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Research Article

Efficacy of Upright vs. Standard Resuscitation Bags in Elevating Heart Rate in Late Preterm Newborns: A Randomized Clinical Trial

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ABSTRACT

Background: In the transitional cycle from intrauterine to extrauterine life, with aeration of the lungs, gas exchange shifts from the placenta to the lungs. This is the most fundamental process that the vast majority of term and near-term infants undergo to adapt to extrauterine life (approximately 85%), leaving the rest of the infants unable to perform it without PPV, making birth the most challenging phase of their existence. For neonates depressed by any cause who are unable to establish functional residual capacity (FRC) by replacing the liquid in the alveoli with atmospheric gas through spontaneous breathing and forming a tidal volume (TV) at birth, healthcare providers must intervene with manual ventilation and alveolar ventilation to replace alveolar fluid with atmospheric gas and establish functional residual capacity (FRC). Given that currently self-inflating bags (SIBs) are a central component in any setup related to the neonatal resuscitation program (NRP) and the recent availability of the upright-bag design of SIB, this study investigates the number of ventilations of neonates requiring positive pressure ventilation (PPV) after birth using two approaches: the upright bag and the classic design of SIB, known as the standard bag.
Methods: This is a randomized clinical study. Neonates with a gestational age of 35+0/7 to 36+6/7 weeks who required PPV due to a heart rate of less than 100 bpm after the initial steps of newborn care after birth were divided into two groups, each including 30 neonates (60 in total). Both groups received PPV using SIB, with one group experiencing ventilation using standard bags and the other receiving ventilation using upright bags. Shahid Beheshti Hospital in Isfahan conducted this study from September 2020 to February 2024.
Results: The study showed that the average number of ventilations needed to achieve a heart rate of 100 bpm or higher was significantly lower (P value = 0.029) using the upright bag. The average gas leakage around the mask during ventilation was significantly less (P value = 0.018) using the upright bag. The need for oral and nasal suction with an open mouth was significantly lower (P-value = 0.020) with the upright bag. The requirement for intubation during ventilation was significantly lower (P value = 0.010) using the upright bag. Pneumothorax was also significantly less common (P value = 0.030) in neonates ventilated using the upright bag.
Conclusion: This study suggests that, considering the two available designs of self-inflating resuscitation bags, upright resuscitation bags are more effective in rapidly increasing an infant's heart rate compared to standard resuscitation bags, offering a superior alternative for neonatal resuscitation.

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Introduction

The most fundamental process that fetuses and neonates undergo at birth to adapt to extrauterine life is the initiation of breathing. During the second half of pregnancy, the production of fluid by the lung epithelium at a rate of 4-5 mL/kg/hr results in a volume of approximately 50 mL/kg in the lung structure, decreasing to 25 mL/kg at birth. This volume must be replaced by atmospheric gas with the first breaths, establishing functional residual capacity (FRC) [1-2].

The first spontaneous breaths of a neonate have a short inspiration time with a prolonged expiration period, in which the maximum inspiratory pressure can be estimated at around -50 to -100 cm H_2O. However, an opening pressure of approximately -5 cm H_2O allows gas flow from the terminal bronchioles to the alveolar structures. [3-4].

If a neonate is not depressed at birth, significant reductions in pulmonary vascular resistance (PVR) occur while FRC is established following the first breaths. Within the first 30 minutes after birth, PVR drops by 70%, and within 60-90 minutes, it reaches a 100% reduction without the need for supplemental oxygen. Following umbilical cord clamping, peripheral and central chemoreceptors are stimulated, combined with thermal and tactile stimuli, leading to increased systemic blood pressure and, ultimately, transforming the parallel circulation system into a serial blood flow cycle [5-7].

In a depressed neonate, unable to establish functional residual capacity (FRC) with atmospheric gas content through spontaneous respirations to clear fetal lung fluid from the alveoli at birth, healthcare providers must institute ventilation and alveolar recruitment by delivering tidal volumes (TV) to the airways. Healthcare providers facilitate the transfer of these gas volumes (estimated to be around 8 mL/kg) to the airways using manual resuscitators interfaced with face masks, supraglottic airway (SGA) devices, or endotracheal tubes. The actual volume delivered to the airways depends on various factors, including spontaneous breathing effort, lung compliance, laryngeal obstruction, gas leakage, oral and nasal obstruction, type of resuscitator, and the level of applied pressure [8-11].

Based on their need for a gas flow source, manual resuscitators fall into either of these two categories: flow-inflating bags (FIB) and T-piece devices, which require a continuous gas flow, and self-inflating bags (SIB), which do not. The use of FIB not only requires a continuous gas flow but also experienced personnel. The T-piece device is recognized as a manual resuscitator with flow-controlled and pressure-limited capabilities. Although resuscitation setups can include T-piece devices or FIB, their dependence on a continuous gas flow, considered a critical limitation, makes the presence of SIB essential in any resuscitation configuration [12-15]. SIBs, which rapidly reinflate after compression, offer a significant advantage over FIBs and must be present in every neonatal resuscitation set. Healthcare providers will not face significant challenges using these bags, making them an integral part of the global Helping Babies Breathe program. One limitation is the potential for high pressures, up to 100 cm H_2O, if used too quickly or forcefully. Typically, an opening pressure of 13-32 cm H2O is sufficient to provide a tidal volume of 6-8 mL/kg for neonates without spontaneous breathing [16].

Although SIBs designed for neonates may have a capacity of around 240 mL, they have been shown to be capable of delivering tidal volumes of up to 20 mL/kg or more if compressed excessively. However, studies indicate that SIBs provide better feedback on lung compliance compared to FIB and T-piece devices, helping health providers prevent the delivery of excessive tidal volumes. In other words, our improved understanding of injuries resulting from volume trauma and monitoring volume during PPV rather than monitoring peak pressure have proven to be of higher importance [17].

Objectives

In 2015, the Laerdal Corporation introduced a novel design for self-inflating bags used vertically (known as Upright Self-Inflating Bags) (USIBs) to enhance optimal control over volume and pressure during ventilation and to maintain these parameters consistently during the PIP (Peak Inspiratory Pressure) phase. This new design has been assessed in a number of studies [18-21]. Given that about 4%-10% of term and late preterm newborns require positive pressure ventilation (PPV) during resuscitation at birth, and considering that PPV is recognized as the most important and effective intervention for a neonatal provider during newborn resuscitation, and that upright self-inflating bags have already been introduced, we decided to challenge them against conventional standard self-inflating bags in a clinical trial.

Methods

Design and Setting

This study is an RCT conducted from September 2020 to February 2024 at Shahid Beheshti Hospital in Isfahan. The inclusion criteria were all newborns with a gestational age of 35 0/7 to 36 6/7 weeks. These newborns were transferred to a radiant warmer post-delivery based on the Neonatal Resuscitation Program (NRP) guidelines (7th edition) and entered the Initial Steps of Newborn Care. If a newborn's heart rate was less than 100 beats per minute, they were included in the study since they required PPV intervention. Exclusion criteria included congenital abnormalities; evidence of birth asphyxia, defined as the presence of at least one or two components such as an Apgar score<6 within 10 minutes of birth, the need for PPV, or chest compressions along with PPV within 10 minutes of birth; any acute perinatal sentinel event that could lead to hypoxic-ischemic encephalopathy (e.g., placental abruption, umbilical cord prolapse, and severe abnormality in FHR); and pH<7 or BE ≤ -16 mmol/L in the umbilical cord or arterial sample within an hour of birth. Written consent was obtained from the parents before the birth of the newborn. This study was registered on the Iranian Registry of Clinical Trials (reference number: IRCT20120728010430N11).

Participants

According to their case numbers, eligible newborns were divided into two groups and subjected to PPV interventions. Dividing the newborns into the interventional and control groups was done using the last digit of the newborns' case number, being either even or odd. The demographic characteristics of these infants are shown in (Table 1). Each group required 30 infants to participate in the study.

Intervention

Infants in the SSIB (standard self-inflated bag) group were ventilated using a conventional/standard self-inflating resuscitator (Laerdal Silicone Resuscitators 220 mL, Laerdal Medical Corporation, Stavanger, Norway) with Fisher facial masks sized 50-60 mm in diameter (Fisher & Paykel Healthcare, Auckland, New Zealand), fitted using the C-Hold (OK rim) method over the mouth and nose. The initial peak inspiratory pressure was set at 20 cm H_2O. Heart rate and the need for supplemental oxygen beyond 21% were monitored using pulse oximetry (Nellcor Bedside SpO_2 Patient Monitoring System, Minneapolis, US) and cardiac monitoring (Saadat Company, Tehran, Iran). Volume measurement was conducted using a hot-wire anemometer (Bear Cub 750 Flow Sensor—Viasys Healthcare, Ohio, US) placed between the patient outlet and the mask.

Infants in the USIB (upright self-inflated bag) group were ventilated using the upright self-inflating bag (Laerdal Silicone Resuscitators 320 mL, Laerdal Medical Corporation, Stavanger, Norway).

The infants' demographic characteristics, the number of ventilations required to reach a heart rate of 100 bpm, expiratory tidal volume, the percentage of gas leak during ventilation, the need for MR, the need for SO, the need for increased PIP levels, maximum pressure levels, the need for intubation, the need for supplemental oxygen beyond 21%, and the incidence of air leak syndrome within the first 72 hours of birth were monitored and recorded. The resuscitation process was recorded using surveillance cameras, and the videos were reviewed to accurately document variables.

Main Outcome Measures

The primary objective of this research was to evaluate the number of ventilations required using the upright bag to achieve a heart rate of ≥100 bpm in newborns with a gestational age of 35+0/7-36+6/7 weeks requiring PPV after completing the initial steps of newborn care.

Results

(Table 2) illustrates the study objectives. This study demonstrated that the average number of ventilators required to achieve a heart rate of 100 bpm or higher was significantly lower in infants ventilated using the upright bag (P = 0.029). The average gas leakage around the mask during ventilation was also significantly lower using the upright bag (P=0.018). Infants ventilated using the upright bag experienced significantly less need for oral and nasal suction and open-mouth ventilation (P=0.020). The need for intubation was significantly lower in the upright bag group (P=0.010). One infant in the standard bag group developed pneumothorax on the first day of birth (P=0.030).

Table 1- Demographic characteristics of newborns in two groups

		SSIB	USIB	P value
Sex	Male	21 (70%)	16 (53.3%)	0.026
	Female	9 (30%)	14 (46.6%)	
Gestational age (mean) (wk)		37.66	37.67	0.871
Birth weight (mean) (gr)		3032	3025	0.951
Routh of Delivery	NVD	22	20	1.364
	C/S	8	10	

Table 2- Primary and Secondary outcome in two groups

		SSIB	USIB	P value
Primary outcome	Number of ventilations required to reach HR ≥ 100 bpm (mean)	21.37	17.20	0.029
Secondary outcome	TV (mean) (mL)	26.83	27.20	0.822
	Leak (mean) (%)	20.70%	18.23%	0.018
	MR (%)	15 (50%)	9 (30%)	0.155

SO (%)	12 (40%)	4 (13.33%)	0.020
PIP (Mean) (cm H2O)	24.07	22.27	0.123
Intubation	2 (6.66%)		0.010
need to Supplemental oxygen beyond 21%	16 (53.33%)	14 (46.66%)	0.250
Chest Compression			
Drug			
Air leak	1 (3.33%)		0.030

Discussion

In a study conducted by Coffey in 2015 at Seattle Children's Hospital Research Center, they used a NeoNatalie manikin (Laerdal Global Health) equipped with an ASL 5000 test lung (Ingmar Medical, Pittsburgh, Pennsylvania). Two groups, each including 19 healthcare providers, one with extensive experience in neonatal care and another trained in SIB use in a simulated environment, alternately ventilated the manikin using USIB and SSIB for 4 minutes. The study showed that unacceptable tidal volumes (<5 mL/kg) were significantly more frequent while using SSIB [18].

In a 2015 study by Thallinger at Stavanger University Hospital, 87 medical and nursing students, including 46 from Tanzania, were asked to participate in a training course on SSIB and USIB. This study was based on lung ventilation of a neonatal manikin that allowed for defining lung compliance. The manikin was ventilated using either bag at compliances of 0.8 mL/cm H_2O and 0.2 mL/cm H_2O. The study revealed that the average tidal volumes and PIP were significantly higher using USIB [19]. In Narayanan's 2016 study at Georgetown University Medical Center, 65 healthcare providers were divided into two groups, each allowed to choose either USIB or SSIB to ventilate a manikin with variable lung compliance and resistance. The study found that tidal volumes were consistently higher using USIB [20].

In a study conducted by Rafferty et al. in 2017 at the Neonatal Research Center of the Royal Women's Hospital in Melbourne, the USIBs and SSIBs were compared alongside the T-piece resuscitator during the ventilation process of a manikin. Two groups, each consisting of twenty healthcare providers, with one group having sufficient experience with these resuscitators and the other having been trained to use these resuscitators prior to the study, performed the ventilation intervention, aiming for chest rise. The tidal volume, PIP, and amount of leakage were analyzed. While the percentage of leakage did not show a significant difference among the three resuscitators, the PIP level and tidal volume were significantly higher while using the USIB compared to the SSIB and T-piece resuscitator [21]. Currently, the only similar study at the site of termination of pregnancy was the research study conducted by Thallinger et al., hosted by Hydom Lutheran Hospital in Tanzania and published in Resuscitation journal (2017), in which infants were divided into two groups, namely USIB (201 infants assigned) and SSIB (148 infants assigned), for resuscitation purposes after birth and underwent ventilation using a bag and mask. The mean TV and leak percentage were not shown to be significantly different, while the PIP mean was observed to be significantly higher (P value<0.0001) in the USIB group [22]. Apart from Thallinger et al.'s study (2017), the other studies utilized simulators, and a common finding among them was increased tidal volumes during ventilation using USIBs. Based on the findings of this article, the present study seems to be the second research project conducted on USIB in a real-world setting to assess its capabilities. Given the primary goal of this research, which was the average number of ventilations required to achieve a heart rate of 100 bpm or higher in a newborn with a heart rate <100 bpm, this study shows that the use of USIBs has been more successful compared to the SSIBs, achieving a stable heart rate with fewer ventilations and consequently in a shorter time from the start of the intervention, yielding more reliable heartbeats. In this study, the tidal volumes during ventilation with the USIB compared to the SSIB showed increased records, similar to those of the studies conducted on simulators. However, this difference was seen to be insignificant, which was in line with the findings of the study done by Thallinger et al. (2017). Gas leakage was also significantly less during ventilation with the USIB. However, in Thallinger et al.'s study (2017), it was found to be insignificant.

During the intervention, the need for MR (mask adjustment and repositioning) and SO (suction and open mouth) was less in the USIB group, with the reduction in SO being statistically significant. PIP levels were higher in the SSIB during ventilation compared with the USIB, while PIP mean levels were not only higher in the USIB group, but also significantly higher mean values were obtained in Thallinger et al.'s study (2017). Moreover, in the present study, the mean need for intubation as well as the air-leak syndrome were significantly lower in the USIB group.

Conclusion

Despite its limited sample size, the present study demonstrated that the resuscitation process of positive pressure ventilation was effectively capable of stabilizing the newborn's cardiovascular status (achieving HR ≥ 100 bpm) with fewer ventilations when using the USIB compared with the SSIB. Overall, the need for ventilation corrective steps (MR SOPA) increased while utilizing the SSIB, whereas the increased need for some of these steps was not statistically significant (likely due to the small sample size). Given the critical nature of this intervention (ventilation), recognized as the most effective and important intervention in newborn resuscitation, and given the shorter time neonates reach stability in terms of their cardiovascular status, it seems that USIBs can lead to fewer ventilations more quickly. However, further studies with larger sample sizes are undoubtedly necessary.

What did we already know in this domain?

Effective ventilation in the resuscitation process of a newborn is closely linked to an increase in heart rate.

What did this study add to this knowledge?

Ventilation with the USIB can achieve target heart rates (HR $\geq$ 100 bpm) in a shorter time (fewer ventilations) compared to the SSIB.

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