Oxygenation with T-Piece versus Self-Inflating Bag for Ventilation of Extremely Preterm Infants at Birth: A Randomized Controlled Trial

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Objective To investigate whether infants <29 weeks gestation who receive positive pressure ventilation (PPV) immediately after birth with a T-piece have higher oxygen saturation (SpO_2) measurements at 5 minutes than infants ventilated with a self inflating bag (SIB).

Study design Randomized, controlled trial of T-piece or SIB ventilation in which SpO_2 was recorded immediately after birth from the right hand/wrist with a Masimo Radical pulse oximeter, set at 2-second averaging and maximum sensitivity. All resuscitations started with air.

Results Forty-one infants received PPV with a T-piece and 39 infants received PPV with a SIB. At 5 minutes after birth, there was no significant difference between the median (interquartile range) SpO_2 in the T-piece and SIB groups (61% [13% to 72%] versus 55% [42% to 67%]; $P = .27$). More infants in the T-piece group received oxygen during delivery room resuscitation (41 [100%] versus 35 [90%], $P = .04$). There was no difference in the groups in the use of continuous positive airway pressure, endotracheal intubation, or administration of surfactant in the delivery room.

Conclusion There was no significant difference in SpO_2 at 5 minutes after birth in infants <29 weeks gestation given PPV with a T-piece or a SIB as used in this study. *(J Pediatr 2011;158:912-8)*.

Positive end expiratory pressure (PEEP) is important for the establishment and maintenance of functional residual capacity (FRC).[1,2] In preterm infants, there is a strong association between a low FRC and subsequent respiratory distress syndrome (RDS) requiring ventilation.[3] In very preterm lambs, 4 cm H_2O PEEP improved oxygenation by about one third, and 8 cm H_2O PEEP halved oxygen requirements in the first 15 minutes after birth.[4]

Several manual ventilation devices, including self-inflating bags (SIB), flow-inflating bags, and T-pieces are recommended for positive pressure ventilation (PPV) in the delivery room.[5] The most widely used are SIBs and T-pieces.[6-8] Consistent PEEP is provided during PPV with a T-piece. The addition of a PEEP-valve to a SIB allows delivery of some PEEP,[9,10] but not continuous positive airway pressure (CPAP).[11] Although PEEP is always used during mechanical ventilation, the routine use of PEEP during PPV in the delivery room is not yet recommended.[5,12-14] Studies investigating the use of PEEP during neonatal resuscitation recommend it.[13,15]

We hypothesized that in infants <29 weeks gestation who received PPV in the delivery room, the use of a T-piece rather than a SIB would result in higher oxygen saturation (SpO_2) levels at 5 minutes after birth. We chose 5 minutes after birth as the time to assess the primary outcome because clinicians participating in the study wanted to be able to give CPAP to any infant without adequate oxygenation by this time.

Methods

The Royal Women's Hospital (RWH) in Melbourne, Australia, is a tertiary perinatal center with approximately 6000 deliveries per year. One hundred inborn

CPAP	Continuous positive airway pressure
FRC	Functional residual capacity
HR	Heart rate
PEEP	Positive end expiratory pressure
PIP	Peak inflating pressure
PPV	Positive pressure ventilation
RWH	Royal Women's Hospital
SpO_2	Oxygen saturation
T_i	Inflation time
V_T	Tidal volume
V_{Te}	Expiratory tidal volume

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infants <29 weeks gestation are admitted annually. Both T-piece and SIB were equally available to staff resuscitating newborn infants in the delivery room at the hospital, and all staff had been trained to use both devices.

This trial was conducted at RWH between February 2007 and February 2009. Infants born at <29 weeks gestation who received PPV in the delivery room in the first 5 minutes after birth because of inadequate respiration, a heart rate (HR) <100 bpm, or both were eligible for enrollment. Infants were excluded when there was uncertainty about their gestational age or when they had a congenital abnormality that might have an adverse effect on breathing.

Infants were randomly allocated to PPV with the T-piece or SIB. Allocation was stratified in gestational age groups (23 to 26 weeks and 27 to 28 weeks) and block randomized with variable sized blocks (4 to 8). A sequentially numbered, sealed, opaque envelope containing the allocation was opened by a researcher when the resuscitation trolley was set-up and checked in the delivery room before the birth of an eligible infant. A member of the research team ensured that the allocated resuscitation equipment was available on the resuscitation trolley. The randomized device was used when PPV was required in the first 5 minutes. Twins and triplets were randomized as individuals. Caregivers were not masked to the allocated device. All other resuscitative measures (eg, intubation, cardiac massage, and administration of oxygen or other drugs) were at the discretion of the clinical staff involved, following a standardized protocol. The alternative device was available when there was a failure of the allocated device.

Consent was obtained before birth when the mother was not in established labor and when time permitted. When this was not possible, retrospective consent was obtained as per Australian National Health and Medical Research Council guidelines for studies in emergency medicine.[16] Consent to use data was sought from the parents as soon as possible after the birth.

Immediately after birth, infants were placed in a polyethylene bag supine under radiant heat, and an SpO_2 sensor (LNOP Neo-L, Masimo Corporation, Irvine, California) was applied to the right hand/wrist and connected to the pulse oximeter.[17]

Infants received PPV with the allocated device, either the Neopuff T-piece (Neopuff Infant Resuscitator Fisher & Paykel Healthcare, Auckland, New Zealand) or the Laerdal 240 mL self inflating bag (Laerdal Silicone Resuscitator Preterm, Laerdal, Stavanger, Norway) without a PEEP valve attached according to a standard protocol for that device (Figure 1). Both devices were used with a Laerdal 0/1 face mask (Laerdal, Stavanger, Norway).

PEEP is defined as positive end expiratory pressure provided by the resuscitation device during PPV. CPAP is defined as continuous positive airway pressure given to spontaneously breathing infants.[15] The initial PEEP set on the T-piece was 5 cm H_2O. The initial CPAP was 5 cm H_2O and could be increased to 8 cm H_2O when infants were breathing regularly with signs of respiratory distress (eg, expiratory grunt, chest recession). Infants with signs of respiratory distress who were allocated to the T-piece could receive mask CPAP in the first 5 minutes after birth, whereas infants allocated to the SIB could only receive mask CPAP with the T-piece after 6 minutes. When CPAP was given during transport from the delivery room to the neonatal intensive care unit, it was given via a short nasopharyngeal tube at 5 to 8 cm H_2O.

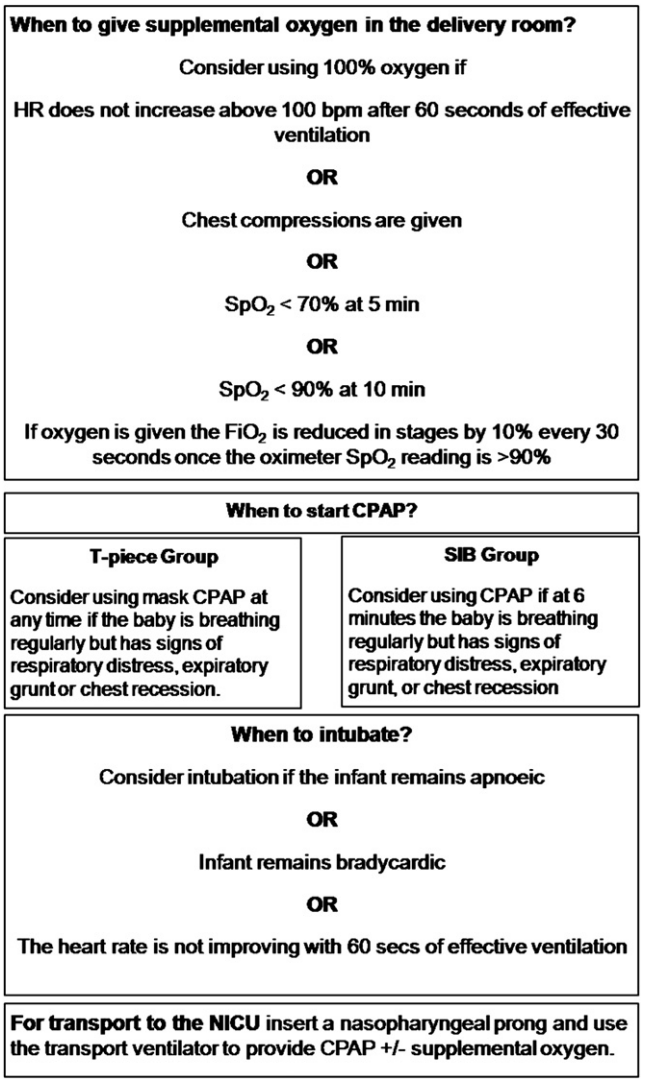

Figure 1. Guideline for delivery room management of enrolled infants.

Air was used initially for all infants. One hundred percent oxygen was used with PPV when the HR was <100 bpm and not rising after ventilation, when cardiac massage was given, or when the SpO_2 was <70% at 5 minutes. We chose 70% at this time because this was the tenth centile for the SpO_2 and that was the lower limit we considered acceptable. The FiO_2 was then adjusted with an air/oxygen blender in conjunction with SpO_2 measurement (Figure 1). Free-flow oxygen without PPV could be given with the T-piece[18] or via the SIB.[19]

The pulse oximeter was set to acquire data with maximal sensitivity and averaged at 2-second intervals. SpO_2, HR, and signal quality were displayed continuously by the pulse