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## July 2009: VOLUME 6, NUMBER 11

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1.0 hour Physicians  
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### Release Date

July 23, 2009

### Expiration Date

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### *T-Piece Resuscitators in the Delivery Room*

#### In this Issue...

The ideal device for delivering positive pressure ventilation during neonatal resuscitation has not been clearly established. While the most common practice remains the use of either flow-inflating or self-inflating bags, use of the T-piece resuscitator, a pressure-limited, manually cycled device, is becoming more common. The device is simple to use and requires a minimum of training. Recent research on all manual resuscitation devices used in the delivery room has focused on the amount of ventilation that is sufficient, how consistently it can be provided, and whether pressure or volume measurements are better than chest wall movement as an indicator of adequate ventilation.

In this issue, we review publications that describe the risks and benefits of T-piece resuscitators compared with other resuscitation devices, including consistency of peak inspiratory pressure, volume/rate, and positive end expiratory pressure. Additional concerns, including the safety of the device, the ability of the T-piece resuscitator to overcome leaks, and whether users can recognize and adapt to compliance changes using the T-piece, are also reviewed. Because the face mask is the first and most critical interface to the infant lung used by caregivers, this issue will also cover the impact of the mask and its design on the efficacy of these resuscitation devices.

At the conclusion of this activity, participants should be better able to:

- Describe the risks and benefits of the T-piece resuscitator
- Discuss the disadvantages associated with the use of pressure-limited devices during resuscitation
- Identify two methods of ensuring that mask pressure is being properly delivered to the infant

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#### Program Directors

#### **Edward E. Lawson, MD**

Professor of Pediatrics  
Johns Hopkins University  
School of Medicine  
Chief, Division of Neonatology  
Vice Chair, Department of Pediatrics  
Johns Hopkins Children's Center

#### **Christoph U. Lehmann, MD**

Associate Professor  
Department of Pediatrics  
Division of Neonatology  
The Johns Hopkins University  
School of Medicine

#### **Lawrence M. Noguee, MD**

Professor  
Department of Pediatrics  
Division of Neonatology  
The Johns Hopkins University  
School of Medicine

#### **Mary Terhaar, DNSc, RN**

Assistant Professor  
Undergraduate Instruction  
The Johns Hopkins University  
School of Nursing

#### **Anthony Bilenki, MA, RRT**

Technical Director  
Respiratory Care Services  
Division of Anesthesiology and Critical  
Care Medicine  
The Johns Hopkins Hospital  
Baltimore, Maryland

## GUEST AUTHORS OF THE MONTH

#### Commentary & Reviews

#### **Wade Rich, BSHS, RRT, CCRC**

Research Coordinator  
Division of Neonatology  
University of California,  
San Diego  
(UCSD) Medical Center  
San Diego, California



#### **Guest Faculty Disclosure**

**Wade Rich, BSHS, RRT, CCRC** has no relevant financial relationships to disclose.

**Neil Finer, MD** has no relevant financial relationships to disclose.



Commentary  
**Neil Finer, MD**  
Professor of Pediatrics  
UCSD Medical Center  
San Diego, California

### **Unlabeled/Unapproved Uses**

Dr. Finer has indicated that he does reference the off-label use of the Pedi-Cap® in the Commentary.

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## COMMENTARY

Currently, three different types of bag and mask devices are used for neonatal resuscitation: self-inflating bags, flow-inflating bags (also called anesthesia bags), and the T-piece resuscitator. The T-piece resuscitator is a device that was first described (by Hoskyns, Milner, and Hopkin in 1987)<sup>1</sup> as a tool that allowed them to consistently provide prolonged inflations. Little evidence is available regarding which bag-mask device is the most effective for neonatal resuscitation. The most recent edition of the *Neonatal Resuscitation Program Textbook*<sup>2</sup> is the first to include the T-piece resuscitator as a manual ventilation option. In a 2004 survey by O'Donnell and colleagues,<sup>3</sup> a questionnaire sent to 46 neonatal intensive care units (NICUs) in 23 countries showed that the Neopuff™ (Fisher & Paykel Healthcare, Auckland, New Zealand) was used in 30% of the responding centers. A more recent (2009) review from Spain<sup>4</sup> indicated that 45% of all level III NICUs had the device available.

In 2001, Finer and associates published the first trial comparing the Neopuff with two styles of anesthesia bags (see Review #1). Experience told us that this was the most common bag in use, a fact later confirmed by Leone and coworkers,<sup>5</sup> in a 2006 survey of U.S. centers. The comparison showed that only the Neopuff was able to consistently provide a target peak inspiratory pressure (PIP) or positive end expiratory pressure (PEEP) when used by operators with varying levels of education and experience. It also demonstrated that the prolonged inflation envisioned by Hoskyns and colleagues<sup>1</sup> was easily and consistently achievable. In a later trial, which is reviewed herein, Bennett and associates repeated this comparison using a self-inflating bag, and still found the T-piece resuscitator to be superior in terms of consistency when used by a variety of operators. The most significant limitation in Bennett's trial was that changing the pressure rapidly was difficult to accomplish using the Neopuff. Several turns of a knob are required to change the pressure by 20 cm H<sub>2</sub>O.

In their comparison of the T-piece resuscitator with anesthesia and self-inflating bags, Hussey and coworkers<sup>6</sup> also found more consistency when using the Neopuff. The significant difference in this trial is that the investigators used an intubated manikin, thus eliminating issues of leaks and the difficulty involved in holding a mask while operating the ventilation device. This study was a better comparison of the bag and T-piece devices than the others, as it eliminated mask leaking. Our experience with these manikin trials, as well as with reviews of hundreds of resuscitation videos, has taught us that the interface between the mask and the infant is the most challenging part of the ventilation process. Even when the user is able to secure the mask and is then able to deliver a reliable PIP, he/she cannot be assured that gas is being delivered into the infant's lungs. The initial breaths, particularly in the extremely low birth weight (ELBW) population, are often obstructed. Our group analyzed recordings of ELBW resuscitations, demonstrating that airway obstruction occurred in 75% of infants during initial bag and mask inflations, and that the number of obstructed breaths ranged from 4 to 37 before achieving actual pulmonary ventilation as indicated by a colorimetric CO<sub>2</sub> detector.

Breath-to-breath variation in delivered pressure and volume is an issue with T-piece resuscitators. Hawkes and colleagues (see Review #4) demonstrated that the T-piece resuscitator was flow-dependent, and that significant increases in flow rate could yield pressures well above those previously set. Comparing operators with different levels of

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experience, McHale and colleagues<sup>7</sup> reported variable inspiratory times and mean airway pressures (MAPs). O'Donnell and associates<sup>3</sup> focused on pressure leaks between the mask and the infant's face. In spite of a 94% preference for the T-piece resuscitator among participants, the investigators observed that a self-inflating bag could deliver a slightly greater volume in the presence of a leak compared with the Neopuff. Part of this difference may have been because the T-piece resuscitator also provides a PEEP of +5 cm H<sub>2</sub>O, hence limiting tidal volume. Unless equipped with a PEEP valve, self-inflating bags are unable to deliver any PEEP. What is unclear and warrants additional investigation is whether the act of compensation — in essence, providing so much flow that the leak is overcome and the target pressure or expired volume is achieved — is a more appropriate and safer method of manual ventilation. We believe that the best response to a mask leak is to correct for the leak at the face, not with the use of excess flow.

In a recent trial, Kattwinkel et al. (see Review #3) tested operators' ability to "feel" compliance changes in a 3-kg infant model with variable compliance and no leak. The investigators found that with or without volume displayed, operators did not consistently meet the target volume under low compliance conditions. In a similar report, Hussey and coworkers<sup>6</sup> found that when using a self-inflating bag, with no manometer, connected to a fixed compliance device, only 4 of 35 physicians and allied health care professionals were able to achieve a mean PIP within 20% of the target. The authors reported that independent of provider skill level, a self-inflating device without a manometer was the least reliable and the T-piece resuscitator the most reliable with respect to delivered maximum PIP, mean PIP, mean PEEP, MAP, and percentage of breaths within target range. For example, they reported that the maximum PIP delivered using the self-inflating bag was nearly 4 times the target pressure of 20 cm H<sub>2</sub>O,<sup>6</sup> suggesting that "feeling" appropriate ventilation is not a universal skill.

The ability of T-piece resuscitators to deliver a consistent PIP and PEEP in the hands of a variety of operators has been well described. The major caveat is that as a pressure-limited device, the T-piece resuscitator does not allow the user to determine if a breath has been delivered. The use of a simple, disposable CO<sub>2</sub> detector can provide the resuscitation team with the knowledge that there is detectable CO<sub>2</sub>, thus indicating that the airway is patent and that fresh gas has been delivered to the lung. Another methodology for confirming adequate breath delivery is the use of a volume-measuring device during bag and mask ventilations.

## Commentary References

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## T-PIECE VS FLOW-INFLATING BAGS FOR NEONATAL RESUSCITATION

Finer N, Rich W, Craft A, Henderson C. **Comparison of methods of bag and mask ventilation for neonatal resuscitation.** *Resuscitation.* 2001;49(3): 299-305.

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The authors compared several manual ventilation devices used in resuscitation, including two types of flow-inflating bags — one disposable (Model 5126, Vital Signs, Totawa, NJ, USA) and one permanent (Model E191, Anesthesia Associates, San Marcos, CA, USA ) — and a T-piece resuscitator (Neopuff). Operators included neonatologists, neonatal fellows, and pediatric residents, as well as neonatal nurses, neonatal nurse practitioners (NPs), and neonatal respiratory therapists. The requested intervention was to bag a neonatal manikin using a face mask at pressures of 25/5 cm H<sub>2</sub>O (PIP/PEEP) and at a rate of 30 breaths per minute over 30 seconds, and then to provide a 5-second inflation. The entire intervention was then repeated. Prolonged initial inflation pressure during newborn infant resuscitation is a recommended practice to overcome initial poor pulmonary compliance, which is a characteristic of first neonatal breaths, in order to efficiently develop functional residual capacity.

Significant performance differences were found among the operator groups using the anesthesia bags. However, the PIP and PEEP delivered using the Neopuff was consistent among all operator groups, which was in contrast to the findings with use of the other devices. The rate of ventilation did not differ between the two types of flow-inflating bags or between groups of operators. When the anesthesia bags were used, the PIP and PEEP were more consistently delivered by the therapist compared with the delivery by all other operator groups. Only the therapists were able to consistently generate target PEEP with the flow-inflating bags, whereas all the operators were able to do so by using the T-piece resuscitator. In the sustained inflation trial, the inflation pressure delivered during the first and the fifth seconds were compared. The differences between the pressures, regardless of pressure direction, varied by as much as 30% from the desired target pressure using the anesthesia bags, but by <1% using the Neopuff device.

Experienced respiratory therapists were able to use the anesthesia bags safely and effectively, but all operators could provide consistent ventilation and prolonged inflations using the Neopuff. Prolonged inflation was the original reason that the T-piece was used in neonatal resuscitation, a finding that was successfully reproduced in this trial.

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## T-PIECE VS FLOW-INFLATING AND SELF-INFLATING BAGS

Bennett S, Finer NN, Rich W, Vaucher Y. **A comparison of three neonatal resuscitation devices.** *Resuscitation.* 2005; 67(1):113-118.

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In this study, the authors compared use of three resuscitation devices on a neonatal manikin. The 31 operators included neonatologists, neonatal fellows, pediatric residents, neonatal nurses, neonatal NPs, and neonatal respiratory therapists. The devices used included a self-inflating bag with a PEEP valve (Baby Blue II, Vital Signs, Totowa NJ, USA); a flow-inflating bag (Model E191); and a T-piece resuscitator built specifically for



neonatal resuscitation (Neopuff). Participants were evaluated for their ability to provide consistent PIP, PEEP, and breath rate or ventilatory rate, along with a 5-second prolonged inflation and a transition between two PIP levels. All operators repeated the interventions with a Pedi-Cap (Nellcor, Pleasanton, CA, USA) colorimetric CO<sub>2</sub> detector in place. This was performed in order to determine if the change in positioning required to use the Pedi-Cap would affect the consistency of resuscitation.

At a target PIP of 20 cm H<sub>2</sub>O, a breath >23 cm H<sub>2</sub>O was delivered using the flow-inflating bag and self-inflating bag by 36.7% and 65% of the operators, respectively. No breaths >23 cm H<sub>2</sub>O were delivered by any operator with the T-piece resuscitator. At a target PIP of 40 cm H<sub>2</sub>O, both the flow-inflating and self-inflating bags exhibited mean pressures greater than the target (44.0, 45.3) and significantly ( $P=0.01$ ) higher than the T-piece (39.7). The flow-inflating bag and T-piece resuscitator yielded similar levels of PEEP (4.4 cm H<sub>2</sub>O). The self-inflating bag was not able to consistently provide adequate PEEP (mean, 3.6 cm H<sub>2</sub>O) or a sustained prolonged inflation. Utilization of the Pedi-Cap had no significant effect on an operator's ability to perform using any of the tested devices. No consistent differences were found between disciplines or levels of experience. The flow-inflating bag transitioned between the two target pressure levels in a mean of 2.2 seconds, which was significantly ( $P<.001$ ) faster than with the Neopuff (5.7 seconds).

The T-piece resuscitator provided consistent PEEP and a more consistent PIP with less variability, but required significantly more time to change peak inspiratory pressures. The study also answered the question of whether the PediCap colorimetric CO<sub>2</sub> device, which is placed between the resuscitation device and the mask, and causes the operator to connect the device at a 90 degree angle from the normal position, was in itself a detriment to the effective use of the T-piece or bag. The self-inflating bag yielded the highest PIP in the overall study—that is, 22 cm H<sub>2</sub>O over target—which is in accordance with previous studies of the device.

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## RESPONSE TO PULMONARY COMPLIANCE CHANGES: DISPLAY OF VOLUME VS PRESSURE

Kattwinkel J, Stewart C, Walsh B, Gurka M, Paget-Brown A. **Responding to compliance changes in a lung model during manual ventilation: perhaps volume, rather than pressure, should be displayed.** *Pediatrics*. 2009;123(3):e465-e470.

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The author of this study maintains that excessive tidal volume, with or without excessive PIP, injures the lungs of premature infants during resuscitation. Since pulmonary compliance declines during initial neonatal resuscitation, resulting in increased tidal volume at the same PIP, varying inspiratory pressure to minimize increases in tidal volume may prevent lung trauma during resuscitation. The premise of this article is that changes in compliance may be more readily recognized using one type of device (flow-inflating or self-inflating bag vs T-piece resuscitator) over another, and that it would be advantageous to view tidal volume, rather than inspiratory pressure, with either or both types. The three standard resuscitation devices were compared using 45 operators from various professions. The operators used an electromechanical lung model (ASL5000 InfMar Medical, Pittsburgh, PA, USA) that simulated a 3-kg infant with the ability to vary “lung” compliance. Data were analyzed for two compliance ranges, and the transition time between ranges—approximately 20 breaths—was ignored.

When tidal volume values were visible, the operators were able to change applied inspiratory pressures in the appropriate directions. Changes with the self-inflating bag were greater than those with the other two devices. Variation between individuals using the flow-inflating bag was greater in all cases than between those using the T-piece

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resuscitator. When only volume was visible, operators were able to deliver tidal volumes much closer to the target range, with the self-inflating bag performing better than either of the other two devices.

The objective of this study was for operators to provide appropriate changes in ventilation technique in response to changes in lung compliance. It would seem unlikely that anyone who could see the achieved tidal volume would be unable to deliver the target volume and thus respond appropriately to compliance changes. However, the data suggest that this is exactly the case with all devices in the low-compliance category and with two of the three devices in the high-compliance category. The authors noted that no prospective data are available that establish optimum tidal volume and functional residual capacity during initial neonatal resuscitation, but they believe that informing operators of achieved tidal volume rather than achieved inspiratory pressure would enhance the prevention of lung injury.

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## SAFETY OF THE NEOPUFF DEVICE: LIMITATION OF GAS FLOW RATES

Hawkes CP, Oni OA, Dempsey EM, Ryan CA. **Potential hazard of the Neopuff T-piece resuscitator in the absence of flow limitation.** *Arch Dis Child Fetal Neonatal Ed.* 2009;Apr 8. [Epub ahead of print]

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The manufacturer of the Neopuff device does not provide safety guidelines regarding the use of specific flow rates. The objective of this trial was to see what the effect of differing flow rates, which were changed after the device was set up, would do to set pressures. A total of 5 devices were set at 20/5 cm H<sub>2</sub>O (target PIP/PEEP), with the secondary pressure relief set to 30 cm H<sub>2</sub>O at a flow rate of 5 liters per minute (LPM). Flow rates were changed to 10, 15, and 85 liters per minute (LPM), with the subsequent achieved pressures measured.

When the flow rate was increased from 5 to 15 LPM, the mean PEEP increased to 20 cm H<sub>2</sub>O, the PIP to 28 cm H<sub>2</sub>O, and the secondary relief to 40 cm H<sub>2</sub>O. At 85 LPM, the maximum flow possible, the PEEP increased to 79 cm H<sub>2</sub>O and the PIP to 103 cm H<sub>2</sub>O. The secondary pressure relief also increased with increasing flow rates. At a fixed flow rate of 10 LPM, the maximum possible PIP was 73 cm H<sub>2</sub>O and the maximum PEEP was 36 cm H<sub>2</sub>O. With a gas leak of 50%, these levels decreased to 69 cm H<sub>2</sub>O and 21 cm H<sub>2</sub>O, respectively.

This is a brief report of the authors' experience, which points out two relevant issues. The first, which is the one on which the investigators focused, is that increased flow through a distal fixed orifice will increase proximal pressure. Because the Neopuff is designed to be driven by a flow meter, it is easy to increase the flow, either on purpose or inadvertently, while using the device. It is rare to change the flow rate in the middle of a resuscitation. But it is important to recognize that the secondary pressure relief, which may be set once and not checked every time it is used, is also flow-dependent. The second, and perhaps more critical, issue is the fact that no device can be safely and effectively used in a resuscitation scenario without proper and constantly updated training on the part of the operator.

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## A COMPARISON OF VENTILATION DEVICES AND FACE MASKS FOR NEONATAL RESUSCITATION

O'Donnell CPF, Davis PG, Lau R, Dargaville PA, Doyle LW, Morley CJ. **Neonatal resuscitation 2: an evaluation of manual ventilation devices and face masks.** *Arch Dis Child Fetal Neonatal Ed.* 2005;90(5):F392-F396.

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This trial investigated the performance differences between a pressure manometer–equipped flow-inflating bag (Laerdal Medical, Victoria, Australia) and a T-piece resuscitator (Neopuff) in delivering target pressures and tidal volume using two different styles of face mask and a neonatal manikin. Operators included consultants, fellows, residents, and neonatal nurses. The operators were instructed to deliver 25/5 cm H<sub>2</sub>O (PIP/PEEP) and to ensure adequate chest excursion. Airway pressure and flow, as well as inspiratory and expiratory volume, were measured, but the operators were allowed to observe only the airway pressure and manikin chest excursion.

No significant differences with respect to groups or devices were reported with delivered PIP. PEEP could be delivered with the Neopuff but not with the flow-inflating bag. Overall expiratory tidal volume was less with the Neopuff than with the bag. The overall mean percentage of gas leak (inspiratory tidal volume minus expiratory tidal volume/inspiratory tidal volume x 100) was greater with the T-piece resuscitator than with the Laerdal resuscitator. This was likely due to the operators concentrating on the machine-mounted manometer of the T-piece resuscitator, thus diverting their attention away from observing the infant. The average leak was 65 ± 33% of the inspiratory volume. This experience demonstrates the possibility of delivering highly variable tidal volumes despite generating similar airway pressures. The type of mask used did not impact the results of the study, emphasizing the ability to overcome leaks by increasing administered flow to achieve target PIP without affecting actual tidal volume. All but 2 of the 34 operators preferred the T-piece resuscitator, but the basis for this preference was not discussed.

This trial brings to light the need to better understand differences between these devices, especially when variability in mask fit affects performance. Although everyone expressed a preference, performance with the various masks did not differ. The T-piece resuscitator was preferred by most operators, delivered the most consistent pressures, and was able to provide PEEP. Additionally, the T-piece resuscitator had a significantly ( $P=.001$ ) greater percentage of leak and would appear to have been less able to compensate for this leakage. The reason for the higher rate of leakage is unclear, but it is known that a constant-flow device such as the Neopuff cannot compensate for a leak with breath-to-breath changes in flow rate and pressure as a self-inflating bag can. Again, it cannot be emphasized enough that maintaining the pressure gradient from device to lung, whether by correcting a leak or by eliminating an obstruction, is critical to making any resuscitation device work. None of the devices studied in any of these reviews will deliver a breath in the presence of an airway obstruction.

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# OBSTRUCTED BREATHS USING PRESSURE-LIMITED DEVICES IN VLBW INFANTS

Finer NN, Rich W, Wang C, Leone T. **Airway obstruction during mask ventilation of very low birth weight infants during neonatal resuscitation.** *Pediatrics*. 2009;123(3):865-869.

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This trial analyzed the frequency and duration of obstructed breaths in very low birth weight infants enrolled in a previous prospective, randomized trial of neonates of <32 weeks' gestation who were resuscitated with either room air or 100% oxygen. Review was conducted using video recordings and analogue data files from the resuscitations. An obstructed breath was defined as a peak pressure plateau of >0.2 seconds that was not associated with a color change on a qualitative CO<sub>2</sub> detector.

A total of 24 infants with a mean gestational age of 27 weeks and a mean birth weight of 955 grams were delivered at University of California, San Diego Medical Center. Of the 24 neonates studied, 6 had a patent airway from the first breath. Of the remaining 18 infants, the median number of consecutive obstructed breaths, beginning with the first attempted breath, was 14. Repositioning of the head was the intervention most likely to be successful when an obstruction was recognized. Of the 18 neonates who received positive-pressure ventilation, 13 were intubated in the delivery room.

Data from this analysis demonstrate that use of a colorimetric CO<sub>2</sub> detector provides the resuscitation team with a visible signal that can help to assess airway patency, and that this signal can then be used to make corrections to clear an obstructed airway. The recommendations of the Neonatal Resuscitation Program include using heart rate and chest wall movement to assess adequacy of ventilation during resuscitation. Chest wall movement is difficult to view with an occlusive wrap in place, and ventilating to the level of good chest expansion may be traumatic. Oximetry is now available in the delivery room, but is not fast enough to allow for breath-to-breath changes and is not always functional in the first minute of life. Heart rate changes are too slow for adjusting airway position to correct an obstruction.

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