele Mega, professore associato in Clinica Ostetrica e Ginecologica dell'Università degli Studi di Padova e Primo Presidente del Diploma Universitario in Ostetricia, ha deciso di finanziare due borse di studio l'anno per dieci anni (dal 2016 al 2025) per gli studenti che stanno frequentando il secondo o il terzo anno del CdL in Ostetricia.

Il progetto ha lo scopo di formare gli studenti sulle diversità del nascere nelle differenti culture africane e dei relativi bisogni che quelle realtà generano.

Per me, vincere questa Borsa è stata una grande occasione per la formazione e per una presa di consapevolezza maggiore di quale sia il vero significato di "contesto a basse risorse". Da qui, parte l'idea di sviluppo di questo progetto pilota incentrato sull'aspirazione delle prime vie aeree del neonato effettuato con due metodiche diverse tra loro sia per il funzionamento, sia per il costo e infine anche per la maneggevolezza e sui diversi outcomes emersi a seguito dell'utilizzo di queste due tecniche nella Sala Parto (Delivery Unit) di Wolisso.

CHAPTER 1 - INTRODUCTION

1.1 Need for assistance after birth

1.1.1 Epidemiology

According to the "United Nations Inter-Agency Group for Child Mortality Estimation (UN IGME)" 2021 Report, more than 5.0 million children under age 5 died in 2020 and half of those deaths, 2.4 million, occurred among newborns (0-27 days).

Therefore, this massive loss of life was mainly due to preventable or treatable causes. [1]

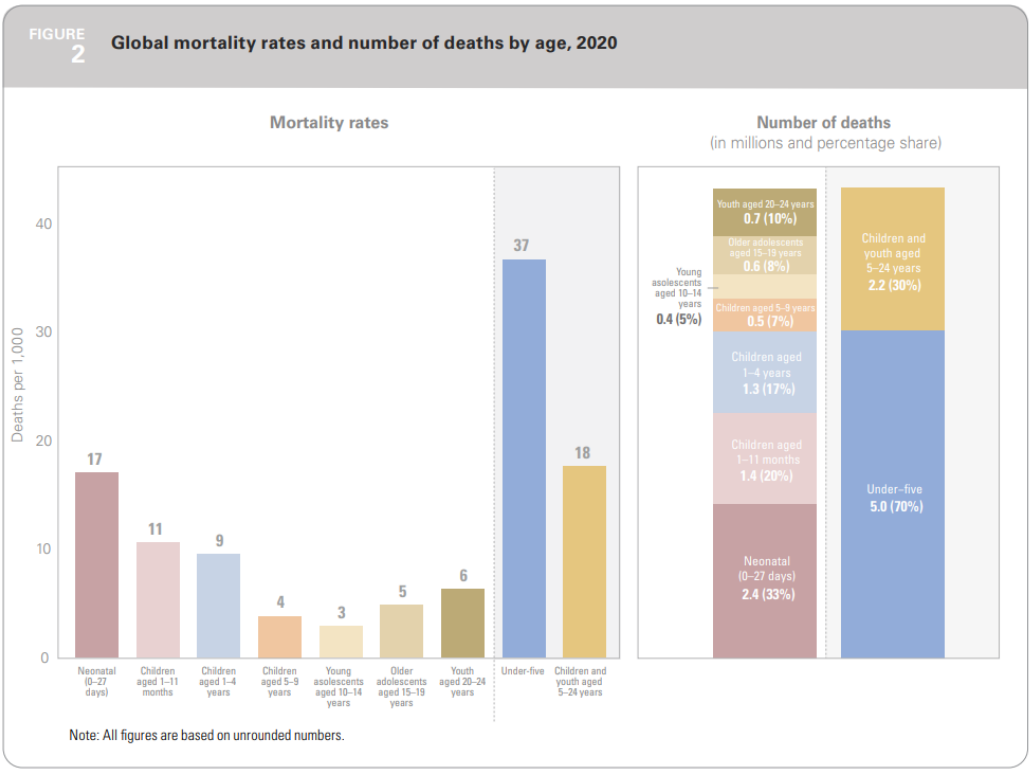


Figure 1 - Global mortality rates and number of deaths by age, 2020 (UN IGME: levels and trends in child mortality, report 2021)

Geographic and economic disparities heighten the risk of death for children as the following world map can show. In sub-Saharan Africa, alone, for example, 2.7

million children died before reaching their fifth birthday – this is 54 per cent of all under-five deaths.

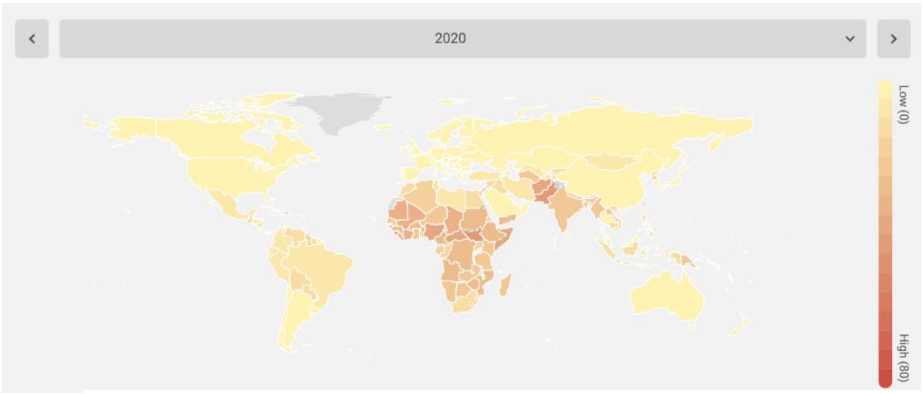


Figure 2 - Figure 2 - Distribution of deaths according to geography ((UN IGME: Levels and trends in child mortality, report 2021)

The leading causes of these under-five deaths are mostly due to premature births, birth complications (intrapartum and postpartum complications), pneumonia and diarrhea.[2]

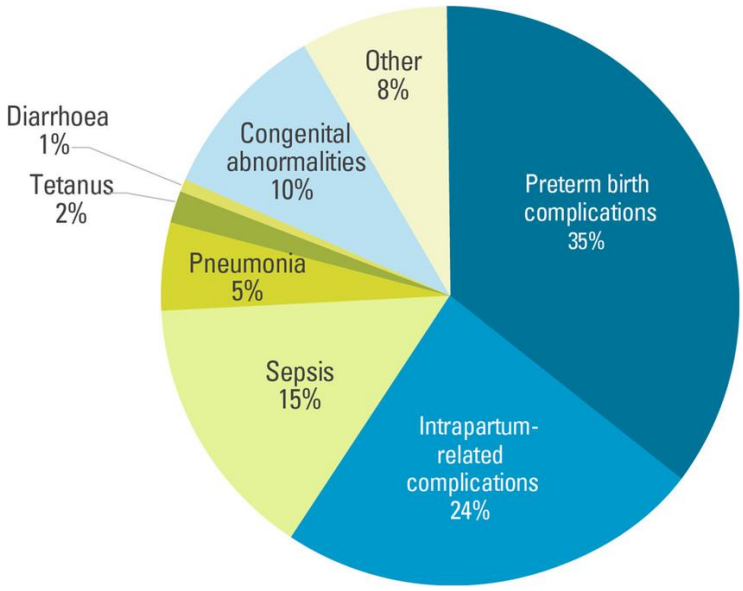


Figure 3 - Causes of death visually displayed on a pie-chart (UN IGME: Levels and trends in child mortality, report 2021)

As the pie-chart displays, up to 24% of deaths are caused by intrapartum-related complications. Transition from intrauterine to extrauterine life at birth involves many critical interdependent events that culminate in the conversion from placental

to pulmonary gas exchange. Globally, this is a physiological process. Data in the literature actually indicate that up to 85% of babies born at term will start breathing within 10 to 30 seconds.[3,4]

Another 10% will initiate breathing once accomplished two actions: stimulation and drying. [5] However, a small but not unremarkable percentage, around 5% of newborns, receive positive-pressure ventilation[5,6] to breathe autonomously. 0.4% to 2% of newborns need to be intubated and less than 0.3% of infants receive chest compressions. Only 0.05 of babies receive epinephrine (10-30 micrograms kg^{-1} is recommended, repeated every 3-5 min in the absence of a response). [7,8]

Neonatal resuscitation and care can be very critical especially in low-resource countries where the lack of equipment and training of birth attendants cannot ensure safety and well-being of newborns infants.

Implementation strategies to improve the practices of unskilled birth attendants can lead to better outcomes in preventing asphyxia. [9]

1.1.2 Risk factors

The ability to predict whether to perform an advanced resuscitation would be extremely useful for the provision of care to the vulnerable patients.

Scientific literature suggests that it is possible to determine a list of risk factors that can help predict the need for advanced life support prior to delivery. It is advisable to consider both antepartum and intrapartum risk factors. [10–12]

Among maternal factors, we find no prenatal care, infection, gestational diabetes, pregnancy-induced hypertension, pre-eclampsia, high BMI, short stature, and preterm lack of antenatal steroids.

Among fetal factors, we have intrauterine growth restriction (IUGR), gestational age < 37, multiple pregnancies, serious congenital abnormality, oligo, and polyhydramnios

Concerning intrapartum risk factors, there are evidence of fetal compromise, like non-reassuring CTG, meconium-stained amniotic fluid, delivering vaginally by

breech, forceps or vacuum delivery, significant bleeding, C-section before 39 weeks, emergency C-section, general anesthesia.

A multicenter, case–control study was conducted from December 2011 to April 2013.[11] They recruited a total of 61 593 births and 58 429 were reported as an GA ≥34 weeks, and of these, only 219 (0.37%) received ANR. They highlighted the risk factors that have an impact on neonatal resuscitation. They found 3 antepartum factors (IUGR, GA 34-37, gestational diabetes), and 7 intrapartum factors (forceps delivery, emergency cesarean section, general anesthesia, abruptio placentae, meconium-stained amniotic fluid, fetal bradycardia and clinical chorioamnionitis).

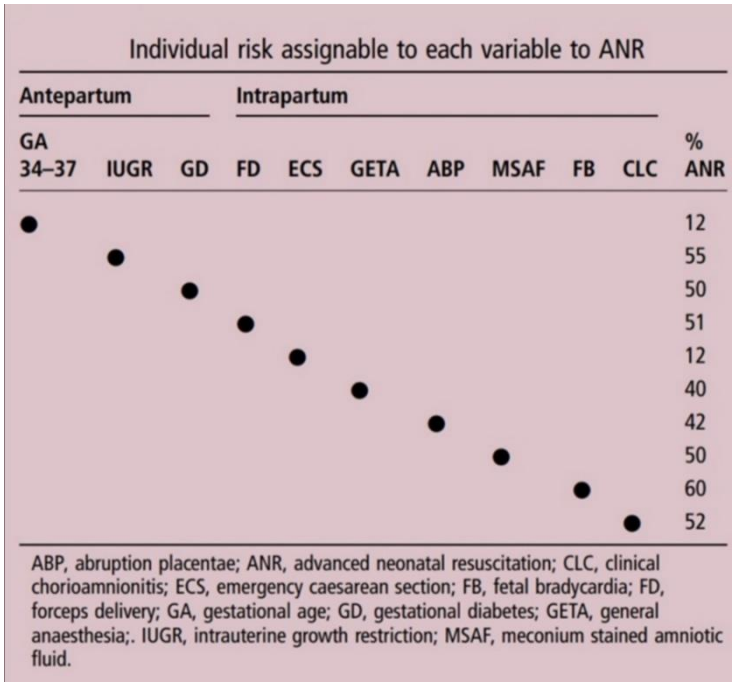


Figure 4 - Individual rate of risk assignable to each variable to antenatal resuscitation (Risk factors for advanced resuscitation in term and near-term infants: a case- control study, Berazetegui et al.)

They evaluated then, as the graphic up above shows, each pregnancy for the presence or absence of antepartum factors or intrapartum factors obtaining a rate of the risk for the need of ANR.

Moreover, several guidelines recommend having people skilled and trained in full resuscitation in order to not only predict but also perform in a proper way all the resuscitative procedures. [9]

And besides, all the equipment should be regularly checked and ready for use. Resuscitation should take place in a warm, draught-free area with a flat surface and a radiant heater. Equipment aimed to monitor the condition of the infant and to support ventilation should be available, too.

1.1.3 Physiology of birth

During fetal life the respiratory function in performed by the placenta instead of the fetal lungs. The fetus lives in a hypoxemic environment where the oxygen is carried from the maternal blood to the fetus through the free-following placental space.

The oxygen is transferred into chorionic villi formed by capillaries that merge to form the umbilical vein. The oxygen saturation of the umbilical venous blood is approximately 70-80%. This oxygenated blood reaches the liver and enters the ductus venosus. Moreover, the blood is directed from the right atrium to the left side of the heart, crossing the foramen ovale, and finally it also reaches the carotid and the coronary arteries.

The poor oxygenated blood coming from the inferior vena cava and the superior vena cava reaches the right atrium, but it is preferably directed into the right ventricle. A little quantity of blood goes to the lungs, but the rest is shunted across the ductus arteriosus to the descending aorta. The oxygen saturation is 60%.

The reason why only a little quantity of blood reaches the lungs is the tight constriction of the pulmonary vessels. This is indeed due to the fact that fetal lungs are not involved in gas exchanges because they’re filled with alveolar fluids.

During the development of alveolar ducts distal pulmonary epithelial cells actively secrete a chloride-rich fluid that goes into the bronchial tree.

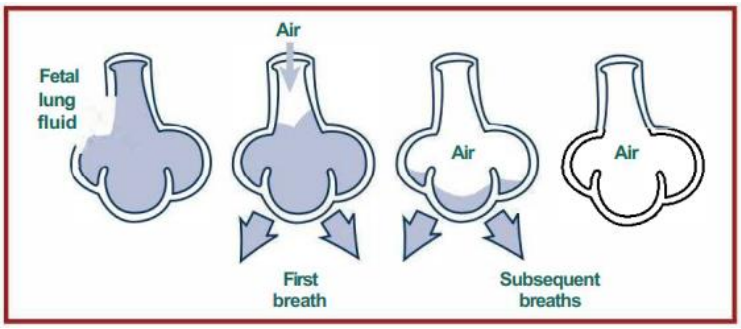


Figure 5 - The movement of fluid in the airways from the proximal to the distal finally reaching the interstitial tissue space

The hyper expansion of the fetal lungs due to the accumulation of fluid increases intrapulmonary vascular pressure. The hypoxemia suppresses the production of nitric oxide (NO) and prostaglandin I_2 (PGI_2). All these factors help increase the pulmonary vascular resistance.

At birth, the transition from fluid-filled environment to the air-filled one requires physiological adaptation.

First of all, the lungs require the removal of fluid, the secretion of surfactant and the onset of consistent breathing.

During spontaneous labour, the mechanical compression of the thorax due to the crossing of the birth canal is responsible for the partial ejection of pulmonary fluid. Furthermore, the progressive increase in cortisol and thyroid hormone levels activate the basal Na^+, K^+ and ATPase of type II cells on the airway epithelium. Sodium is pumped into the interstitium with water and other electrolytes following passively, thus removing fluid from the airways.[13] Increased oxygenation after birth helps to maintain the expression of sodium-mediated channels.

The breathing activity then plays the most important role in the transition to air-filled environment. The inspiratory act reduces intrapleural and interstitial tissue pressures, by expanding the chest wall. Moreover, it creates a gradient between the interstitial tissues and the airway lumen and between upper and lower airways.

As a result, the liquid is carried from the proximal airways to the distal ones through the distal airway wall reaching then the surrounding interstitial tissue space. From

this point, the fluids can be removed by the pulmonary microcirculation and lymphatic vessels.

Thanks to the ventilation of the lungs, the levels of oxygen increase along with the levels of NO and PGI_2 causing a rapid fall of the resistance in pulmonary vessels. Then, the blood coming from the right ventricle flows through pulmonary bloodstream until it reaches the capillaries of the lungs. The blood goes then first to the left side of the heart and after to the systemic bloodstream.

The higher oxygen levels implies the closure of ductus arteriosus.

After the cord clamping, the low-resistance vascular bed of the placenta is disconnected, leading to an increase of resistance in systemic vascular system. The pressure of the left atrium, then, becomes higher than the one of the right atrium allowing the closure of the foramen ovale.

As the pulmonary resistance decreases while the systemic one increases and the right-left shunt starts to close, the circulation changes from "parallel circulation" to "series circulation" with an increase of ventricular output. [14]

The effective ventilation of the lungs thus appears to be the key element of the entire process of the transition to extrauterine life.

1.1.4 Neonatal resuscitation algorithms: initial assessment

Once defined the risk factors for every pregnant mother, it is essential to make an assessment immediately after birth to establish if the newborn needs resuscitation maneuvers. If the transition to extrauterine life is altered or impair, an effective neonatal resuscitation can reduce the risk of mortality and morbidity.

How to make a proper initial assessment and the all the sequence of life-saving actions are carefully described in neonatal resuscitation algorithms.

Here below, we compare 3 neonatal resuscitation guidelines: 2020 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care[15], the European Council Guidelines 2021[10] and Helping Babies Breathe 2nd edition algorithm[16].

Before starting to assess the conditions and parameters of the newborn baby, birth attendants should also take care of the environment. It should be warm at 23-25°C and for infants <28 weeks gestation the delivery room should be >25°C. [17]
The baby should maintain a body temperature between 36.5 and 37.5°C.
Healthy babies should be skin- to- skin after birth. For preterm and low-birth weight babies or babies requiring resuscitation, warming adjuncts (as for example radiant warmers, plastic wraps) should be considered. [18,19]

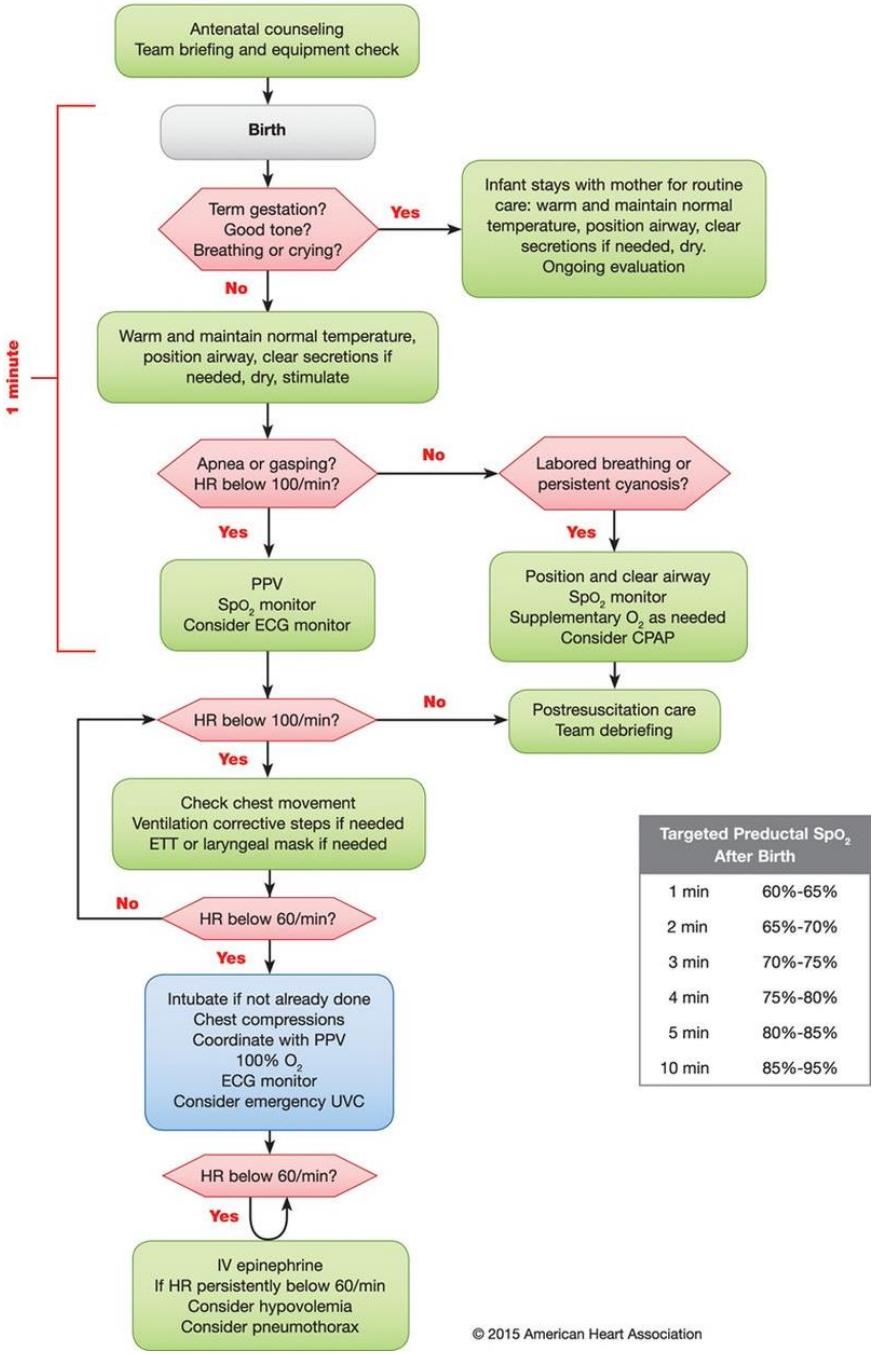


Figure 6 - Neonatal Resuscitation Algorithm according to American Heart Association Guidelines (2020)

In the American Heart Association guidelines, the initial assessment requires the evaluation of gestational age, breathing, and tone.

Healthy term babies should be managed skin-to-skin with their mothers.

Babies who are breathing well do not need interventions such as routine tactile stimulation or suctioning.

During uncomplicated births, it may be reasonable to defer cord clamping. [20,21]

After having determined the gestational age, it is important to assess heart rate in order to define the effectiveness of respiratory effort and the need for interventions.

Satisfactory heart rate should be > 100 bpm. [22,23]

Concerning breathing, as mentioned before, the vast majority of newborns breathe spontaneously within 30-60 seconds after birth and some others after drying and stimulation.

If a neonate does not breathe within the first 60 seconds after birth or is persistently bradycardic (HR < 100 bpm) despite drying and tactile stimulation, PPV (positive pressure ventilation) should be performed. [24,25]

Peak inflation pressures of up to 30 cm H2O in term newborns and 20 to 25 cm H2O in preterm newborns are usually sufficient to inflate the lungs. Peak inflation pressures greater than what is needed to increase heart rate and achieve chest expansion should be avoided. [26]

Suctioning may be considered before PPV if airways appear to be obstructed. [3]

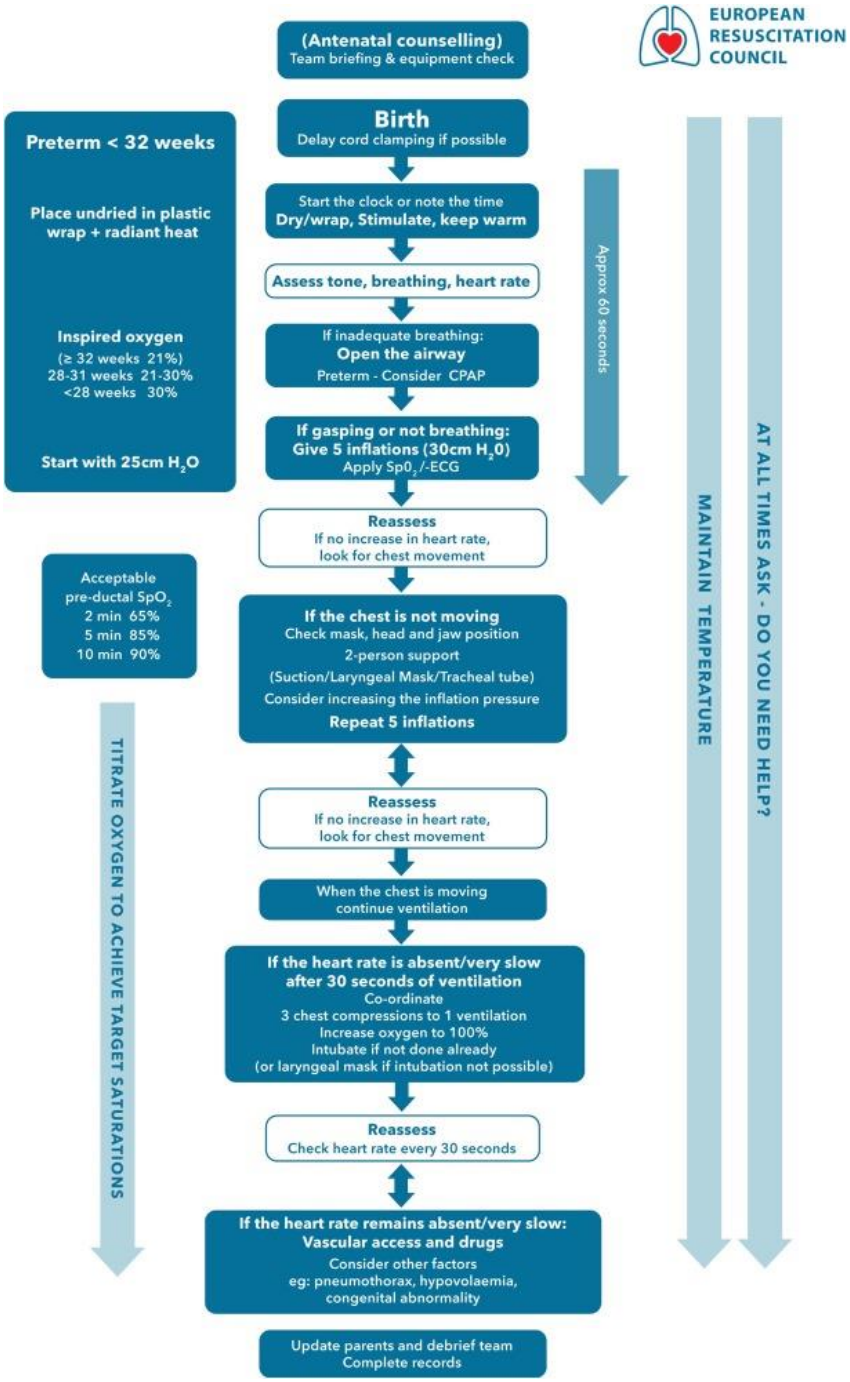


Figure 7 - Neonatal Resuscitation Algorithm according to European Resuscitation Guidelines (2021)

European Council Guidelines suggest, first of all, to keep dry and warm the newborn baby. It is essential to cover the head and body of the infant to prevent heat loss. The temperature of newborn infants should be maintained between 36.5 °C and 37.5 °C.

After this essential action, tone, and color, breathing and heart rate should be evaluated. This guideline identifies the need for support and/or resuscitation and the duration of delaying umbilical cord clamping.

While assessing the general conditions, one should continue drying the infant and softly stimulate the newborn by rubbing the sole of the feet or the back of the chest. If the baby has a good tone, adequate breathing or crying and fast heart rate (>100/min) we can consider the transition as satisfactory. It is possible then, to delay cord clamping and consider skin to skin with the mother. In order to maintain the right body temperature, the baby should be covered with a dry and warm towel while doing skin-to-skin.

If the tone is reduced and the baby is apnoeic with a slow heart rate (<100/min), delaying the cord clamping should be considered only if it is possible to perform adequate support.

Keeping the infant warm is necessary to maintain the airway for lung inflation and ventilation. While ventilating the newborn, one should continue to assess changes in heart rate and breathing. If there's no improvement, ventilation should be continued, and some other help may be needed.

If the baby is floppy and pale, the breathing is inadequate and heart rate is below 60 bpm, the transition to extrauterine life must be considered as failed.

The cord should be immediately clamped, and the baby transferred to the resuscitation platform. Airway should be maintained for lung inflation and ventilation. Assessing continuously heart rate and breathing can help establishing if the ventilation is effective. If it is not, newborn life support should be continued with other more invasive actions, as for example intubation, chest compressions up to medications as epinephrine.

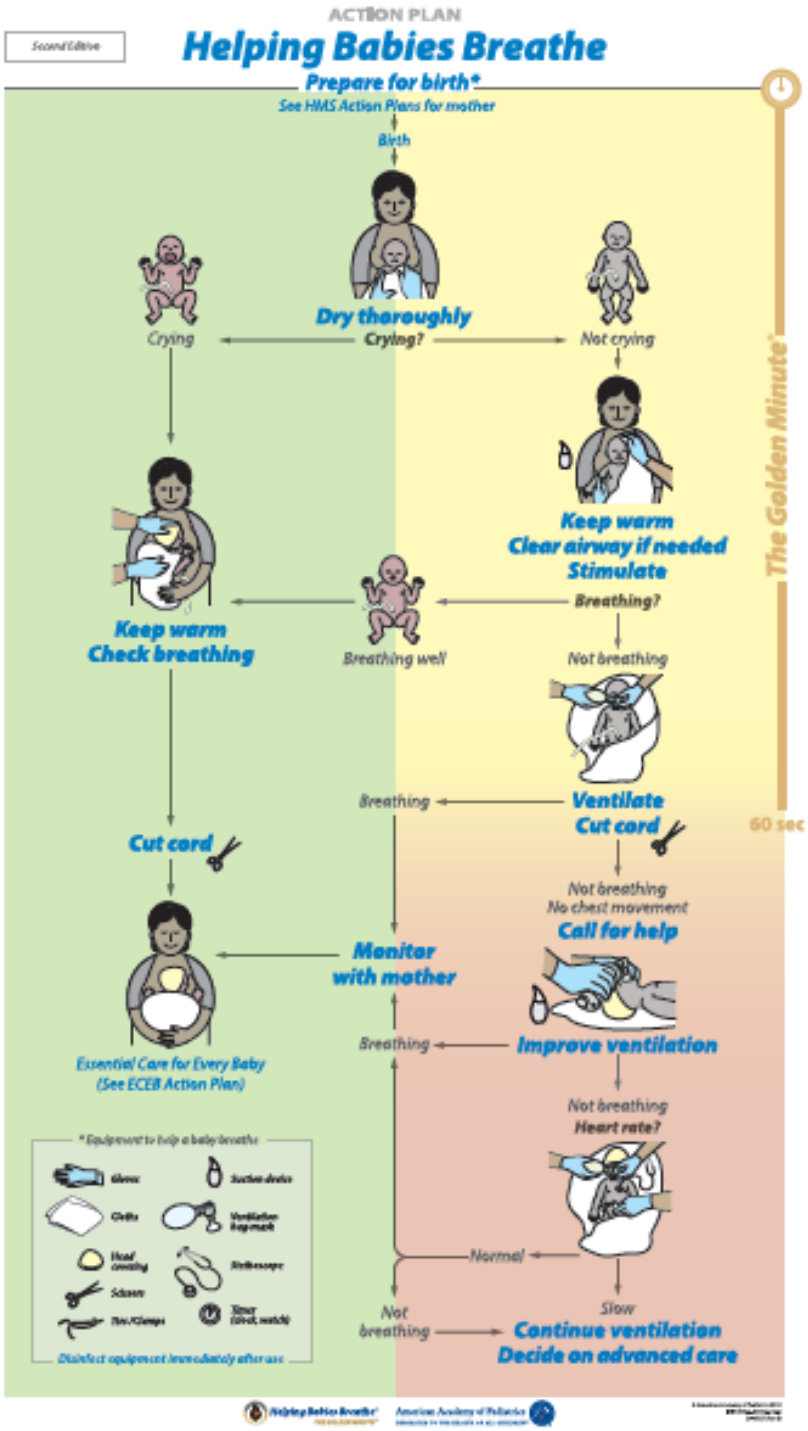


Figure 8 - Helping Babies Breathe Algorithm 2nd edition

The Helping Babies Breathe (HBB) is born with the aim of achieving a considerable reduction in neonatal morbidity and mortality through reinforcing the performance of providers who prevent and manage newborn asphyxia in low-resource settings.
The HBB was founded in 2010 by its five core member organizations: the American Academy of Pediatrics (AAP), the United States Agency for International Development (USAID), Laerdal Global Health, Save the Children, and the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD).
Between June 2010 and December 2014, HBB was introduced in 77 countries and approximately 52 of these introductions were coordinated by national governments.
Program reports from several countries indicate a high rate of successful resuscitation (79%-89%). [27]
7 countries including *Ethiopia* have begun to implement HBB in over 40% of health facilities. [28]

The first step of HBB algorithm [16,29] is preparing for a birth. This means preparing the area for delivery and all the equipment that must be disinfected, assembled and tested. [30]
Once prepared the ventilation bag, mask and suction device it is essential to maintain the birthing room temperature between 23 and 25°C.
If the baby breathing, heart rate and tone are adequate, the birth attendant should dry the baby with a cloth by gently rubbing his back and in a second step place the neonate, covered with a dry cloth, skin-to-skin with mother.
If the transition to extrauterine life is successfully accomplished, it is possible to wait 1-3 minutes before cutting the cord.
The neonates who have shallow and irregular breathing with chest indrawing will require close monitoring.
Some of these babies will improve and begin breathing normally, others need to be stimulated and their airways have to be cleaned by suctioning.

If the situation does not improve, other resuscitation maneuvers must be considered starting with the ventilation with bag and mask.

The algorithm suggests giving 40 ventilation breaths per minute. If the chest is moving, the ventilation must be continued for 60 seconds until spontaneous breathing begins.

It is important to continue assessing heart rate while ventilating the baby. The expansion of the lungs is associated with a rapid rise in the heart rate as well as the improvement of tone and color.

If the breathing does not improve despite all the efforts in ventilating performed within 20 minutes, stopping ventilation should be considered.

The algorithm, unlike the others previously presented does not include chest compressions, intubation, or pharmacological intervention with epinephrine.

However, in some hospitals adopting this HBB protocol, as for example, *Saint Luke Catholic Hospital in Wolisso, Ethiopia*, medications like epinephrine for neonatal resuscitation were available.

1.1.5 Oropharyngeal suctioning

Suctioning is one of steps of neonatal resuscitation, but the guidelines do not recommend it as a routine practice in the healthy newborn infant.

Oronasopharyngeal suction (ONPS) may help the expulsion of pulmonary fluid from the trachea and the entrance of air, and it can prevent the aspiration of mucus and blood. On the other hand, it can be harmful because it is associated to vagal-induced bradycardia or apnea, irritation of the mucus membranes and to an increased risk for iatrogenic infections.

Suction may be performed only if the newborn has secretions, airway obstruction due to mucus, vernix, blood clots or meconium even if it does not prevent the meconium aspiration syndrome. It can be useful also for example, if PPV is required as the next step. [31]

Wiping mouth and nose with a towel appears to have equal efficacy as suction has considering several parameters as for example heart rate. [32]

While performing suctioning maneuvers in the newborn, it is fundamental to begin from the mouth and then continuing the procedure suctioning the nostrils.[33] Maintaining this order is important in order to prevent the reflex inspiration and possible inhalation of oropharyngeal fluids due to the stimulation of the nostrils.
Pulse oximetry with a saturation sensor on the right hand should be used during resuscitation procedures. It gives information about the preductal oxygen saturation and heart rate.

Targeted Preductal SpO_2 After Birth	
1 min	60%-65%
2 min	65%-70%
3 min	70%-75%
4 min	75%-80%
5 min	80%-85%
10 min	85%-95%

Figure 9 - Targeted preductal SpO2 in a normal newborn infant (American Heart Association algorithm, 2020)

Normally the increase of SpO2 levels occurs gradually in the first 10 minutes of life and most of the newborns reach a SpO2 ≥ 92%.
Besides, monitoring oxygen saturation (every 30 seconds) allows to avoid hypoxia and hyperoxia. [10]
Heart rate is monitored in order to assess the effectiveness of spontaneous respiratory effort, the need for interventions and response to resuscitation.
Pulse-oximetry may be inaccurate in detecting the values of SpO2 and heart rate in the first minutes of life. It is thus preferable to use the ECG system or the stethoscope especially in the low resource settings. [34]
APGAR score (Appearance, Pulse, Grimace, Activity, Respiratory effort) is another commonly used procedure for assessing immediate neonatal well-being at birth. But it is considered as a subjective measurement and its diagnostic value in fetal asphyxia is not significant. [31]

1.1.6 PPV and CPAP

After the initial maneuvers as for example tactile stimulation and suctioning the baby can still be apneic, the breathing can be characterized by gasping and heart rate less than 100 bpm. This requires the positive pressure ventilation (PPV). This PPV procedure should be started within 60 seconds of birth. For every 30 seconds

delay in starting ventilation after birth there is an increase of about 16% in mobility and mortality. [6]

In order to provide PPV properly, it is necessary to apply a fitting face mask and choosing the right position of the newborn. This position is called the "sniffing position".[14] The baby is placed on his back with his head supported in a neutral position: the face mush be horizontal, neither flexed nor extended. It helps to open airways and ensures an effective aeration of the lungs.

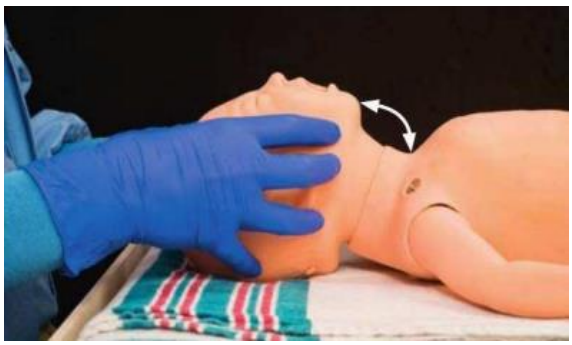


Figure 10 - Sniffing position (Textbook of Neonatal Resuscitation, 8th edition)

Figure 11 - Mask ventilation with self-inflating bag (Textbook of Neonatal Resuscitation, 8th edition)

After applying the face fitting mask, the ventilation can be started: five initial breaths with inflation pressures maintained for up to 2-3 seconds. [26,35] This may help lungs expansion.

For a term infant, it is advisable to provide an initial inflation pressure of 30 cmH2O of air while for a preterm infant, the birth attendant provides a pressure of 25 cm H20 using 21-30% of inspired oxygen.[25]

Observational studies on newborn infants breathing suggest that PPV aim is to reach a respiratory rate of 30/40 breaths per minute considering an inspiratory time of 0.3-0.4 seconds. [24,36]

Adequate ventilation is confirmed by a rapid improvement (30 seconds) or stabilization in heart rate. [37]

If there is a heart rate response to ventilation, it is necessary to continue ventilating until the pulse rate is > 100 bpm.

If there is no improvement in heart rate, the reason can be found in inadequate airway control or inadequate ventilation. All this considered, the healthcare provider should check face mask size and placement, head, and airway position, opening of the mouth, inflation pressure and secretions in the airways.
If every element is properly arranged, it is possible to consider tracheal intubation or the insertion of laryngeal mask.
Another significant element must be considered in defining a successful ventilation: chest wall expansions. This most likely indicate that there is no obstruction of the airways, and moreover the inflation pressure is suitable to aerate the lungs.
Concerning the devices used for the ventilation procedure, there are three different types: the self-inflating bag (SIB) usually employed in a low resource setting, the flow-inflating bag (FIB) or T-piece resuscitator (TPR). [38]

Figure 12 - Self inflating bag (left), flow-inflating bag (middle), T-piece resuscitator (right

In preterm infants when respiratory distress requires respiratory support, it is recommended to use Continuous Positive Airway Pressure (CPAP) instead of intubation and PPV. It may reduce the risk of death and bronchopulmonary dysplasia. [3]
Furthermore, literature suggests applying a Positive End Expiratory Pressure (PEEP) of approximately 5-6 cmH20 immediately after birth in those who need PPV. This may improve lung aeration, functional residual capacity and facilitate gas exchange in order to prevent lung collapse at the end of expiration. [39]
However, in term infants, caution in using CPAP is required. This may lead to the development of pneumothorax. [40]

This difference between the two groups is probably due to higher surfactant load at delivery time, lower surface tension and higher compliance in term newborns.

1.1.7 Oxygen

During resuscitation, in term and late preterm newborns (≥ 35 weeks of gestation) requiring respiratory support at birth, it is reasonable to start by administering room air which means 21% oxygen rather than 100% oxygen. [41] This choice is based on a statistically significant benefit in short-term mortality.

In preterm newborns (< 35 weeks of gestation), the concentration in oxygen depends on the gestational age. 21% of oxygen in preterm ≥ 32 weeks, 21 – 30% in 28 – 31 weeks, 30 % in < 28 weeks. [42]

Oxygen saturation of the newborn should be monitored with pulse-oximetry every 30 seconds, if necessary. Supplemental oxygen, then, can be administered to prevent hypoxemia that means the inadequate oxygen supply to peripheral tissues. This hypoxemia may result in developing hypoxic-ischemic encephalopathy or necrotizing enterocolitis. [43]

However, high exposure to oxygen (hyperoxia) may cause tissues damages through reactive oxygen intermediates and peroxidation of membrane lipids.

Premature infants having severely reduced antioxidant defenses are more vulnerable to the toxic effects of oxygen thus developing retinopathy, bronchopulmonary dysplasia and intraventricular hemorrhage. [44]

1.1.8 Chest compressions

If heart rate value is less than 60 bpm despite adequate ventilation for at least 30 seconds, it is advisable to start with chest compressions.

Circulatory support with chest compressions is effective only if the lungs have been successfully inflated thus allowing oxygen to reach the heart. [15]

It is preferable to rely on endotracheal intubation rather than face-mask ventilation since it can be difficult to coordinate face-mask ventilation and chest compressions.[45]

While performing cardiovascular support maneuvers, it may be reasonable to increase inspired oxygen to 100% and maintain it until the achievement of spontaneous circulation (ROSC). [46]

The optimal compression to ventilation ratio is 1:3 (3 compressions followed by 1 inflation) [47] aiming to achieve approximately 90 compressions and 30 ventilations per minute.

The thorax should be compressed to a depth or one-third of the antero-posterior diameter of the chest thus allowing the chest wall to return to its relaxed position between compressions.

The most effective method is considered to be the two-thumb-encircling hand technique.[48] The two hands encircle the chest and support the back while the two thumbs depress the lower third of the sternum.

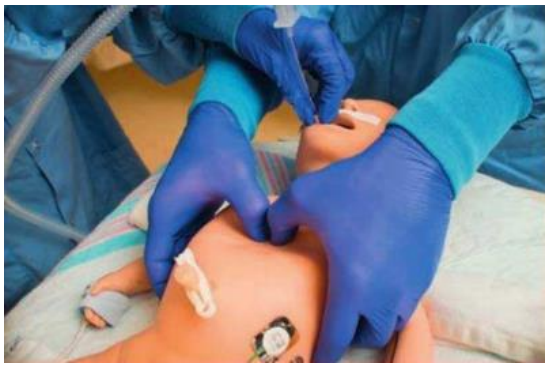


Figure 13 - Two-thumb-encircling hands technique (Textbook of Neonatal Resuscitation, 8th edition)

Compared with the two-finger technique, this one allows to achieve greater depth with less fatigue and less variability of each compression. In addition, the coronary and cerebral perfusion and blood pressure seem to improve in a better way.

It is reasonable to discontinue chest compressions if a hear rate > 60 bpm is achieved. It is nevertheless recommended to check heart every 30 seconds using ECG system.

1.1.9 Drugs

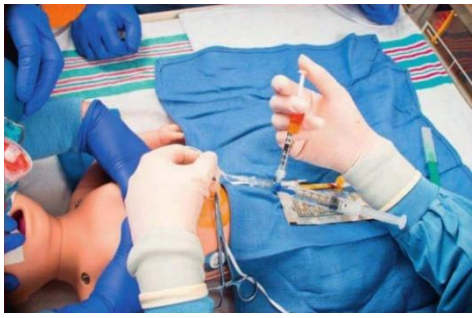


Figure 14 - Drug infusion in Umbilical Vein during Neonatal Resuscitation (Textbook of Neonatal Resuscitation, 8th edition)

Drugs are rarely required in newborn resuscitation and the evidence for their efficacy is limited.

If the heart rate is less than 60 bpm, despite effective ventilation and chest compressions, drugs can be taken into account.

Umbilical vein catheterization (UVC) is the primary method of vascular access to drugs administration. If UVC is not available, the intraosseous (IO) access is a reasonable alternative. [49]

- Epinephrine (adrenaline): with an initial dose of 0,1 – 0,3 mL/kg given intravenously, is the primary choice in neonatal resuscitation. It allows to increase the heart rate above 60 bpm. If the heart rate remains less than 60 bpm further doses every 3 – 5 minutes are suggested.[50]
- Glucose: in protracted resuscitation endogenous glycogen stores are rapidly depleted due to prolonged hypoxia, and this leads to blood glucose decrease. It is therefore reasonable to give a bolus of glucose (250 mg/kg) to prevent brain injury related to hypoglycemia.[51]
- Volume replacement: if the newborn infant has a blood loss or a hypovolemic shock early volume replacement, with crystalloid or red cells, is indicated.
- Sodium bicarbonate: may be helpful in prolonged unresponsive resuscitation to reverse intracardiac acidosis, but with no strong evidence in literature.[52]
- Naloxone: can be reserved for infants whose cardiac output has been restored yet remaining apneic despite resuscitation and in case the mother has received opioid analgesia, with no strong evidence.[53]

1.1.10 Absence of response

In all the guidelines presented above, after 20 minutes of no response of the neonate, the parents should be consulted in order to decide with them whether continue to resuscitate or to discontinue life support in compromised infants. [54]

In situation where mortality is highly predictable, it is reasonable to withdraw resuscitation. Discontinuation of life support is considered to be ethical if prolonged resuscitation would no longer be in the best interests of the neonate. [55,56]

In some other cases, after all the steps of resuscitation have been completed and if the clinical condition of the baby allows it, it is possible to consider other advanced care options as for example therapeutic hypothermia if available.

Palliative and supportive care plan should be always developed and ready throughout the process of neonatal resuscitation.

CHAPTER 2 - OROPHARYNGEAL SUCTIONING: IS ROUTINARY PRACTICE APPROPRIATE?

Historically, oronasopharyngeal suction has been used to remove secretions, blood and in some cases, meconium with the aim to facilitate airflow. [57] However, in absence of meconium staining, oronasopharyngeal suction at birth has been shown to have negative effects as, for example the onset of bradycardia that can also be associated with apnoea, lowering saturations taking more time to reach the SaO2 ≥ 92%, and delaying neonates' transition back to normal. [58,59]

In newborn infants born through meconium-stained amniotic fluid intrapartum suction could be performed (after the delivery of the head but before the first breath starts). After that, the baby can be intubated and suctioned once more below the cords.

The use of this practice is based on the belief that it can prevent meconium aspiration syndrome (MAS) but new observational studies do not show any benefit from suctioning. [60,61]

In vigorous term infants delivered vaginally or by cesarean section, suction should be avoided.

In addition to the adverse effects previously mentioned, one should also consider that the volume of fluid eliminated by suction procedure is only a minimal fraction and the rest is eliminated by physiological mechanisms.

Also in non-vigorous infants, routine suction is not recommended. The suction procedure should be considered if the PPV ventilation is required but on the other hand it is likely to delay initiating ventilation. Considering this, in order to perform adequate interventions for respiratory support, it is preferable to initiate ventilation and consider the use of suction if the initial attempts at aeration and ventilation are unsuccessful due to airways obstruction. To establish whether there are secretions obstructing airways, the inspection of the pharynx is required. [10]

Even for newborn babies requiring tracheal intubation, some indications for airway suctioning have been identified: breath sounds, visual secretions in the artificial airways saw-tooth pattern on the mechanical ventilation waveform and an increase

in airway resistance that results from frictional forces of the airways that which oppose airflow. When airway resistance is elevated, air can be trapped in the lungs thus limiting gas exchange and perhaps cause respiratory failure. [62]

To support the theory of non-routinary use of suction practice, it is useful to mention a Cochrane Review by Foster JP et al. focused on routine oro/nasopharyngeal suction versus non suction at birth concluding that there was no significant statistical difference between the two groups regarding the outcomes of mortality, need for resuscitation, admission to NICU, Apgar score at five minutes, length of hospital stay, hypoxic ischaemic encephalopathy and infection. [13]

Dealing with the suction practice, it is also necessary to illustrate also which are the devices used while suctioning.

This procedure can be provided with a sterile soft rubber bulb syringe or penguin or with a sterile polyethene electric catheter.

Figure 15 - Bulb syringe device (left), penguin suction device (middle), suction catheter (right)

The suction has to begin from the mouth continuing then in the nose. Maintaining this order is important because it helps preventing the reflex inspiration and possible inhalation of oropharyngeal fluids due to the stimulation of the nostrils.

To use a bulb syringe or the penguin, first, the air should be squeezed out of the bulb keeping then the bulb squeezed. The tip of the squeezed bulb has to be then placed into the mouth or nostril and once placed, one should let go of the bulb allowing the air back into it thus pulling the secretions out.

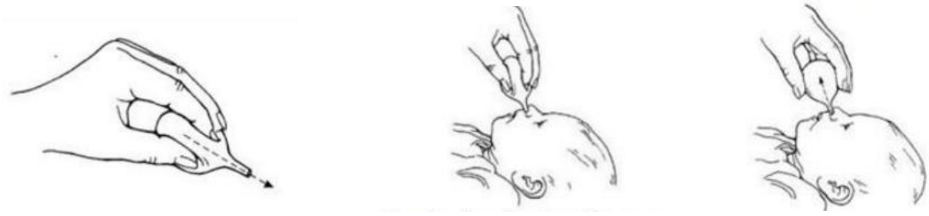


Figure 16 - How to perform bulb syringe suction (www.nationchildrens.org)

For the other method, the electric suction catheter, normally a 10 Fr Gauge catheter for a term infant is chosen. It has to be then connected to a mechanical negative pressure source. The maximum negative pressure should not exceed 100 mmHg with the tube occluded.

The neonate should be put in a neutral position. Always suction the mouth before the nose to prevent aspiration. The catheter then has to be inserted into the infant's mouth and oropharynx until the back of the throat is reached. While inserting the catheter, the health assistant should not occlude it. The negative pressure of 100 mmHg should be generated once reached the suction site.

Figure 17 - How to perform suctioning using a suction catheter (NEST-ED, newborn essential solutions and technologies, clinical module June 2020)

Currently literature does not recognize the superiority of one suction device over the other. They are considered equivalent. [13]

CHAPTER 3 - AIM OF THE STUDY

International guidelines recommend the use of a bulb syringe/penguin device or a suction catheter in newborn infants needing suctioning at birth, but literature does not provide any information on clinical difference between the two procedures. The use of a suction catheter implies a suction system which is often unavailable in low-resource settings, hence bulb syringe/penguin device is the most used method in such settings.

This pilot study is designed to compare two different methods of oropharyngeal suctioning in newborn infants needing suctioning at birth in order to explore potential clinical differences between the two groups.

The primary outcome of the study is the oxygen saturation during the first ten minutes of life.

CHAPTER 4 - METHODS

4.1 Setting

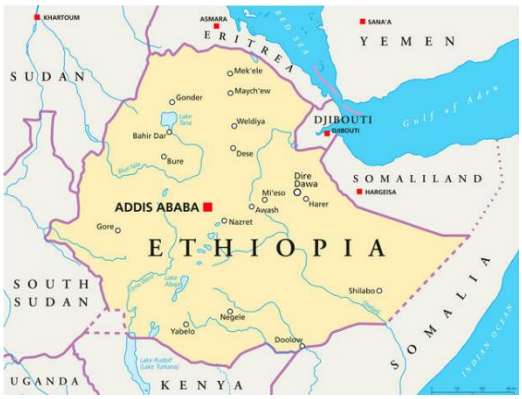


Figure 18 - Ethiopia map (shutterstock.com)

Ethiopia is a landlocked country in the Horn of Africa. It shares borders with Eritrea to the North, Djibouti to the Northeast, Somalia to the East and northeast, Kenya to the South, South Sudan to the West and Sudan to the Northwest.

Ethiopia has a 1,100,000 square kilometers area and it counts around 123.5 million inhabitants thus becoming the 12th-most populous country in the world and the 2nd-most populous in Africa after Nigeria.

Despite its growing economy, with a 6.3% growth in FY2020/21, it remains one of poorest country of Africa with a per capita gross national income of $890. However, the high economic growth resulted in positive trends in poverty reduction in both urban and rural areas. The share of the population living below the national poverty line decreased from 30% in 2011 to 24% in 2016 leading to an improvement also in development indicators. [63]

Concerning health issues, Ethiopia has a made a progress in reducing maternal and under-five mortality, HIV and malaria rates too. Nevertheless, this country is still characterized by a sub-optimal health system setting, insufficient skilled and specialized health care providers in rural and remotes areas, inadequate response to health needs and a poor links between health services. [64]

Evidence have been showing a decline in maternal and child deaths thus remaining intolerably high. This may be imputable to the lack of access to quality antenatal obstetric and postnatal health services especially in rural areas. All these elements undermine any attempt in reducing maternal deaths and those occurring in the first 28 days of life.

To be more precise, here are shown the health-related findings of UNICEF 2021 Ethiopia Report. [65]

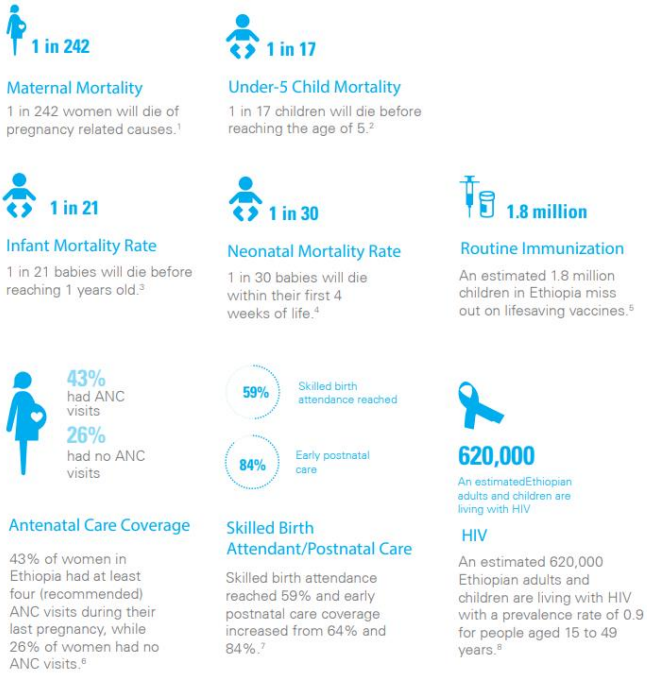


Figure 19 - Unicef 2021 Ethiopia Report

Even though some progress has been made, there still a long way to go in order to guarantee an adequate health and care access level to the Ethiopian population.

4.2 Doctors with Africa Cuamm

This study was conducted at the St. Luke Catholic Hospital in Wolisso (Ethiopia) which a III level hospital with around 3,600 deliveries per year. This is a referral, private, non-profit hospital located in Wolisso town, which is the capital of the Southwest Shoa Zone in the Oromiya region.

Figure 20 - Saint Luke Catholic Hospital, Wolisso, Ethiopia

This area has a population of about 1.1 million inhabitants and is served by 81 health facilities (including only one hospital). At St. Luke Hospital, midwives are responsible for maternal and neonatal management at delivery. Midwives receive education on neonatal resuscitation (Helping Babies Breathe program) and courses on postnatal management. This study is a part of collaborative project between the St. Luke Catholic Hospital and Doctors with Africa CUAMM, a non-governmental organization.

CUAMM was founded in 1950 and it was the first non-governmental organization focused on healthcare to be recognized by the Italian government. Its primary aim is to improve the wellbeing and health of vulnerable communities in Sub-Saharan Africa. CUAMM provides medical aid and expertise in 8 African countries: Angola, Central African Republic, Ethiopia, Mozambique, Sierra Leone, South Sudan, Tanzania, Uganda.

Doctors with Africa CUAMM has been working in Ethiopia since 1980, when the first CUAMM doctors was deployed at the leper colony of Gambo.
CUAMM collaborates with the Ethiopian Catholic Secretariat at the national level to enhance the management of the country's diocesan health facilities. [66,67]

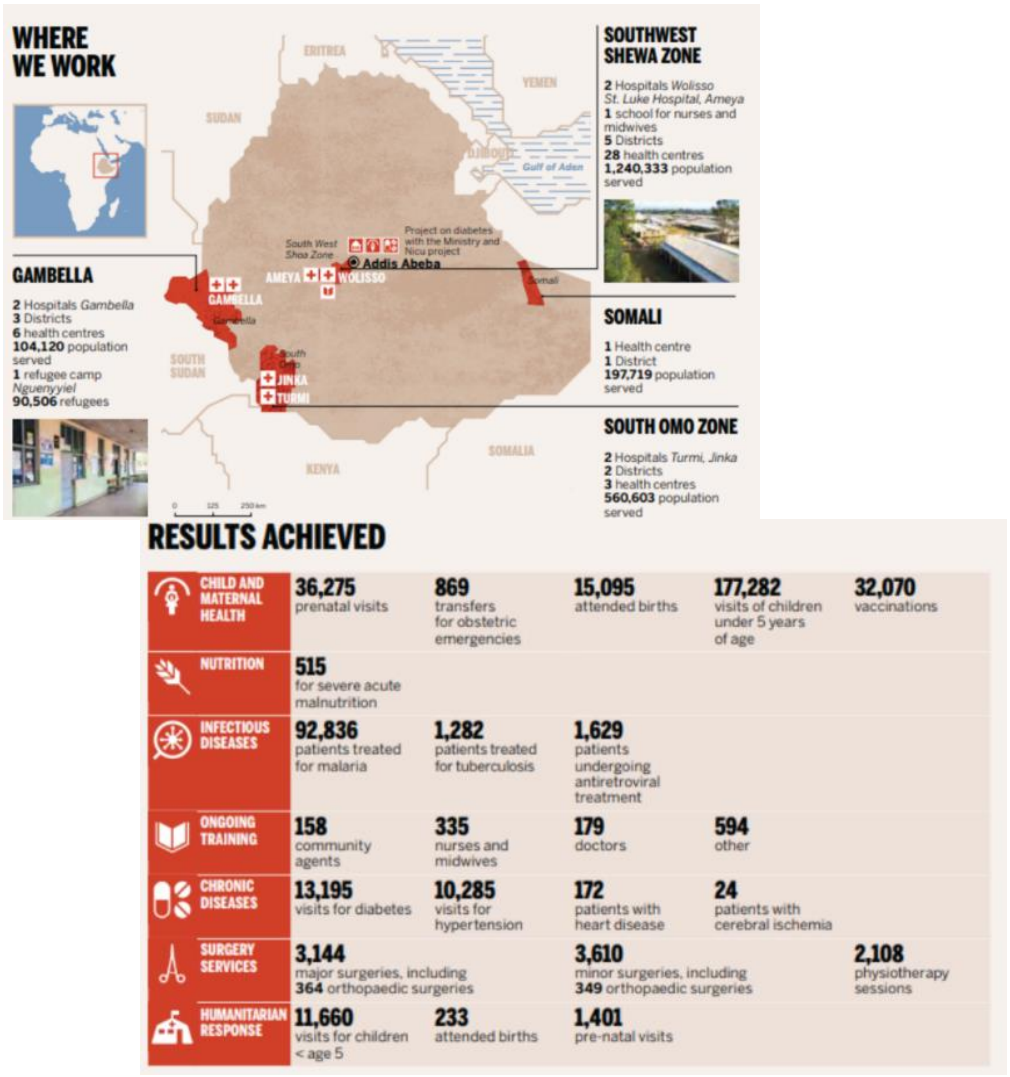


Figure 21 - 2020 snapshot, Ethiopia report (doctorswithafrica.org)

4.3 Study design

This is a single center, prospective randomized clinical trial comparing two different methods of oropharyngeal suctioning (with bulb syringe/penguin or suction catheter in newborn infants needing suctioning at birth.

4.4 Inclusion and exclusion criteria

Infants satisfying the following inclusion criteria were eligible to participate in the study:

- Inborn infant AND
- Absence of major malformations AND
- Parental consent AND
- Need for suctioning at birth (defined as difficult breathing due to the presence of abundant oronasopharyngeal secretions or need for positive pressure ventilation).

Concerning the exclusion criteria:

- Major congenital malformations;
- Parental refusal to participate in the study.

4.5 Outcome measures

The primary outcome is the oxygen measure was the oxygen saturation during the first 10 minutes of life.

The secondary outcomes are

1. Heart rate during the first 10 minutes of life;
2. The proportion of neonates with heart rate > 100 bpm at 5 minutes;
3. Episodes of bradycardia (defined as heart rate < 100 bpm) in the first minutes of life;
4. The proportion of neonates with saturation > 80% at 5 minutes;
5. Time to achieve transcutaneous saturations > 90%;
6. Need for face-mask ventilations;

7. Need for supplemental oxygen in delivery room;
8. Admission to special care unit;
9. Occurrence of local lesions (defined as bleeding from the mouth and/or the nose) due to suctioning procedure;
10. Occurrence of respiratory distress defined as need for supplemental oxygen and/or nasal-CPAP during the first 48 hours of life.

4.6 General usability

The findings of this study will be important to understand if there may be some clinical differences between oropharyngeal suctioning using a penguin suction device or a suction catheter in newborn infants needing suctioning at birth. The results of the present study will be useful to assess the presence and the magnitude of such clinical differences and will be the basis for the design of a future larger randomized controlled trial.

4.7 Sample size

The sample size could not be calculated a priori given the lack of information in the literature regarding the study question. Hence, an arbitrary sample size of 60 newborns (30 in each arm) was chosen for this pilot study.

4.8 Recruitment

Newborn infants were recruited in August, September, and October 2021 and the between the months of July 2022 and September 2022.

Newborn babies of any gestational age (preterm and term babies) and needing suctioning at birth were eligible to be recruited. Gestational age was approximately estimated and based on obstetrics techniques.

Written and oral information will be offered to parents at maternal admission to the obstetrical ward or prior to delivery. A senior investigator was available all the times to discuss concerns raised by parents or clinicians during the course of trial.

4.9 Randomization

Each eligible newborn was randomly assigned to either oropharyngeal suctioning with the penguin suction device or the suction catheter in a 1:1 ratio by using a small opaque plastic container concealing n/2 white and n/2 black toothpicks. The color of the randomly plucked toothpick determined whether penguin suction device or suction catheter would be used.

If the baby needed suctioning, the toothpick was broken and removed from the container.

If the baby didn't need suctioning, the toothpick was put back into the container.

This randomization method is considered appropriate for a low-resource setting with limited space and power availability.

The assigned procedure was hence perfumed without allowing contamination between the two arms.

4.10 Blinding

Due to the characteristics of the intervention, neither caregivers nor outcome assessors were masked to treatment allocation. Caregivers were masked to oxygen saturation and heart rate values provided by the pulse-oximeter. The statistician was masked to the arm allocation during data analysis.

4.11 Guidelines for management

Before starting the study, all those involved in the study participated to a meeting where all the details of the study were presented. A one-day refresher course of neonatal resuscitation based on Help Baby Breathe version 2 algorithm was offered to the midwives responsible for neonatal management at birth, with a specific focus on the use of penguin suction device/bulb syringe device and suction catheter.

Written and oral information was offered to parents or guardians by research assistant at maternal admission to the obstetrical ward or before delivery. Parents

or guardians were asked to sign a written informed consent. After obtaining parental consent, the neonate was considered for inclusion in the study.

Immediately after birth, all infants needing suctioning were randomized to receive suctioning with penguin suction device or suction catheter.

Suctioning with bulb syringe was performed following Help Baby Breathe algorithm and using a penguin suction device made by silicon (Laerdal Global Health, Laerdal, Norway). Suctioning with the suction catheter was performed following the Neonatal Resuscitation Program algorithm and using a 8-fr flexible catheter made by polyethene (Covidien, Dublin, Ireland connecting to an electrical negative pressure source The maximum negative pressure did not exceed 100 mmHg.

Figure 22 - Infant warmer located in St. Luke Catholic Hospital Delivery Unit

Figure 23 - suction catheter used for the trail

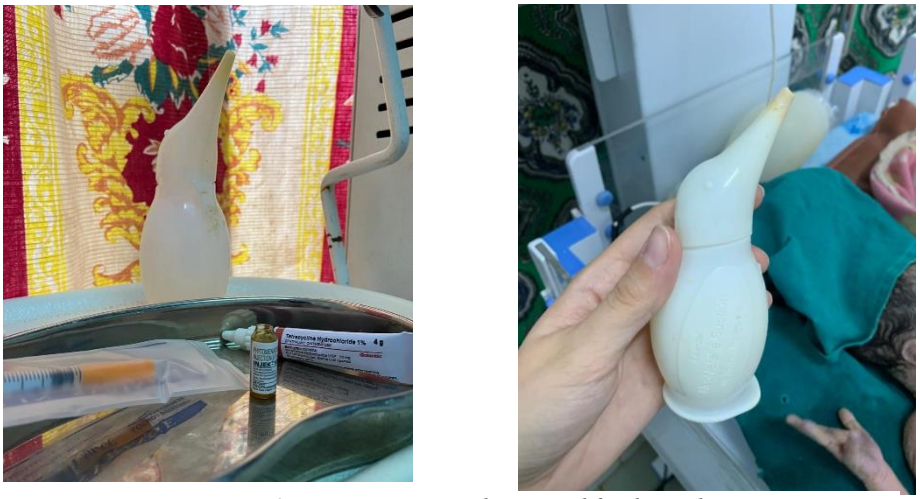


Figure 24 - penguin suction device used for the trial

Figure 25 - scan to watch the two videos showing the two different methods

An external observer who was not involved in the newborn care procedures, was responsible for the positioning of the probe of the pulse oximeter on the baby right foot or hand.

Heart rate and oxygen saturation values displayed on the pulse oximeter were collected from the first minute to the tenth minute of life.

If the newborns didn't need any other resuscitative maneuvers after suctioning, they were brought to their mothers for skin-to-skin contact.

If the newborns required other resuscitative maneuvers (PPV, oxygen supplementation, chest compressions, adrenaline), they were brought to Neonatal Intensive Care Unit (NICU) for observation and recovery.

They were placed under observation for 48 hours of life to check the outcome and the presence of local lesions due to suctioning and to see if they needed more support as for example supplemental oxygen and/or nasal CPAP.

While conducting this pilot study, a survey was administered to the midwives of St. Luke Hospital who took part to the study.

They were asked their age, years of work, which is the average monthly number of newborns requiring suctioning, which suctioning device leads to better outcomes according to their experience and why and which way of suctioning is easier to handle.

This allowed to have a more complete view of the perception of the local staff about suctioning.

4.12 Data collection

Data was recorded in a data sheet deigned for this study, where all the data obtained during delivery room management was collected by an observer not involved in the care of neonates (pediatric resident).

Registered clinical information was

- Eligibility and randomization
- Maternal and neonatal characteristics
- All data above listed in "Primary outcomes measures"

- “Secondary outcome measures” sections
- Length of stay and in-hospital mortality

Further information was collected as notes.

4.13 Abbreviations

ONPS: oronasopharyngeal suction; CPAP: continuous positive airway pressure; PPV: positive pressure ventilation; NICU: neonatal intensive care unit; PEEP: positive and expiratory pressure ; BMI: body mass index; EC/S: emergency cesarean section; SVD: spontaneous vaginal delivery; ABP: abruptio placentae; ANR: advanced neonatal resuscitation; CLC: clinical chorioamnionitis; GA: gestational age; GD: gestational diabetes; GETA: general anesthesia; IUGR: intrauterine growth restriction; MSAF: meconium stained amniotic fluid; MAS: Meconium Aspiration Syndrome; APGAR: appearance, pulse, grimace, activity, respiration; NO: nitric oxide; PGI_2: prostaglandin I_2;

4.14 Trial registration

The study has been registered in ClinicalTrials.gov NCT05472155.

CHAPTER 5 - STATISTICAL ANALYSIS

All data was analyzed on an intention-to-treat basis.

Categorical data was summarized as frequency and percentage, and continuous data was summarized as median and interquartile range (IQR).

Oxygen saturation and heart rate during the first 10 minutes of life were compared between the two arms using linear regression models (including the arm and time as fixed effects, and the neonate as random effect).

The other secondary outcome measures were compared between arms using Chi Square test or Fisher's exact test (binary data), or Mann-Whitney test (numerical data). All tests were 2-sided and a p-value less than 0.05 was considered statistically significant. Statistical analysis was performed using GraphPad Prism version 9 (Dotmatics, San Diego, California).

CHAPTER 6 - RESULTS

6.1 Participant characteristics

Data collection was concluded in October 2022 and at the time of the analysis a total of 61 patients (31 in electrical arm and 30 manual arm) were enrolled. All participants received the allocated intervention.

Baseline characteristics are displayed in Table I.

Table I. Baseline characteristics

	Electrical arm (n=31)	Manual arm (n=30)
Maternal age, years: median (IQR)	25 (22-28)	25 (22-28)
ANC: n (%)	27/31 (87%)	24/30 (80%)
Steroids: n (%)	0/31 (0%)	1/30 (3%)
Meconium: n (%) No Grade 1 Grade 2 Grade 3	 22 (71%) 2 (6%) 0 (0%) 7 (23%)	 21 (70%) 4 (13%) 3 (10%) 2 (7%)
HIV negative: n (%)	31/31 (100%)	30/30 (100%)
Caesarean section: n (%)	10/31 (32%)	6/30 (20%)
Males: n (%)	15/31 (48%)	20/30 (67%)
Birthweight, g: median (IQR)	2980 (2650-3325)	3035 (2709-3408)
GA, weeks: median (IQR)	40 (38-40)	40 (37-40)
Apgar 1 minute: median (IQR)	7 (5-8)	7 (5-8)
Apgar 5 minutes: median (IQR)	9 (7-9)	8 (7-9)
Apgar 10 minutes: median (IQR)	9 (8-9)	9 (8-9)

6.2 Primary outcome measure

The primary outcome measure is oxygen saturation in the first minutes of life. The oxygen saturation increased in both arms over time ($p < 0.0001$) with a similar slope between the two arms ($p = 0.7728$) (Figure 26).

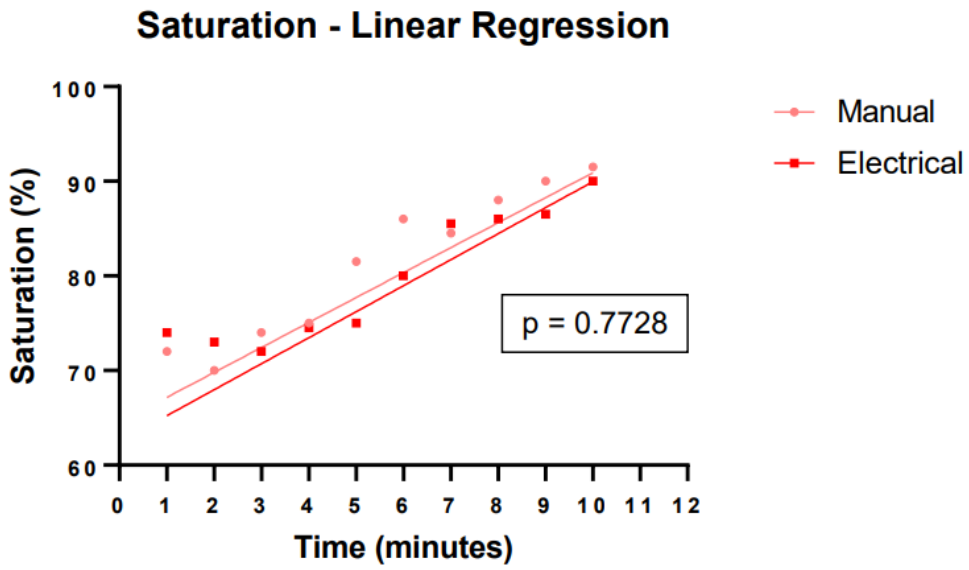


Figure 26 - Oxygen saturation during the first 10 minutes of life

6.3 Secondary outcome measures

Heart rate increases over time in both arms ($p < 0.0001$), with no different slope between the two arms ($p = 0.9089$) (Figure 27). Admission to special care unit appear to be more frequent in electrical vs. manual arm (61% vs. 33%, $p = 0.0288$; Table II). The other secondary outcome measures did not differ between the two arms, neither (Table II). No local lesions occurred during the study.

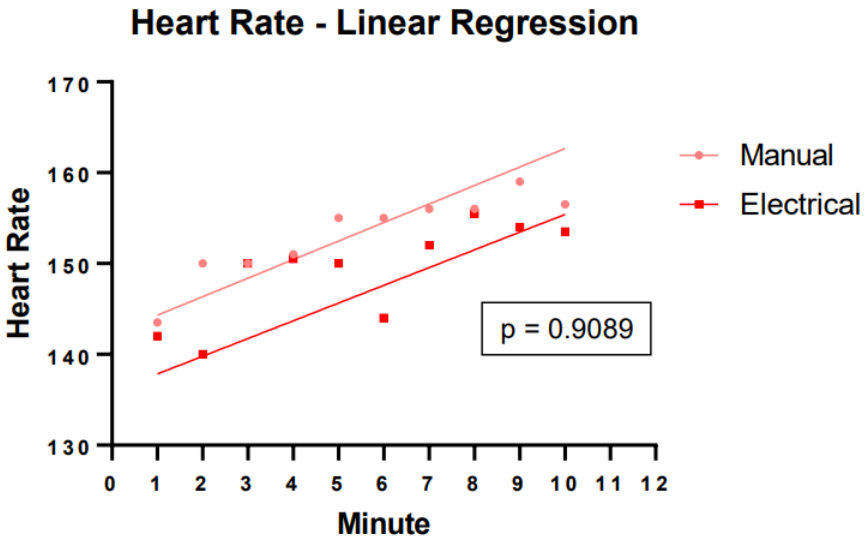


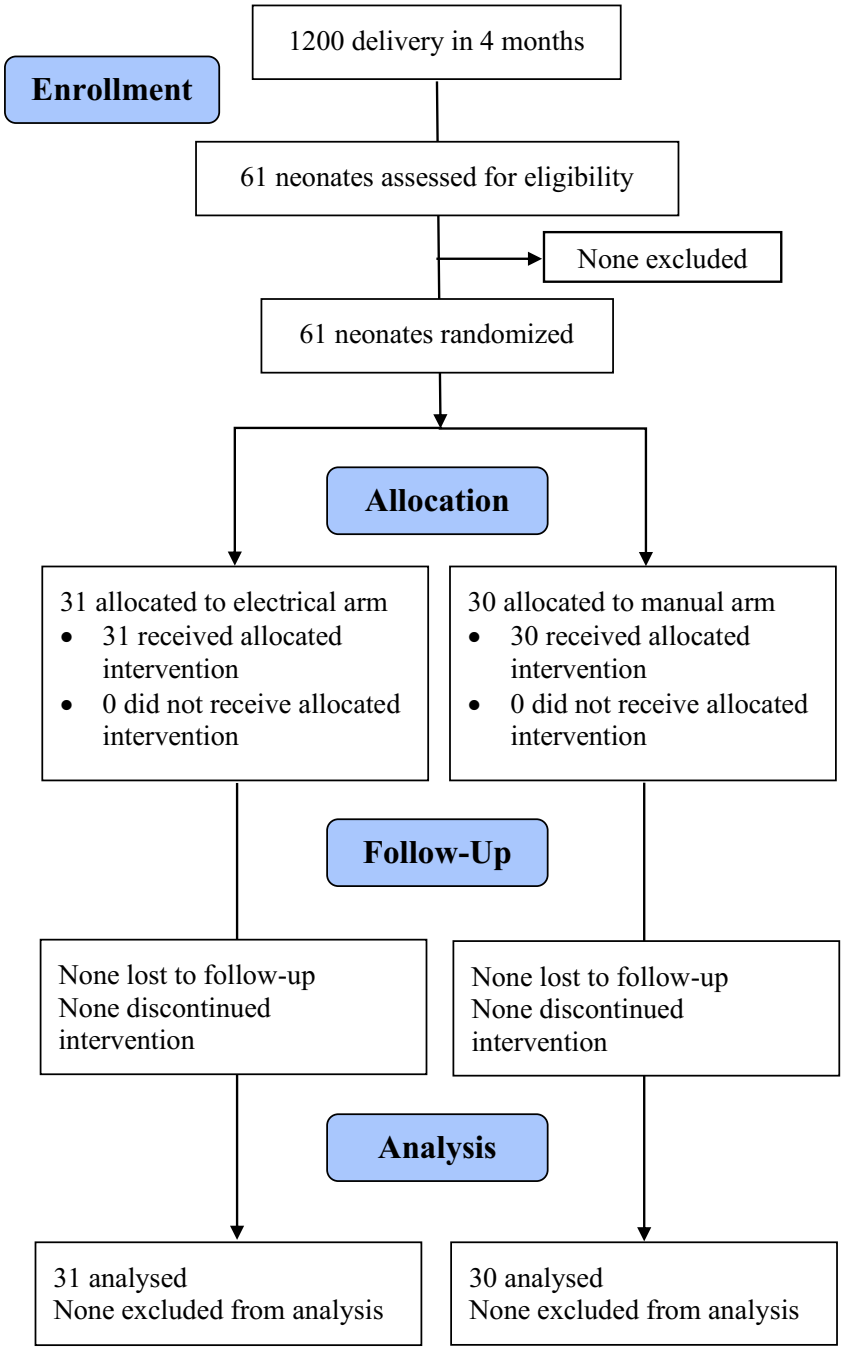
Figure 27 - Heart rate in the first 10 minutes of life

Table II. Secondary outcome measures

	Electrical arm (n = 31)	Manual arm (n = 30)	p-value
The proportion of neonates with heart rate > 100 bpm at 5 minutes: n (%)	27/30 (90%)	25/27 (93%)	> 0.9999
Episodes of bradycardia (defined as heart rate <100 bpm) in the first 10 minutes of life: n (%)	6/31 (19%)	3/31 (10%)	0.4729
The proportion of neonates with saturation > 80% at 5 minutes: n (%)	11/30 (83%)	14/29 (48%)	0.4348
The proportion of neonates with saturation > 90% at 10 minutes: n (%)	25/30 (83%)	20/31 (65%)	0.1455
Need for face-mask ventilation: n (%)	13/31 (42%)	10/30 (33%)	0.5996
Need for supplemental oxygen in delivery room: n (%)	11/31 (35%)	5/30 (17%)	0.1455
Admission to the special care unit: n (%)	19/31 (61%)	10/30 (33%)	**0.0288**
Length of hospitalization: median (IQR)	4 (1 – 7)	4 (1 - 7)	0.4236
Occurrence of local lesions (defined as bleeding from the mouth and/or the nose) due to suctioning procedure: n (%)	0 (0%)	0 (0%)	-
Occurrence of respiratory distress (defined as need for	10/19 (53%)	6/10 (22%)	> 0.9999

supplemental oxygen and/or nasal-CPAP during the first 48 hours of life): n (%)			

6.4 Consort Diagram



CHAPTER 7 – DISCUSSION

7.1 Discussion

This pilot study showed that there is no clinical difference comparing heart rate and oxygen saturation values during the first ten minutes of life obtained when using the penguin suction device or the suction catheter.

Concerning the other secondary outcome measures, findings showed there is no significant difference between the two arms, except for the admission to neonatal intensive care unit (NICU). Newborns belonging to the electrical arms were likely to be admitted to NICU compared to those belonging to the manual arm (19 [61%] vs. 10 [33%], p = 0.0288). It is noteworthy that 33% of patients enrolled in the manual arm were admitted to NICU, this suggests that suctioning was provided for a moderately ill population.

We can furthermore add that despite the progressive improvement of heart rate and oxygen, a considerable proportion of neonates was admitted to NICU immediately after birth. This leads to think that suctioning maneuver was appropriate, thus performed in newborns indeed needing help in breathing at birth.

Moreover, in spite of the difference highlighted in the admission to neonatal intensive care unit, the length of hospitalization is almost identical between the two groups (4 [1-7] vs 4 [1-7], p = 0.4236). In addition, most of newborns belonging to manual arm and electrical arm both stayed in NICU just for one day for observation. However, this result should be interpreted with caution because the study was not aimed at assessing this outcome.

The result of the present trial should be confirmed by a larger randomized controlled trial focused on the impact of suctioning at birth on NICU admission.

Currently airway suctioning is part of the neonatal resuscitation algorithms, and it is only required if there is airway obstruction due to mucus, vernix, meconium, blood clots etc. [10] Furthermore, one should know that non-vigorous newborn infants delivered through meconium-stained amniotic fluid are at significant risk for requiring advanced resuscitation: PPV should be initiated as soon as possible but

whether the attempts in aeration and ventilation are not successful, it is advisable to examine the pharynx and to perform suctioning. [10,15]

Even though oronasopharyngeal suctioning is mostly performed in newborns with meconium-stained amniotic fluid, there is no evidence that suggests ONPS prevents Meconium Aspiration Syndrome (MAS). [60]

After defining the aim of suctioning, further studies have been conducted. Many of them compared suctioning with no suctioning in newborns.

Bulb syringe suctioning could lead to a lower oxygen saturation levels and a slower achievement of normal range of 86% to 92% saturation. [33]

In addition, improperly performed, deep and prolonged bulb suctioning could stimulate the vagus nerves of the posterior pharynx thus inducing bradycardia and lower arterial oxygen saturation levels.

Carrasco's study on oronasopharyngeal suction at birth reinforced the link between ONPS and lower SpO_2 thus considering the practice not appropriate for normal, term, vaginally born infants. [68]

Another study published by Bancalari et al. compared oronasopharyngeal suction vs no suction in healthy newborns delivered by cesarean section. This study led to conclude that not performing ONPS in newborns did not affect SpO_2 and HR in the first postpartum hour. [69]

A perspective randomized controlled trial performed at a Turkish tertiary hospital enrolled a total of 140 normal, term and vaginally born infants in order to evaluate the effects of ONPS done by a polyethylene tube vs no ONPS. The findings showed that patients belonging to the suction group had lower SpO_2 valued compared to the no suction group while heart rate values appeared to be lower in the no suction group. [31]

Additionally, it is appropriate to mention another randomized equivalency trial showing that wiping the nose and the mouth with a towel has equivalent efficacy to routine use of ONPS. [32]

The Foster JP et al. Cochrane Review added more information about ONPS vs no suction at birth in healthy term newborns. This highlighted no statistical difference

between ONPS and no ONPS for the outcomes of mortality, need for resuscitation, admission to NICU and Apgar scores at five minutes. [13]

All these studies comparing suction vs no suction in newborn with or without air obstruction prove that ONPS has to be avoided as a routine practice. However, literature does not provide any information about the comparison between the use of the penguin suction device and the use of a suction electric catheter in terms of clinical differences in newborns needing suctioning. Guidelines consider the two procedures as equal but there is no evidence thereupon.

This is the first study that compares penguin suction device and suction catheter for ONPS in newborn infants needing postnatal suctioning, according to guidelines.

7.2 Strength points

This study has several strength points. First of all, this has to be considered a pilot study because, to our knowledge this is the first study that compares the penguin suction device with the suction catheter.

In addition, this study was conducted in a low-resource setting in which strengthening the performance of the first steps of Helping Babies Breathe algorithm (version 2) should reduce the need for PPV and intubation, the admission to NICU and in the last instance, the neonatal mortality rates.

The study was hence appropriate for a low-resource setting allowing to assess primary and secondary outcomes (Appendix 1).

In addition, in this randomized controlled trial all the local staff was involved working as a multicultural team. In order to use appropriate techniques and to obtain appropriate results, a refresher course for Delivery Unit midwives was provided by a pediatrician.

Moreover, a survey was administered to the local staff with the purpose of understanding their habits and preferences concerning neonatal suctioning.

16 midwives filled the survey. 14 of them considers manual suctioning easier to use (Appendix 3).

Furthermore, the protocol was registered in ClinicalTrial.Gov before starting to collect data. It was then scrupulously respected and followed in all its points (Appendix 1).

Lastly, the study aims to optimize the resources. If the penguin suction device is equivalent to the suction catheter, it can be used more in low-resource settings. It turns out to be cheaper than the suction catheter, reusable after an accurate washing and disinfection. In addition, if electricity is not available, the suction step of neonatal resuscitation can be performed in any case because the penguin suction device does not require a negative pressure source.

7.3 Limitations

However, this study has some limitations. First, midwives performing suctioning couldn't be masked to the study intervention. However, they were masked to the SpO_2 and heart rate values while performing suctioning at birth. Data were collected by an external observer not involved in the care of neonates.

Besides, the findings reported in the survey suggest that midwives are more at ease with the penguin suction device. This implies they are more experienced and trained in using it compared to the suction catheter. However, a refresher course was provided at the beginning of the trial.

CHAPTER 8 – CONCLUSIONS

This pilot study shows that there is no statistical difference between the use of the penguin suction device and the suction catheter regarding SpO_2 and heart rate values in the first ten minutes of life. Findings only show a difference in admission to NICU: newborns receiving suctioning maneuver with a suction catheter are more likely to be admitted to neonatal intensive care unit.

The two methods hence appear to be equal. This could lead to choose manual suctioning especially in low-resource settings in which optimizing the resources is essential. The penguin suction device can be reusable after washing and disinfection.

Despite our findings supporting the use of penguin suction device immediately after birth, further studies are required to confirm our data.

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APPENDIX 1 – STUDY PROTOCOL

TITLE: A RANDOMIZED CONTROLLED TRIAL FOR NEONATAL SUCTIONING IN A LOW-RESOURCE SETTING DELIVERY ROOM: A COMPARISON BETWEEN PENGUIN AND CATHETER

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Abstract

Background: Evidence from literature showed that suctioning should be offered only to newborn infants who have obvious obstruction to spontaneous breathing or who require positive pressure ventilation. International guidelines recommend the use of a penguin suction device or a suction catheter in newborn infants needing suctioning at birth, but literature does not provide any information on clinical differences between the two procedures.

Objective of the study: This trial aims to compare two different methods of oropharyngeal suctioning (with penguin suction device or suction catheter) in newborn infants needing suctioning at birth.

Primary outcome measure: Oxygen saturation during the first 10 minutes of life.

Study design: This is a single center, prospective, randomized clinical trial comparing two different methods of oropharyngeal suctioning (with penguin suction device or suction catheter) in newborn infants needing suctioning at birth.

Setting: The study is conducted at the St. Luke Catholic Hospital in Wolisso (Ethiopia), which is a level III hospital with around 3,600 deliveries per year.

Study procedures: Before starting the study, all those involved in the study will participate to a meeting (where all the details of the study will be presented). A one-day refresher course of neonatal resuscitation (Help Babies Breathe version 2) will be offered to the midwives responsible for neonatal management at birth, with particular focus on the use of penguin suction device and suction catheter.
Written and oral information will be offered to parents or guardians by the research assistant at maternal admission to the obstetrical ward or before delivery. Parents or guardians were asked to sign a written informed consent.

Immediately after birth, all infants needing suctioning will be randomized to receive suctioning with penguin suction device or suction catheter. All resuscitative procedures will be performed following the Help Babies Breathe algorithm. An external observer, not involved in the care of the newborn, will be responsible of the positioning the probe of the pulse oximeter and the collection of the data. We aim to enroll 60 neonates.

Introduction

A quarter of neonatal deaths are due to intrapartum-related events, with around 99% occurring in low-resource settings [1]. Education on neonatal resuscitation is most urgent in settings with poor access to intrapartum obstetric care, where immediate postnatal mortality can be reduced by 30% with basic training in neonatal resuscitation [2-4].

Management of newborns at birth includes different interventions based on progressive steps (initial steps, ventilation, chest compressions, and medications) [5,6]. Initial steps include oropharyngeal suctioning (with penguin suction device or suction catheter), which is recommended in infants who have obvious obstruction to spontaneous breathing or who require positive pressure ventilation [7]. Such restriction has been recommended since 2010 because of concerns related to adverse events associated with routine suctioning [8].

International guidelines recommend the use of a penguin suction device (Helping Baby Breathe) or a suction catheter (Manual of Neonatal Resuscitation) in newborn infants needing suctioning at birth [9,10], but literature does not provide any information on clinical differences between the two procedures.

This study is designed to compare two different methods of oropharyngeal suctioning (with penguin suction or suction catheter) in newborn infants at birth.

Literature review

Previous studies assessed the effect of routine oropharyngeal/nasopharyngeal suction compared to no suction in newborn infants [11]. Evidence from literature

showed that suctioning should be offered only to newborn infants who have obvious obstruction to spontaneous breathing or who require positive pressure ventilation [7]. International guidelines recommend the use of a penguin suction device or a suction catheter in newborn infants needing suctioning at birth [9,10], but literature does not provide any information on clinical differences between the two procedures. The use of a suction catheter implies a suction system which is often unavailable in low resource settings, hence penguin suction device is actually the most used method in such settings. This study is designed to compare two different methods of oropharyngeal suctioning (with bulb syringe or suction catheter) in newborn infants needing suctioning at birth.

Methods/Design

Aim

This pilot study aims to explore potential clinical differences between two methods of oropharyngeal suctioning (with penguin suction device or suction catheter) in newborn infants needing suctioning at birth.

Study design

This is a single center, prospective, randomized clinical trial comparing two different methods of oropharyngeal suctioning (with penguin suction device or suction catheter) in newborn infants needing suctioning at birth.

Setting

The study was conducted at the St. Luke Catholic Hospital in Wolisso (Ethiopia), which is a level III hospital with around 3,600 deliveries per year. This is a referral, private, nonprofit hospital located in Wolisso town, which is the capital of the Southwest Shoa Zone in the Oromiya region. The area has a population of about 1.1 million inhabitants and is served by 81 health facilities (including only one hospital). At St. Luke Wolisso Hospital, midwives are responsible for maternal and neonatal management at delivery. Midwives receive education on neonatal

resuscitation (Helping Babies Breathe program) and courses on postnatal management. This study will be part of a collaborative project between the St. Luke Catholic Hospital in Wolisso and Doctors with Africa CUAMM, a non-governmental organization. [12]

Inclusion criteria

Infants satisfying the following inclusion criteria will be eligible to participate in the study:

- inborn infants (and)
- need for suctioning at birth (and)
- parental consent; a written informed consent will be obtained by a member of the neonatal staff involved in the study from a parent or guardian at maternal admission to the obstetrical ward or prior to delivery.

The need for suctioning at birth is defined as difficult breathing due to the presence of abundant oronasopharyngeal secretions or need for positive pressure ventilation.

Exclusion criteria

- major congenital malformations;
- parental refusal to participate to the study.

Primary outcome measure

The primary outcome measure will be the oxygen saturation during the first 10 minutes of life.

Secondary outcome measures

1. Heart rate during the first 10 minutes of life;
2. The proportion of neonates with heart rate >100 bpm at 5 minutes;
3. Episodes of bradycardia (defined as heart rate <100 bpm) in the first 10 minutes of life;
4. The proportion of neonates with saturation >80% at 5 minutes;

5. Time to achieve transcutaneous saturations >90%;
6. Need for face-mask ventilation;
7. Need for supplemental oxygen in delivery room;
8. Admission to the special care unit;
9. Occurrence of local lesions (defined as bleeding from the mouth and/or the nose) due to suctioning procedure;
10. Occurrence of respiratory distress defined as need for supplemental oxygen and/or nasal-CPAP during the first 48 hours of life.

General usability

The findings of this study will be important to understand if there may be some clinical differences between oropharyngeal suctioning using a penguin suction device or a suction catheter in newborn infants needing suctioning at birth. The results of the present study will be useful to assess the presence and the magnitude of such clinical differences, and will be the basis for the design of a future larger randomized controlled trial.

Sample size

The sample size could not be calculated a priori given the lack of information in the literature regarding the study question. Hence, an arbitrary sample size of 60 infants (30 in each arm) was chosen for this pilot study.

Recruitment

Written and oral information will be offered to parents at maternal admission to the obstetrical ward or prior to delivery. A senior investigator will be available at all times to discuss concerns raised by parents or clinicians during the course of the trial.

Randomization

Each eligible newborn will be randomly assigned to either oropharyngeal suctioning with penguin suction device or suction catheter in a 1:1 ratio by using a small opaque plastic container concealing n/2 white and n/2 black toothpicks. The color of the randomly plucked toothpick will determine if penguin device or suction catheter would be used. If the baby will need suctioning, the toothpick will be broken and removed from the container. If the baby will not need suctioning, the toothpick will be put back into the container. This randomization method is considered appropriate for a low-resource context with limited space and power availability [13]. The assigned procedure (penguin suction device or suction catheter) will then be performed. Contamination between arms will not be allowed.

Blinding

Due to the characteristics of the intervention, neither caregivers nor outcome assessors will be masked to treatment allocation. Caregivers will be masked to oxygen saturation and heart rate values provided by the pulse-oximeter. The statistician will be masked to the arm allocation during data analysis.

Guidelines for Management

Before starting the study, all those involved in the study will participate to a meeting where all the details of the study will be presented. A one-day refresher course of neonatal resuscitation (Help Babies Breathe version 2) [9] will be offered to the midwives responsible for neonatal management at birth, with particular focus on the use of bulb syringe and suction catheter.

Written and oral information will be offered to parents or guardians by the research assistant at maternal admission to the obstetrical ward or before delivery. Parents or guardians were asked to sign a written informed consent. After obtaining parental consent, the neonate was considered for inclusion in the study.

Immediately after birth, all infants needing suctioning will be randomized to receive suctioning with bulb syringe or suction catheter. Suctioning with bulb syringe will be performed following the Help Babies Breathe algorithm and using penguin

suction device (Laerdal Global Health, Laerdal, Norway) [9]. Suctioning with suction catheter will be performed following the Neonatal Resuscitation Program [10] and using an 8-Fr catheter (Covidien, Dublin, Ireland) connected to an electrical aspirator (Aesculap, Tuttlingen, German) with a maximum negative suctioning value of 100 mmHg. As indicated by the guidelines, the mouth will be suctioned before the nose [10]. All other resuscitative procedures will be performed following the Help Babies Breathe algorithm [9]. An external observer, not involved in the care of the newborn, will be responsible of the positioning the probe of the pulse oximeter and the collection of the data.

Data collection

Data will be recorded in a data sheet designed for this study, where all the data obtained during delivery room management will be collected by an observer not involved in the care of the neonates (pediatric resident). Registered clinical information will be: eligibility and randomization; maternal and neonatal characteristics; all data above listed in 'Primary outcome measure', 'Secondary outcome measures' sections; length of stay and in-hospital mortality. Further information will be collected as notes.

Statistical analysis

Categorical data will be summarized as number and percentage, and continuous data will be summarized as mean and standard deviation or median and interquartile range. Categorical data will be compared between arms using Fisher test or Chi Square test, and effect size will be reported as risk ratio with 95% confidence interval. Continuous data will be compared between arms using Student t test or Mann-Whitney test, and effect size will be reported as mean difference or median difference with 95% confidence interval. The trend of oxygen saturation, heart rate and respiratory rate over time will be assessed in the two arms using linear regression models. All tests will be 2-sided and a p-value less than 0.05 will be

considered statistically significant. Statistical analysis will be performed using GraphPad Prism version 9 (Dotmatics, San Diego, California).

Duration of study

The trial will terminate when the last recruited infant is discharged from hospital, or dies. Based on preliminary observations, we consider the following duration of the study (10 months):

- 1 month: ethics committee approval;
- 3 months: data collection
- 1 month: analysis of the data;
- 2 months: preparation of the manuscript.

Ethical considerations

Written parental consent is necessary before enrollment of the patients in the study. We consider that there will be not risks for both study groups. Clinical conditions will be strictly monitored in both groups during the study.

Ethics Committee approval

The study needs to be approved by the Institutional Review Board of the St. Luke Catholic Hospital.

Compliance to protocol

Compliance will be defined as full adherence to protocol. Compliance with the protocol will be ensured by some members of the project (FC, EF, DM) responsible for local data collection, who will weekly monitor the adherence to the study protocol.

Data Safety and Monitoring Board

Safety measures will include incidence, severity and causality of reported severe adverse events, represented by changes in occurrence of the expected common

neonatal complications and the development of unexpected severe adverse events. All severe adverse events will be followed until complete resolution or until the clinician responsible for the care of the recruited patient considers the event to be chronic or the infant to be stable.

A monitoring board including an independent assessor (not involved in the study) from the University of Padova and an assessor from St. Luke Wolisso Hospital will review all the deaths and adverse effects. If there is a reasonable suspected causal relationship with the intervention, severe adverse events will be reported to the Institutional Review Board to guarantee the safety of the participants.

Discussion

Neonatal resuscitation guidelines recommend naso-oropharyngeal suctioning a birth in newborn infants who have obvious obstruction to spontaneous breathing or who require positive pressure ventilation. The suctioning device can be a penguin suction device or a suction catheter, but literature does not provide any information on clinical differences between the two procedures. This study aims to provide more information on this topic and will provide the baseline findings for designing further confirmative trials.

Trial status

The trial is complete for submission to the Institutional Review Board of the St. Luke Catholic Hospital.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

All authors have made substantial contributions to the conception and design of the study protocol and have given final approval of the actual version.

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APPENDIX 2 – STUDY CASE REPORT FORM

1. Inclusion criteria

Infant **MUST** present with all of the following (please tick the items below as appropriate):

☐ Inborn infant AND

☐ Absence of major congenital malformations AND

☐ Parental consent AND

☐ Need for suctioning at birth (defined as difficult breathing due to the presence of abundant oronasopharyngeal secretions or need for PPV).

Please indicate if the suctioning was needed due to:

☐ difficult breathing due to the presence of abundant oronasopharyngeal secretions

☐ need for positive pressure ventilation

☐ both of them

2. Randomization

RANDOMIZED TO:

- Suctioning with bulb syringe ☐
- Suctioning with suction catheter ☐

THE PATIENT WAS NOT RANDOMIZED DUE TO:

- Major congenital malformations ☐
- Parental refusal to participate to the study ☐
- Other reasons (specify)…… ☐

3. Baseline Information

IDENTIFICATION	
ID number	
Name of the patient	
Date of birth	
Hour of birth	
ANTENATAL RECORDS	
Mother's name	
Mother's age	
Did the mother attend antenatal clinic?	
Did the mother receive antenatal steroids?	
Pregnancy complications	
HIV serology (positive/negative)	
Other	
NEONATAL HISTORY	
Mode of delivery (vaginal/cesarean section)	
Indication to cesarean section	
NEONATAL INFORMATION	
Sex of the neonate	
Birth Weight	
Gestational Age	
Apgar score 1 min	
Apgar score 5 min	
Apgar score 10 min	
Resuscitation interventions:	- Stimulation - Face-mask ventilation - Chest compressions
Time of the first breath (sec.)	

Time of regular breathing (sec.)	
Episodes of bradycardia (defined as heart rate <100 bpm) in the first 10 minutes	
Time to achieve transcutaneous saturations >90%;	

4. Outcome measures

Date and hour of birth: ……

Name of the midwife attending the birth: ……

Year of experience in delivery room: …….

Postnatal time (minutes)	**1 mi**	**2 mi**	**3 mi**	**4 mi**	**5 mi**	**6 mi**	**7 mi**	**8 mi**	**9 mi**	**10 mi**
OXYGEN SATURATIO										
HEART RATE (bpm)										

Did the baby need face-mask ventilation? ☐ YES ☐ NO

Did the baby need supplemental oxygen in delivery room? ☐ YES ☐ NO

Was the baby admitted to the special care unit? ☐ YES ☐ NO

Occurrence of local lesions (defined as bleeding from the mouth and/or the nose). ☐ YES ☐ NO

Occurrence of respiratory distress defined as need for supplemental oxygen and/or nasal-CPAP during the first 48 hours of life. ☐ YES ☐ NO

Postnatal time (hour)	**1 hour**	**2 hour**	**3 hour**	**4 hour**	**5 hour**	**6 hour**
RESPIRATORYRATE						

5. Discharge data:

Dead

- Date of death: ……...

- Diagnosis: ☐Prematurity ☐Asphyxia ☐ Infection/sepsis ☐ Other (specify)

Alive

- Admitted to the NICU: …….

- Date at discharge: ……... Weight at discharge (kg) …….

- Diagnosis: ☐ Prematurity ☐Asphyxia ☐ Infection/sepsis ☐Other (specify)

Local lesions due to sucioning (i.e. blodd from the mouth/nose) ☐

Need for supplemental oxygen and/or nasal-CPAP during the first 48 hours of life ☐

APPENDIX 3 – SURVEY FOR MIDWIVES

1. How old are you?

.....……

2. How long have you been working in Delivery Unit?

……

3. Can you tell me the average number of newborns requiring suctioning?

……

4. In your opinion which way of suctioning (electrical vs manual) leads to better neonatal outcomes? And why?

……

……

5. In your opinion which way of suctioning (electrical vs manual) is easier to employ?

……

……

Age	**Years of work**	**Average number of newborns requiring suctioning**	**Which way of suctioning for better neonatal outcomes?**	**Why?**	**Which one is easy to use?**
21	1 year	50 per month	**Electrical**	It helps more in case of critical condition	**Manual**
25	4 years	50%	**Manual**	It protects the newborn preventing	**Manual**

				from vagal reflex	
26	4 years	40%	**Manual**	It protects the newborn preventing from vagal reflex	**Manual**
28	6 years	40%	**Manual**	Easier and faster to use	**Manual**
21	2 years	50%	**Electrical**	It can remove a large amount of secretions	**Manual**
24	2 years	30%	**Manual**	The Delivery Unit staff know how to use it properly	**Manual**
27	6 years	25%	**Manual**	Electrical suctioning can cause damages in respiratory trait	**Manual**
25	6 years	20%	No difference between the two	/	**Manual**
20	2 years	30%	**Electrical**	1.It removes a large amount of secretions 2.You can reach the stomach	**Manual**

25	4 years	30%	**Electrical**	It prevents from meconium swallowing	**Manual**
24	4 years	40%	**Manual**	It is more available	**Manual**
28	1 year	2/day	**Electrical**	It is faster and easier to use	**Electrical**
24	3 years	20%	**Manual**	It protects the newborn preventing the vagal reflex and bradycardia.	**Manual**
23	3 years	20%	**Manual**	Electrical suctioning could cause bradycardia and damage the respiratory trait	**Manual**
20	2 years	10%	**Electrical**	It is more effective in neonatal resuscitation	**Electrical**
27	1 year	15%	**Electrical**	It is more effective in distressed babies	**Manual**

1. 16 midwives filled the form for this survey
2. 50% of them consider manual suctioning more effective. The other half prefers electrical.
3. The reason why 50% prefers electrical suctioning is the effectiveness of this method. In critical conditions or in case of a large amount of secretions, it is possible to clean the airways better.
4. It seems that experienced midwives prefer manual suctioning.
5. 14 over 16 considers manual suctioning easier to use.

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