Comparison of Devices for Newborn Ventilation in the Delivery Room

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Objective To evaluate the effectiveness and safety of a T-piece resuscitator compared with a self-inflating bag for providing mask ventilation to newborns at birth.

Study design Newborns at ≥26 weeks gestational age receiving positive-pressure ventilation at birth were included in this multicenter cluster-randomized 2-period crossover trial. Positive-pressure ventilation was provided with either a self-inflating bag (self-inflating bag group) with or without a positive end-expiratory pressure valve or a T-piece with a positive end-expiratory pressure valve (T-piece group). Delivery room management followed American Academy of Pediatrics and International Liaison Committee on Resuscitation guidelines. The primary outcome was the proportion of newborns with heart rate (HR) ≥100 bpm at 2 minutes after birth.

Results A total of 1027 newborns were included. There was no statistically significant difference in the incidence of HR ≥100 bpm at 2 minutes after birth between the T-piece and self-inflating bag groups: 94% (479 of 511) and 90% (466 of 516), respectively (OR, 0.65; 95% CI, 0.41-1.05; $P = .08$). A total of 86 newborns (17%) in the T-piece group and 134 newborns (26%) in the self-inflating bag group were intubated in the delivery room (OR, 0.58; 95% CI, 0.4-0.8; $P = .002$). The mean ± SD maximum positive inspiratory pressure was 26 ± 2 cm H_2O in the T-piece group vs 28 ± 5 cm H_2O in the self-inflating bag group ($P < .001$). Air leaks, use of drugs/chest compressions, mortality, and days on mechanical ventilation did not differ significantly between groups.

Conclusion There was no difference between the T-piece resuscitator and a self-inflating bag in achieving an HR of ≥100 bpm at 2 minutes in newborns ≥26 weeks gestational age resuscitated at birth. However, use of the T-piece decreased the intubation rate and the maximum pressures applied. *(J Pediatr 2014;165:234-9)*.

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Approximately 10% of infants require some assistance to begin breathing at birth. Of these, roughly 50% need assisted ventilation, and less than 10% require extensive resuscitation.[1,2] The most important action in the resuscitation of a depressed newborn in the delivery room is to establish effective ventilation.[3] To date, there is insufficient evidence regarding the optimal device for establishing effective ventilation in newborns at birth. Current International Liaison Committee on Resuscitation (ILCOR) and American Academy of Pediatrics (AAP)/American Heart Association (AHA) recommendations state that ventilation of the newborn can be performed effectively with a flow-inflating bag, a self-inflating bag, or a pressure-limited T-piece resuscitator.[3,4] An increase in heart rate (HR) remains the most sensitive indicator of resuscitation efficacy.[4]

Self-inflating bags are the most commonly used manual ventilation devices for providing positive-pressure ventilation (PPV) at birth.[5] In recent years, the T-piece has been included as an alternative device for ventilation in the delivery room, and its use is becoming more widespread.[5-7] Several studies have compared the effectiveness of both devices by testing providers with different levels of training in simulated neonatal resuscitation on mannequins, and found that the resulting pressures are lower and more consistent when using the

AAP	American Academy of Pediatrics
AHA	American Heart Association
BPD	Bronchopulmonary dysplasia
FiO_2	Fraction of inspired oxygen
GA	Gestational age
HR	Heart rate
ILCOR	International Liaison Committee on Resuscitation
PEEP	Positive end-expiratory pressure
PPV	Positive-pressure ventilation
SpO_2	Oxygen saturation
VLBW	Very low birth weight

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T-piece.[8-11] One small study compared the T-piece with a positive end-expiratory pressure (PEEP) valve and a self-inflating bag without a PEEP valve in extremely preterm infants, and found no difference in oxygen saturation (SpO_2) at 5 minutes after birth.[12] No randomized controlled study has compared the effectiveness of these 2 devices in the delivery room under standard clinical practice. Thus, the aim of the present study was to evaluate the effectiveness and safety of a T-piece compared with a self-inflating bag for providing ventilation through a face mask to newborns at birth.

Methods

This was a cluster-randomized, open-label, 2-period crossover trial performed in 11 centers from 5 countries (Argentina, Chile, Peru, Italy, and the US) that included public, private, and university hospitals. The protocol, the informed consent form, and the parent information material were approved by the Institutional Review Board of each participating center. Following Institutional Review Board guidelines and in compliance with each country's regulations, prenatal consent was requested for each admitted pregnant woman in 4 hospitals in Argentina and 1 hospital in Peru, and postnatal consent to analyze perinatal and follow-up data was requested in 3 centers in Chile, 1 center in Italy, and 1 center in the US. An informed consent waiver using an opt-out approach was approved by the Institutional Review Board in 1 center in the US considering both devices as standards of care.

Newborn infants at ≥26 weeks gestational age (GA) receiving PPV through a face mask at birth, in accordance with current Neonatal Resuscitation Program (AAP/AHA) and ILCOR recommendations,[4,13,14] were eligible for enrollment. Infants were excluded who required immediate endotracheal intubation at birth, presented with a major congenital malformation, or were part of a multiple birth. (Because an extra individual was necessary for each recruited infant, it was considered logistically impossible to enroll most of the multiples, and so to avoid a source of bias, we decided to exclude all of them.) We did not include infants at <26 weeks GA, because many of them would have been intubated immediately after birth, thereby increasing the heterogeneity of the sample. In addition, neonates at <26 weeks GA were also excluded owing to difficulties in standardizing their initial management approach.

Interventions

Each center was randomized to ventilate infants at birth with 1 of 2 devices, a T-piece or self-inflating bag. The order of intervention was assigned at random, and the group assignment was not submitted to the centers until study initiation. Before the start of patient enrollment, health care providers were trained in the use of the device assigned for that period. After 50 patients were enrolled came an interval without intervention ("washout period"), during which the health team was trained in the use of the alternate device and the necessary changes were made to adapt the logistic aspects of delivery room management for the second period.

Subsequently, each center was crossed over to the alternate treatment for the period in which a second set of 50 patients was enrolled. For the self-inflating bag period, each center was assigned at random to use the bag either with or without a PEEP valve, to allow subgroup analysis related to the use of PEEP.

Delivery room management followed AAP/AHA and ILCOR guidelines,[4,13,14] and at least 1 person skilled in resuscitation attended every delivery. In addition, an assistant timed and recorded the HR, actual maximum inspiratory pressure used during ventilation, and other study variables until the HR was stabilized. The self-inflating bag group received PPV with a 300-mL self-inflating bag (Mark IV Baby; Ambu, Ballerup, Denmark) with a manometer attached visible to the provider. In centers randomly assigned to its use, a PEEP valve was attached (PEEP 10; Ambu). The T-piece group received PPV using a Neopuff T-piece resuscitator (Fisher & Paykel, Auckland, New Zealand) with a PEEP valve.

Patients were initially ventilated with the following target pressures: a positive inspiratory pressure of 25 cm H_2O for both devices, and a PEEP of 5 cm H_2O when a PEEP valve was used. The initial fraction of inspired oxygen (FiO_2) was 0.4 for all infants up to September 2011, and 0.21 for term infants (≥37 weeks GA) and 0.4 for preterm infants (<37 weeks GA) thereafter. FiO_2 adjustments were determined by the attending physician. The following masks were available at each delivery: silicon RD (Fisher & Paykel) of various sizes, and Ambu 0A (Ambu). For both devices, blended oxygen flow rate was set at 8 L/minute, and the pop-off valve was set at 40 cm H_2O. If the infant was intubated in the delivery room, then PPV was provided with the device assigned for that period. Each center subsequently followed its usual practices.

Infants were followed until hospital discharge except in cases of prolonged hospitalization. Infants of >32 weeks GA were followed until 28 days postnatal age; those of ≤32 weeks GA, until 36 weeks postmenstrual age.

Outcomes

The primary outcome measure was the proportion of infants with an HR ≥100 bpm at 2 minutes after birth. This outcome was chosen based on published data as a proxy for effective response to resuscitation in the delivery room.[4,15-17] All time measurements were made from cord clamping by a trained observer with a stopwatch. All centers used an early cord clamping strategy throughout the study period. HR was measured by pulse oximetry when possible or, alternatively, with a stethoscope.

Each center used the pulse oximeter available in its delivery room. The probe was placed immediately after birth on the infant's right wrist or hand before being connected to the oximeter cable.[4] Each pulse oximeter was set to the maximum sensitivity and an averaging time of a 2-3 seconds.