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Mini review

Comparison of the T-piece resuscitator with other neonatal manual ventilation devices: A qualitative review

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ABSTRACT

Aim: To review the literature surrounding various aspects of T-piece resuscitator use, with particular emphasis on the evidence comparing the device to other manual ventilation devices in neonatal resuscitation.
Data sources: The Medline, EMBASE, Cochrane databases were searched in April 2011. Ongoing trials were identified using www.clinicaltrials.gov and www.controlled-trials.com. Additional studies from reference lists of eligible articles were considered. All studies including T-piece resuscitator use were eligible for inclusion.
Results: Thirty studies were included. There were two randomised controlled trials in newborn infants comparing the devices, one of which addressed short and intermediate term morbidity and mortality outcomes and found no difference between the T-piece resuscitator and self inflating bag. From manikin studies, advantages to the T-piece resuscitator include the delivery of inflating pressures closer to predetermined target pressures with least variation, the ability to provide prolonged inflation breaths and more consistent tidal volumes. Disadvantages include a technically more difficult setup, more time required to adjust pressures during resuscitation, a larger mask leak and less ability to detect changes in compliance.
Conclusions: There is a need for appropriately designed randomised controlled trials in neonates to highlight the efficacy of one device over another. Until these are performed, healthcare providers should be appropriately trained in the use of the device available in their departments, and be aware of its own limitations.

1. Introduction

Between 5 and 10% of newborn infants require resuscitation at birth.[1,2] Effective positive pressure ventilation can be vital to successful neonatal resuscitation.[3] Current guidelines in neonatal resuscitation recommend three devices; the self inflating bag (SIB), flow-inflating bag (FIB) and T-piece resuscitator (TPR).[4–6]

The prevalence of TPR use varies throughout the world, and many surveys describing their use have been published. In 2004, they were used in 48% of centers in Australia and New Zealand,[7] and 30% of centers in an international survey involving 23 countries.[8] More recent surveys identified that they are used in 31% of centers in Ireland,[9] 45% of resuscitation areas in Spain,[10] 80% of Austrian units, 41% of German units and 20% of Swiss units.[11] These studies describe the Neopuff (Fisher & Paykel Healthcare, Auckland, New Zealand) as the most popular TPR in neonatal use, but other options are available, including the "Tom Thumb" (Viamed, Keighley, West Yorkshire, UK) and "Neotee" (Mercury Medical, FL, USA). Many resuscitaires also include a TPR in the design, including the GE Healthcare (Finland) and Draeger Medical (Lubeck, Germany) models.

The TPR provides pressure controlled, flow delivered positive pressure ventilation. The positive end expiratory pressure (PEEP) valve can be rotated to modify the PEEP provided, and occlusion of the valve by the operator delivers peak inspiratory pressure (PIP). Its main purported advantages are the delivery of consistent pressures, the ability to adjust inspiratory time, and the control of PIP and PEEP.[12]

While PEEP has been shown to be beneficial in preterm animal models,[13–15] human studies have not been performed to assess this.[16] However, the ability of a manual ventilation device to provide PEEP is generally recommended.[17] The optimal starting PIP is unknown, with some users commencing at 30 cm H_2O,[18] others at 25 cm H_2O,[19,20] 20 cm H_2O[21–23] or 18 cm H_2O.[24] While many

Abbreviations: PIP, peak inspiratory pressure; PEEP, positive end expiratory pressure; TPR, T-piece resuscitator; NP, Neopuff; SIB, self inflating bag; FIB, flow inflating bag; NRP, neonatal resuscitation program; IPPV, intermittent positive pressure ventilation; CPAP, continuous positive airway pressure; IT, inspiratory time.

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studies have compared the Neopuff to the SIB and FIB, we do not know which device provides the safest manual ventilation during neonatal resuscitation.

The aim of this article is to review the literature surrounding various aspects of TPR use, with particular emphasis on the evidence comparing the TPR to other manual ventilation devices in neonatal resuscitation.

2. Methods

In April 2011, we performed a literature search using Medline (1966–2011), EMBASE (1986–2011), and Cochrane Register of Controlled Trials. Keywords used were; "t-piece", "manual ventilation", "Neopuff", "Tom Thumb", "Neo Tee" and "resuscitation" and limited to newborn. Searches were restricted to English language publications. Peer reviewed published articles and letters were considered. Ongoing clinical trials were identified using www.clinicaltrials.gov and www.controlled-trials.com.

We determined that the best evidence for comparing the TPR with other devices would be provided by randomised controlled trials comparing each device in newborn resuscitation scenarios, followed by randomised trials in simulation models such as manikin or artificial lung models. However, other study types including TPR use were also considered for inclusion.

We felt a priori that primary determinants of efficacy were: (1) mortality before discharge home, (2) need for endotracheal intubation in the delivery room, (3) incidence of bronchopulmonary dysplasia defined as oxygen requirement at 36 weeks' post menstrual age. Secondary determinants of efficacy were (1) provision of predetermined PIP, (2) ability to provide predetermined PEEP, (3) ability to alter both pressures during resuscitation, (4) inspiratory time provided, (5) ability to provide a prolonged inflation breath, (6) ability to provide consistent targeted tidal volumes, (7) mask leak and (8) the effect of training on device use.

3. Results

Fifty published articles were identified. Nine were review articles,[17,25–32] six were surveys of practice[7,33] and five involved the TPR use but looked at endpoints not relevant to the efficacy or safety of the device.[34–38] One article used the Tom Thumb T-piece,[39] and all others specifically included the Neopuff.

Of the 30 remaining studies, 2 compared devices in infants,[40,41] 14 compared devices in a manikin or lung model,[19–24,39,42–48] one observational study[49] outlined the reduced morbidity associated with changes in delivery room practices, and 13 included the TPR without comparisons.[18,50–61]

4. Primary determinants of efficacy

Dawson et al.[41] randomised infants less than 29 weeks' gestation to receive positive pressure ventilation with the Neopuff or the SIB, and did not find a significant difference in mortality, need for endotracheal intubation or the need for respiratory support at 28 days. They also did not find a significant difference in oxygen saturation at 5 min (Neopuff 49%, SIB 59%) or heart rate at 5 min (Neopuff 135, SIB 138).

Birenbaum et al.[49] in a single institution time series study, noted a reduction in the incidence of chronic lung disease (from 46.5% to 20.5%) from 2002 to 2005 following the introduction of a number of changes, including introduction of Neopuff, in their delivery room management of infants under 1500 g. While changing from the SIB to the Neopuff may have been associated with a reduction in morbidity, many confounding variables make the effect of this change impossible to determine.

5. Secondary determinants of efficacy

5.1. Provision of predetermined peak inspiratory pressure

The provision of predetermined inspiratory pressures using the TPR in comparison to other manual ventilation devices was addressed in 12 studies[19,39,41,44–47] (Table 1), and without comparison in 3 articles.[54,56,58] All of these studies include the Neopuff except for one which includes the Tom Thumb TPR.[39]

In all comparative studies, the Neopuff provided less variation in pressures than the SIB and FIB. Six manikin studies[20,44,47] found that the Neopuff provided a PIP closer to the target pressure, while two studies did not[19,46] (Table 1). The Tom Thumb was also shown to provide a higher percentage of pressures within the target range of 25–34.9 cm H_2O (Tom Thumb 89%, 240 ml, SIB 5%, 500 ml, FIB 17%).[39]

Hussey et al.[21] set a target PIP of 20 cm H_2O and found that the Neopuff provided the lowest maximum PIP (Neopuff 22.4, SIB 75.9, FIB 35.5 cm H_2O), the lowest percentage of breaths with a PIP under 21 cm H_2O (Neopuff 98%, SIB 39%, FIB 92%) and lowest percentage of breaths with PIP over 30 cm H_2O (Neopuff 0%, SIB 45%, FIB 0%).

There were 4 further studies observing the effect of variations in gas flow on the pressures provided by the Neopuff. We showed that when the device was set to provide PIP = 20 cm H_2O with at a gas flow of 5 L/min, increasing gas flow to 15 L/min resulted in a PIP = 28 cmH_2O.[54] A further increase to 85 L/min resulted in a PIP = 92 cm H_2O. This finding of a flow dependent PIP was later confirmed by Schmolzer et al.[56] and Schilleman et al.[59] Gas flow restriction, using a commercially available gas flow restrictor (Flowtec Model HBD2, IN) will allow clinically appropriate PIP and PEEP without the risk of inadvertently providing excessive pressures.[58]

5.2. Provision of predetermined positive end expiratory pressure

Eight studies compared Neopuff PEEP provision with the SIB and/or FIB[19,41,43,46,47] (Table 1), two assessed the Neopuff's ability to provide consistent PEEP,[19,57] and two evaluated the Neopuff's PEEP valve.[50,54]

In all manikin studies, the Neopuff compared favourably to the SIB with[22,43,47] and without[19,46] a PEEP valve, and FIB[20,46] (Table 1). One infant study[41] found that the Neopuff provided a PEEP closer to the target than a SIB without a PEEP valve.

Three studies showed that gas flow affects PEEP. Te Pas et al.[57] found that mask ventilation at 10 L/min was associated with a greater mask leak than at 5 L/min, resulting in a lower PEEP using the higher flow. We showed that half a rotation of the PEEP valve at 5 L/min increased the PEEP from 5 to 11.4 cm H_2O, while at 15 L/min the same rotation only caused an increase in PEEP from 5 to 6.8 cm H_2O.[50] When the Neopuff was set to provide a PEEP of 5 cm H_2O at a gas flow rate of 5 L/min, an increase in gas flow to 15 L/min without adjusting the PEEP valve provided a PEEP of 20 cm H_2O.[54] A similar effect was subsequently shown by Schilleman et al.[59] and Schmolzer et al.[56]

Finer and Rich[61] observed up to three-fold increases in PEEP during video recorded resuscitations, suggesting that the PEEP valve may be inadvertently turned during resuscitation. Dawson et al.[60] have shown that full occlusion of the PEEP valve, with the mask loosely at the baby's face, allows for the provision of close to 100% free flow oxygen with the Neopuff.

5.3. Ability to alter pressures during resuscitation

Two articles compared the ability to change pressure provided during Neopuff ventilation with SIB and FIB.[22,42]

Table 1
Summary of comparative studies including the T-piece resuscitator.

Measure	Study	Findings
Peak inspiratory pressure: close to target PIP	Tracy et al. (m)[46]	Target 18 cm H_2O. NP 16.7 (CV 8%), SIB 17.2 (CV 39%), FIB 17.4 (CV 12%)
	O'Donnell et al. (m)[19]	Target 25 cm H_2O. NP 26.5 (2.2), SIB 26.3 (3.4)
	Tracy et al. (m)[24] [d]	Target 18 cm H_2O. NP 16.6 (95%CI 16.1–17.2), SIB 20.1 (95%CI 18–22.1)
	O'Donnell et al. (m)[44] [c]	Target 25 cm H_2O. NP 24.8 (1.7), SIB 21.3 (4.9)
	Bennett et al. (m)[22]	Target 20 cm H_2O. NP 20.1 (0.8), SIB 21 (1.7), FIB 20.5 (1.5). Target 40cm H_2O. NP 38.2 (0.8), SIB 39.6 (2.7), FIB 39.5 (2)
	Hussey et al. (m)[21]	Target 20 cm H_2O. NP 20.1 (0.1), SIB 44.7 (2.3), FIB 18.1 (0.4)
	Finer et al. (m)[20]	Target 25cm H_2O. NP 24.9 (1.1), FIB 25.7 (4.3)
	Roehr et al. (m)[45]	Target 25 cm H_2O. Median (IQR). *Inexperienced operators*: NP 19.7 (0.4), SIB 34.5 (8) *Experienced operators*: NP 19.7 (0.5), SIB 18.3 (11.8)
	Roehr et al. (m)[23]	Target 20 cm H_2O. Median (IQR). NP 19.7 (0.6), SIB 25.6 (18.2)
	Dawson et al. (i)[41]	Target 30 cm H_2O. NP 30 (1.9), SIB 31.5 (5.6)
	Dawson et al. (m)[47]	Target 30 cm H_2O. Median (range). NP 29 (19–32), SIB 29 (3–39), FIB 29 (6–43)
	Oddie et al. (m)[39]	Target 25–34.9 cm H_2O. Percent within target (95%CI). TT 89% (83–94), 240 ml SIB 5% (0–11), 500 ml SIB 17% (12–23)
PEEP: close to target PEEP	Kelm et al. (m)[43]	Target 5 cm H_2O. NP 5.59 (0.32), SIB[a] 2.95 (1.82)
	Tracy et al. (m)[46]	Target 5 cm H_2O. NP 4.4 (CV 16%), FIB 4.1 (41%)
	O'Donnell et al. (m)[19]	Target 5 cm H_2O. NP 4.5 (1.1), SIB[b] 0 (1)
	Bennett et al. (m)[22]	Target 5 cm H_2O. NP 4.4 (0.6), SIB[a] 3.6 (1.9), FIB 4.4 (1.2)
	Hussey et al. (m)[21]	Target 4 cm H_2O. NP 4.4 (0.1), SIB[b] 0.2 (0), FIB 2.8 (0.2)
	Finer et al. (m)[20]	Target 5 cm H_2O. NP 4.7 (0.4), FIB 1.9 (1.9)
	Dawson et al. (i)[41]	Target 5 cm H_2O. NP 5.6 (1), SIB[b] 0.5 (0.5)
	Dawson et al. (m)[47]	Target 5 cm H_2O. Median (range). NP 4.3 (1.9–6.2), SIB[b] 3.3 (0.4–6.2), FIB 2.3 (0.4–27.6)
Prolonged inflation	Bennett et al. (m)[22]	Target > 18 cm H_2O for 5 s. NP 4 s (1.1), SIB 1.5 s (1.6), FIB 3.7 s (1.7)
	Finer et al. (m)[20]	Difference in pressure between 1st and 5th second of inflation. Target 25 cm H_2O. NP 0.2, FIB 7.1
	Klingenberg et al. (m)[48]	Median (IQR) Target 30 cm H_2O for 10 s. NP 10.7 s (8.9–11.9), SIB 2.5 s (0.8–5.7), FIB 10.6 (8.4–12.9)
Tidal volume	Tracy et al. (m)[46]	NP 15.6 ml (CV 20%), SIB 30.2 ml (CV 36%), FIB 17.8 ml (CV 15%)
	Tracy et al. (m)[24] [d]	NP 21.7 ml (95%CI 19.4–24.1), SIB 36.8 ml (95%CI 33.2–40.4)
	O'Donnell et al. (m)[19]	NP 5.1 ml (4.8), SIB 10.2 ml (3.6)
	O'Donnell et al. (m)[44] [c]	NP 5.2 ml (3.5), SIB 6.2 ml (2.5)
	Roehr et al. (m)[45]	Median (IQR) *Inexperienced operators*: NP 3.5 ml (0.8), SIB 7.3 (8) *Experienced operators*: NP 3.5 ml (0.3), SIB 3.8 ml (2.3)
	Roehr et al. (m)[23]	Median (IQR). NP 3.6 ml (0.8), SIB 5.1 ml (3.2)
	Dawson et al. (i)[41]	Median (IQR). NP 6.6 ml (4.4), SIB 9.2 ml (6.6)
	Dawson et al. (m)[47]	Median (range). NP 10 ml (0.5–13.8), SIB 10.5 ml (0.2–18.8), FIB 10.6 ml (0.2–20.7)
Mask Leak	Tracy et al. (m)[24] [d]	NP 22.2% (95%CI 11.4–33.1), SIB 11.5% (95%CI 6.7–16.6)
	Schmolzer et al. (i)[40]	Leak > 75% occurred during resuscitation of 13 out of 25 infants with NP, and 14 out of 31 infants with SIB
	O'Donnell et al. (m)[19]	NP 73.5% (32.1), SIB 56.2% (31.8)
	O'Donnell et al. (m)[44]	NP 35.8% (40.8), SIB 13.6% (29.1)
	Dawson et al. (i)[41]	NP 42% (18), SIB 35% (17)
	Dawson et al. (m)[47]	Median (range) NP 16% (0–99), SIB 16% (0–99), FIB 45% (0–100)

All values are mean (SD) unless otherwise stated.
(m), manikin study; (i), infant study; NP, Neopuff; TT, Tom Thumb; SD, standard deviation; CV, coefficient of variation expressed as percentage; 95%CI, 95% confidence interval; IQR, interquartile range.
[a] PEEP valve utilised.
[b] No PEEP valve utilised.
[c] Results are from arm of study with manometer use.
[d] Results are from arm of study with a single operator.

Bennett et al.[22] found that Neopuff users took 5.7 (SD 2.2) s to transition from 20 to 40 cm H_2O, longer than the SIB 2.2 (SD 1.5) s and FIB 1.8 (SD 0.8) s. Kattwinkel et al.[42] using a manikin programmed to change compliance, showed that SIB users responded to reducing compliance by increasing PIP, while Neopuff users did not adapt to this change in compliance.

5.4. Inspiratory time

Two manikin studies[45,46] compared inspiratory time (IT) provided by the Neopuff with the SIB, and one studied the Neopuff alone.[51]

Tracy et al.[46] found that the IT used by Neopuff operators at a target rate of 60 inflations per minute was slightly longer than the

SIB and FIB (Neopuff 0.5 s, SIB 0.3 s and FIB 0.4 s). Roehr et al. found that IT was significantly affected by operator experience using a SIB, but not the Neopuff.[45] McHale et al.[51] found that distraction caused Neopuff operators to decrease the IT provided from 0.86 to 0.65 s.

5.5. Prolonged inflation breaths

Three articles compared the ability of different devices to provide a prolonged inflation[20,22,48] (Table 1). The Neopuff provided more consistent prolonged inflation than the SIB in all three studies[20,22,48] and FIB in two studies.[20,22] One did not find a difference between the Neopuff and FIB.[48]

5.6. Tidal volumes

Eight articles compared the tidal volumes provided by different devices[19,23,24,41,44–47] (Table 1), while one included only the Neopuff.[51]

Neopuff users provide lower tidal volumes with less variability than SIB users in all manikin studies.[19,23,24,44–47] Tracy showed this both in single and two person mask ventilation.[24] Roehr found that experienced and inexperienced Neopuff operators provided similar tidal volumes, while inexperienced SIB users provide a greater tidal volume than those with resuscitation experience.[45] In the only infant study, Dawson et al.[41] observed a lower tidal volume provided by the TPR to premature infants less than 29 weeks.

5.7. Mask leak

Six studies compared mask leak[19,24,40,41,44,47] (Table 1), and three studied mask leak only in the Neopuff.[18,55,57] Five[19,24,40,41,44] comparative studies found a lower mask leak associated with SIB use, two of which included preterm infants.[40,41] One manikin study showed no difference.[47]

Tracy et al.[24] found that the Neopuff was associated with a greater leak with one operator (Neopuff 22.2%, SIB 11.5%) in comparison to two (Neopuff 9.1%, SIB 5.4%). O'Donnell et al.[44] found that manometer availability reduced leak in both devices (Neopuff 35.8% vs 34.3%, SIB 33% vs 13.6%).

Schilleman et al.[18] found that training in mask handling can reduce facemask leak with the Neopuff from 71% (IQR 32–95) to 10% (IQR 5–37) immediately after training, and 15% (IQR 4–33) three weeks later. Te Pas et al.[57] found that mask leak was greater at higher gas flow rates (24% at 5 L/min vs 80% at 10 L/min). This group[59] also found that mask leak increased with increases in gas flow without adjustment of the pressure dials (14% at 5 L/min, 98% at 15 L/min), but this did not occur if the pressures remained constant (23% at 5 L/min, 22% at 15 L/min). The only study that did not find a difference in mask leak between the Neopuff and SIB was the manikin study by Dawson et al.[47] (median mask leak: Neopuff 16%, SIB 16%, FIB 45%).

5.8. Training

The effect of training and experience in Neopuff use was addressed in 6 studies,[18,21,23,45,51,52] three of which compared the Neopuff to the SIB.[21,23,45]

Roehr et al. found that operator experience did not significantly influence PIP or tidal volume provided with the Neopuff,[23] which was also shown by Hussey et al.[21] In a different crossover study by Roehr et al, operator experience in Neopuff use did significantly affect PIP and tidal volume provision using a SIB, but not using a Neopuff.[45]

We found that operators with infrequent Neopuff experience had difficulty setting up the device. In the absence of regular training, only 16.7% of postnatal ward midwives were able to set the PIP and PEEP without assistance, while 91.3% and 34.8% of labour ward midwives could set the PIP and PEEP respectively. All could effectively ventilate a manikin with a SIB without assistance.[52] McHale et al.[51] found that inexperienced users of the Neopuff provided a longer inspiratory time; however, the level of operator experience did not affect mean airway pressures or tidal volumes.

6. Ongoing trials

We identified 5 ongoing trials involving the Neopuff.[62–66] Three of these trials involve the use of the Neopuff to provide continuous positive airway pressure in the delivery room.[62–64] These randomised controlled trials aim to determine if Neopuff use reduces the incidence of transient tachypnoea of the newborn,[62] decreases the need for mechanical ventilation and surfactant in very low birthweight infants,[63] and if the Neopuff is effective in establishing the functional residual capacity at birth.[64]

Another neonatal trial intends to compare resuscitation with a Neopuff against a SIB, with and without a PEEP valve, in infants over 26 weeks gestation.[66] The primary outcome is a heart rate over 100/min at 2 min of life, and secondary outcomes include short-term resuscitation and morbidity outcomes. Another ongoing trial compares 15-s inflations at increasing pressures with a Neopuff followed by continuous positive airway pressure against intermittent positive pressure ventilation with a SIB in infants between 27 and 33 weeks gestation, and will determine if there is a difference in the need for endotracheal intubation and mechanical ventilation between groups.[65]

7. Discussion

This review highlights that insufficient evidence exists to determine the optimal manual ventilation device for resuscitation of the newborn infant at birth. However, tentative conclusions can be drawn from the newborn and manikin studies included in this review. These conclusions may have implications for clinical users of manual ventilation devices, neonatal resuscitation instructors, risk management policy makers and researchers.

Clinical users of the TPR can provide PIPs that are closest to the target PIP[20,21,23,39,44,45] with least variation[19,23,44–46] when compared to users of the SIB and FIB. Similarly TPR users should be able to provide a PEEP that is closer the predetermined PEEP value.[19–22,43,46] Volutrauma may potentially be less likely with the TPR as tidal volumes are smaller[19,23,24,44–46] and less variable in comparison to the SIB.[23,24,45,46] TPR operators can provide a more consistent inspiratory time than SIB[46] and this does not depend on experience level.[45] The UK resuscitation council[67] recommends 5 inflation breaths lasting 2–3 s, which can be most reliably provided by the TPR.[20,22,48]

Nevertheless, TPR users should also be aware of certain limitations of the device. Resuscitation is a dynamic process where the resuscitator needs to adapt to the response or non-response of the newborn. TPR users are not as good at detecting changes in compliance[42] as users of the SIB and FIB. TPR users also need more time to change the inflating pressures during resuscitation, compared to users of the SIB or FIB.[22] Mask leak is greater with the TPR than with other devices,[19,24,40,44] and changes to gas flow rate have significant effects on PIP,[54] PEEP[50,54,57] and mask leak.[57]

This device is probably the most technically difficult of the 3 devices to prepare for use, as is shown by the seven-step TPR setup procedure described elsewhere.[52] This has implications for Neonatal Resuscitation Program (NRP) instructors and the training of NRP providers. Operators who do not frequently use the device, and are not receiving regular training in its setup, forget how to prepare

the device for use.[52] Instructors should be aware that increases in gas flow before, or during resuscitation can result in significant increases in pressures unless the operator adjusts the dials accordingly.[53,54,56] This risk can be reduced by restricting gas flow, through the use of low flow flowmeters,[56] or a flow restrictor.[58] The alternatives to the TPR are not without risk, and excessive pressures[21] and tidal volumes[46] are also possible with the SIB and FIB.

The TPR does appear to offer a number of advantages over the SIB and FIB, but at the expense of a more difficult setup and the potential to provide dangerous inflating pressures in inexperienced hands. Like the SIB and FIB, the operator uses heart rate, chest rise, oxygen saturation and, sometimes, disposable colorimeters[68,69] to determine if adequate and safe inflation is taking place. Tidal volume may be a more useful guide, but no currently available manual ventilation device in common use provides this information to the user. Future innovation to the TPR to improve its safety profile and clinical use may include internal gas flow restriction, internal limitation of maximum pressures and feedback on tidal volume delivery.

Randomised controlled trials involving infants addressing short- and long-term morbidity outcomes are now under way,[65,66] and may provide important evidence regarding whether or not the TPR improves resuscitation outcomes and reduces morbidity in comparison to the self inflating bag,[66] or if sustained lung inflation with the TPR is superior to SIB ventilation.[65] Until evidence of clinical benefit is available, we recommend that healthcare providers are appropriately and regularly trained in the use of whatever device being used in their clinical practice, and are aware of the particular limitations of that device.

Conflict of interest statement

The authors have no conflicts of interest to disclose.

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