



REVIEW ARTICLE

T-piece resuscitator or self-inflating bag during neonatal resuscitation: a scoping review

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BACKGROUND: To identify the evidence for administering positive pressure ventilation (PPV) to infants at birth by either T-piece resuscitator (TPR) or self-inflating bag (SIB), and to determine whether a full systematic review (SR) is warranted.

METHODS: Guided by the Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for scoping reviews, eligible studies included peer-reviewed human studies, prospectively or retrospectively comparing a TPR vs. SIB for administering PPV at birth. Databases searched were OVID Medline, PubMed, Embase and the Cochrane Central Register of Controlled Trials. Review Manager software was used for the data analysis.

RESULTS: Following electronic literature search and review, data from four eligible studies (3 RCT and 1 observational study), enrolling a total of 2889 patients, were included. Studies differed regarding the investigated populations, reported outcomes and came from different geographical areas. In particular for preterm infants, use of TPR for providing PPV may improve survival, result in fewer intubations at birth and decrease the incidence of bronchopulmonary dysplasia.

CONCLUSIONS: This scoping review identified two new studies with substantive new evidence, pointing towards improved survival, decreased bronchopulmonary dysplasia and fewer intubations at birth, in particular among preterm infants treated with TPR. Full SR of the literature is advised.

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IMPACT:

- This scoping review identified studies comparing TPR vs. SIB for respiratory support of newborn infants previously not included in the International Liaison Committee on Resuscitation (ILCOR) recommendations.
- Our review found substantive new evidence highlighting that device choice may impact the outcomes of compromised newborn infants’.
- This scoping review stipulates the need for full SR and updated meta-analysis of studies investigating supportive equipment for stabilizing infants at birth in order to inform ILCOR treatment recommendations.

INTRODUCTION AND BACKGROUND

Approximately 3–8% of babies receive interventions to help with breathing at birth.¹ Positive pressure ventilation (PPV) is the most important intervention during neonatal resuscitation.² Identification of the best equipment to administer PPV is a critical research area. Animal studies show that a few large manual breaths at birth may cause structural and functional damage to the lungs,³ and the quality of PPV immediately after birth represents a significant factor in the pathogenesis of bronchopulmonary dysplasia.^{4,5} Thus, staff attending deliveries must be proficient in newborn life support and the appropriate equipment for newborn stabilization and resuscitation must be readily available at all times.^{6–8} While it is accepted that all staff must be trained in newborn resuscitation,^{9,10} equipment provided for newborn resuscitation varies

considerably between centres.^{11–17} A ventilation device that can provide positive end-expiratory pressure (PEEP) during newborn resuscitation is recommended in the 2015 International Liaison Committee of Resuscitation (ILCOR) Consensus on Science and Treatment recommendations (CoSTR),⁶ the American Heart Association⁸ and the European Resuscitation Council (ERC),⁷ and in the course manuals for the neonatal life support (NLS) and neonatal resuscitation programme courses. It is accepted that PEEP aids lung liquid clearance and the establishment of functional residual capacity during transition after birth.^{18–20}

Three device types are commonly used for providing respiratory support, namely the flow-inflating anaesthetic bag, the self-inflating bag (SIB) and T-piece resuscitator (TPR) system.²¹ The anaesthetic bag is used less frequently than the latter two

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devices.^{10,11} Bench-top and animal studies comparing the properties of the SIB and TPR systems are informative. Finer et al.²² and Bennett et al.²³ were among the first to compare the different devices. Their findings that TPR delivered more consistent peak inspiratory pressure and tidal volumes were replicated by others.^{24–27} Recently, Thio et al.²⁸ compared SIBs fitted with PEEP valves with TPR systems with regards to PEEP generation and stability in an animal model. The authors found that SIBs typically deliver less PEEP than that set by the operator and delivery varies with the set PEEP, respiratory rate, gas flow and model of SIB + PEEP valve. Some PEEP is delivered even in the absence of supplemental gas flow. Further, the level of PEEP diminished between inflations with SIBs fitted with PEEP valves. This study suggests that SIB systems may be less effective than T-piece systems in establishing and maintaining lung recruitment.²⁸ In a bench-top study, Rafferty et al.²⁹ found significant differences in the accuracy of target pressure delivery between SIB manometers. Similarly, Hartung et al.³⁰ compared the ability of various SIB and TPR devices to deliver pressure increments. The authors found that operators took longer to change inflation pressures when using TPRs compared with SIBs, but TPRs were more reliable in achieving set inflation pressures and PEEP.

Few clinical trials compared SIB and TPR systems. In 2015, the ILCOR Neonatal Task Force conducted a systematic review (SR) on TPR and SIB for newborns receiving ventilation during resuscitation. The 2015 ILCOR CoSTR,⁶ based on the two available studies,^{31,32} stated “We suggest ventilation can be performed comparably with a self-inflating bag with PEEP, T-piece resuscitator or a self-inflating bag without PEEP in newborns receiving ventilation (PPV) during delivery room resuscitation (weak recommendation, very low and low quality of evidence). We recognized that use of T-piece resuscitator shows marginal but not statistical significant benefits for clinical outcome of achieving spontaneous breathing. In making this suggestion, we also place a value on impacts on resource use and feasibility in resource limited setting.”⁶

In order to investigate whether important new evidence had been published since the above-mentioned 2015 ILCOR SR, we conducted a scoping review on this topic.^{33,34} Reasons for choosing the format of a scoping review were to identify and analyse remaining knowledge gaps since the last (2015) SR and as a potential precursor to a new SR on the topic.^{35,36} Following ILCOR guidelines, upon completion of the scoping review, the need for an SR would need to be determined by the ILCOR NLS taskforce. Therefore, the purpose of this scoping review was to identify new evidence related to devices for administering PPV in newborns needing resuscitation at birth and to determine whether the body of evidence published since the 2015 indicates the need for a full new SR of the evidence.

Objectives

The objectives were to examine the literature to establish whether there was sufficient evidence for advocating a specific device, either SIB or TPR system, for administering PPV during newborn resuscitation in order to determine the need for a full SR. In performing this scoping review, we also sought to identify areas requiring further research.

METHODS

Eligibility criteria

The inclusion and exclusion criteria used in this scoping review were the same as those used in the 2015 CoSTR.⁶ Randomized controlled trials (RCTs) and non-randomized studies (non-RCTs, interrupted time series, controlled before-and-after studies, cohort studies) were eligible for inclusion. Unpublished studies (e.g. conference abstracts, trial protocols) were excluded.

Information sources

The following databases were searched: OVID Medline, PubMed, Embase, and the Cochrane Library. Studies published in any language were included if there was an English abstract. The search that informed the 2015 NLS CoSTR was conducted on 24 April 2014. This subsequent search was date limited from 1 January 2014 to 3 January 2020 to identify studies published since the 2015 ILCOR NLS CoSTR.⁶

Search

The search strategy was the same as that used for the 2015 ILCOR NLS CoSTR SR on TPR and SIB. The search strategy is reproduced in Supplement 1.

Selection of sources of evidence

The results of this most recent search and the two studies included in the 2015 ILCOR NLS CoSTR,^{31,32} in six were downloaded into Microsoft Excel (2016), duplicates were identified and removed. Two authors (D.T. and C.C.R.) independently screened titles and abstracts of studies against the selection criteria. Full-text articles from the 2019 search and the 2015 ILCOR NLS CoSTR⁶ assessed as potentially eligible for inclusion in this review were independently screened against the inclusion criteria (D.T. and C.C.R.). Disagreements were resolved by discussion and consensus.

In addition, we ran searches for ongoing clinical trials or unpublished work in the following registries: (1) International Clinical Trials Registry Platform (www.who.int/ictpr/en/); (2) US clinical trials registry (www.clinicaltrials.gov); (3) Cochrane CENTRAL (<http://www.cochranelibrary.com/about/central-landing-page.html>); (4) EU Clinical Trials Register (<https://www.clinicaltrialsregister.eu>); (5) Australian New Zealand Clinical Trials Registry (<http://www.anzctr.org.au/>). We found one ongoing trial (CTRI/2017/05/008577) in India. Fifty preterm infants <28 weeks gestation will be enrolled, and the primary outcome will be “duration of PPV (baby evaluated at 1, 5 and 10 min time points).” The principal investigator was contacted to ascertain the status of the study, but no reply was received within 14 days of contact.

Data charting process

Data were extracted by one author (D.T.) and ratified by another (C.C.R.). The characteristics of each study were extracted, including: the author(s); year of publication; study design; country; population; intervention and comparator; major findings; and outcome(s) reported.

Data items

The following outcomes were considered: survival to hospital discharge, air leak, development of stable spontaneous breathing (i.e. obviating the need for intubation in Delivery Room (DR)) and bronchopulmonary dysplasia (need for oxygen supplementation at 36 post-conceptual weeks).

Data analysis

Review Manager software (RevMan 5.3, The Nordic Cochrane Centre, Copenhagen, Denmark, 2014) was used to abstract, summarize and analyse the data. Meta-analyses were performed if ≥ 2 studies were available. As multiple small studies (<250 patients) were anticipated, a random effects model was used for analysis. We report pooled unadjusted odd ratios (ORs) and corresponding 95% confidence intervals (CIs) using the Mantel–Haenszel (MH) method for dichotomous variables.

RESULTS

After removal of duplicates, our search returned 329 publications. Three hundred and eighteen studies were excluded during title and abstract screening because they did not meet inclusion

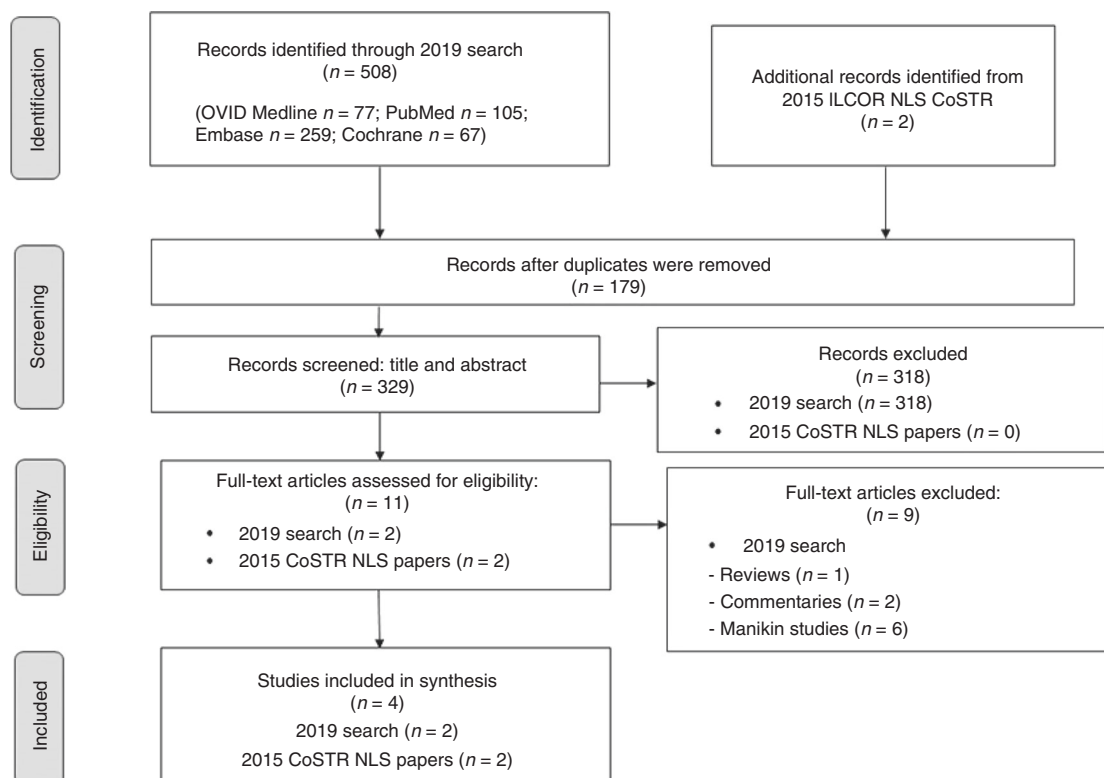


Fig. 1 PRISMA flow diagram showing the results of the structured electronic literature search, retrieval and review process. PRISMA flow diagram.

criteria. In total, 11 full-text publications were screened for eligibility (Fig. 1).

Following screening of the 11 full-text publications, 9 were excluded because they were reviews ($n = 1$), commentaries ($n = 2$) or manikin studies ($n = 6$).

Four studies were included in the final review (Fig. 1). Two were studies included in the 2015 ILCOR NLS CoSTR^{31,32} and two were new studies identified by the 2020 search.^{35,36}

Study characteristics

The characteristics of the four included studies are shown in Table 1. A total of 2889 patients (927 in 3 RCTs and 1962 in 1 observational study) ranging from 80 to 1962 subjects per trial were recruited. One RCT was from India, one from Australia and one included 10 centres from South and North America and Italy; the observational study was from Brazil and reported data from 20 academic hospitals. The studies were published between 2011 and 2018 with patient recruitment from 2007 to 2015. All the included studies compared PPV at birth with TPR and PPV at birth with SIB. Two studies included only preterm infants;^{31,35} two studies enrolled both preterm and term infants, but sub-analyses of preterm neonates (birth weight <1500 g and infants <34 weeks gestation) were available.^{32,36} Primary outcomes were different among the four studies: survival at hospital discharge without BPD, IVH grades III–IV and PVL, duration of PPV during delivery room resuscitation, heart rate (HR) >100 b.p.m. at 2 min after birth and SpO₂ (oxygen saturation of arterial blood) at 5 min after birth.

Outcomes

A summary of outcomes for all neonates (preterm and term) and preterm infants is presented in Table 2.

Survival to hospital discharge

All neonates. Two RCTs involving 1117 neonates (preterm and term infants) reporting survival at discharge were included in the

meta-analysis. The pooled estimate showed no statistically significant difference in survival at discharge between infants treated with TPR or SIB: 547/561 (97%) vs. 548/566 (97%) [OR = 1.23, 95% CI 0.61–2.50, $p = 0.44$].

Preterm infants. Two RCTs involving 117 preterm infants reporting survival at discharge were included in the meta-analysis. There was no statistically significant difference in survival at discharge between infants treated with TPR or SIB: 55/60 (91%) vs. 48/57 (84%) [OR = 2.07, 95% CI 0.65–6.63, $p = 0.14$].

Survival at discharge was reported in one observational study of 1962 preterm infants with 23–33 weeks gestation and birth weight 400–1499 g. Survival at discharge was significantly higher in infants treated with TPR compared to those treated with SIB: 1000/1456 (69%) vs. 282/506 (56%) [OR 1.74, 95% CI 1.42–2.14, $p < 0.001$].

Incidence of air leak (pneumothorax and pneumomediastinum)

All neonates. Incidence of air leak was reported in one RCT involving 1027 neonates. Incidence of air leak was similar between infants treated with TPR and those treated with SIB: 13/511 (2.5%) vs. 8/516 (1.6%) [1.66, 95% CI 0.68–4.03, $p = 0.27$].

Preterm infants. Two RCTs involving 275 preterm infants were included in the meta-analysis. The pooled estimate did not show a statistically significant difference in incidence of air leak between preterm infants treated with TPR and those treated with SIB: 4/126 (3.1%) vs. 4/149 (2.6%) [OR 1.15, 95% CI 0.29–4.64, $p = 0.54$].

Incidence of air leak was reported in one observational study of 1962 preterm infants with 23–33 weeks gestation and birth weight 400–1499 g. Incidence of air leak was similar between preterm infants treated with TPR and those treated with SIB: 99/1456 (7%) vs. 28/506 (6%) [OR 1.25, 95% CI 0.81–1.92, $p = 0.32$].

Table 1. Study details, interventions, outcome measures and patient characteristics from analysed trials.

Author, ref.	Design, country	Population/period of study	Interventions/comparator	Outcomes
Guinsburg et al. ³⁵	Prospective cohort study Brazil (20 academic tertiary centres)	Inborn infants with 23–33 weeks gestation and birth weight 400–1499 g (<i>n</i> = 1962) Jan 2014–Dec 2015	Positive pressure ventilation (PPV) at birth with T-piece resuscitator/PPV at birth with self-inflating bag (SIB) without positive end-expiratory pressure (PEEP) valve	Primary • Survival at hospital discharge without BPD, IVH grades III–IV and PVL Secondary • 5-min Apgar score of 7–10 • Intubation rate in DR • Need for mechanical ventilation • Duration of mechanical ventilation • Need for surfactant replacement therapy • Late-onset sepsis • NEC • Air leak • IVH grades III–IV • Death in DR • Alive at discharge
Thakur et al. ³⁶	Quasi-randomized controlled trial India	Inborn infants with gestational age >26 weeks requiring PPV (<i>n</i> = 90) Aug 2010–Aug 2011	PPV at birth with T-piece resuscitator/PPV at birth with SIB without PEEP valve	Primary • Duration of PPV during DR resuscitation Secondary • Intubation rate in DR • Incidence respiratory distress • Need for mechanical ventilation <48 postnatal hours • Need for surfactant replacement therapy • Mortality during NICU stay
Szyld et al. ³²	Multicenter cluster-randomized two-period crossover trial Argentina, Chile, Italy, Perú, United States (10 centres)	Inborn infants with gestational age ≥26 weeks requiring PPV (<i>n</i> = 1027) Dec 2009–Aug 2012	PPV at birth with T-piece resuscitator/PPV at birth with SIB without PEEP valve/PPV at birth with SIB with PEEP valve	Primary • Heart rate (HR) ≥100 b.p.m. at 2 min after birth Secondary • Time to achieve HR ≥100 b.p.m. • Time to initiation of spontaneous breathing • SpO ₂ at 2 min • Proportion of infants who were intubated after failure of PPV by face mask • Proportion of infants who receive chest compressions and/or medications • Apgar scores at 1 and 5 min • Mortality rate • Maximum ventilation pressures and FiO ₂ in DR • Incidence of air leaks (pneumothorax and pneumomediastinum) • Use and duration of oxygen administration • Duration of mechanical ventilation and/or continuous positive airway pressure, incidence of hypoxic-ischaemic encephalopathy • Incidence of BPD (infants with BW <1500 g) • Mortality rate before hospital discharge
Dawson et al. ³¹	Randomized controlled trial Australia	Inborn infants with gestational age <29 weeks requiring PPV (<i>n</i> = 80) Feb 2007–Feb 2009	PPV at birth with T-piece resuscitator/PPV at birth with SIB without PEEP	Primary • SpO ₂ at 5 min after birth Secondary • Endotracheal intubation • Surfactant administration • Oxygen administration in DR • Oxygen administration <5 min • Time oxygen started • Proportion of infants who receive chest compressions and/or adrenaline • Air leak first 24 h after birth • Incidence of BPD • Mortality rate before hospital discharge

Table 2. Outcomes of infants (preterm and term) from analysed trials.

Studies	Summary of findings
All neonates	
Survival at hospital discharge 2 Quasi-RCT: 1117 infants ^{35,37}	Survival at discharge was similar between infants treated with self-inflating bag (SIB) or T-piece: 547/561 (97%) vs. 548/566 (97%) [OR = 1.23, 95% CI 0.61–2.50, $p = 0.44$]
Incidence of air leaks (pneumothorax and pneumomediastinum) 1 Quasi-RCT: 1027 neonates ³⁵	Incidence of air leaks was similar between infants treated with T-piece and those treated with SIB: 13/511 (2.5%) vs. 8/516 (1.6%) [1.66, 95% CI 0.68–4.03, $p = 0.27$]
Intubation rate in DR 2 Quasi-RCT: 1117 infants ^{35,37}	Intubation rate in DR was significantly lower in infants treated with T-piece compared to those treated with SIB: 92/551 (17%) vs. 134/566 (24%) [OR 0.55, 95% CI 0.41–0.74, $p = 0.02$]
Bronchopulmonary dysplasia (BPD) 1 Quasi-RCT: 1027 neonates ³⁵	BPD was similar between infants treated with T-piece or SIB: 28/511 (5%) vs. 44/516 (8%) [OR = 0.62, 95% CI 0.38–1.02, $p = 0.06$]
Preterm infants	
Survival at hospital discharge 1 Quasi-RCT (sub-group of 37 preterm infants <34 weeks gestation) and 1 RCT (80 preterm infants <29 weeks gestation) ^{34,37} 1 Observational study: 1962 preterm infants 23–33 weeks gestation and birth weight 400–1499 g ³⁶	Survival at discharge was similar between infants treated with T-piece or SIB: 55/60 (91%) vs. 48/57 (84%), [OR = 2.07, 95% CI 0.65–6.63, $p = 0.14$] Survival at discharge was significantly higher in infants treated with T-piece compared to those treated with SIB: 1000/1456 (69%) vs. 282/506 (56%) [OR 1.74, 95% CI 1.42–2.14, $p < 0.001$]
Incidence of air leaks (pneumothorax and pneumomediastinum) 1 Quasi-RCT (sub-group of 195 VLBWI) and 1 RCT (80 preterm infants <29 weeks gestation) ^{34,35} 1 Observational study: 1962 preterm infants 23–33 weeks gestation and birth weight 400–1499 g ³⁶	Incidence of air leaks was similar between VLBWI treated with T-piece and those treated with SIB: 4/126 (3.1%) vs. 4/149 (2.6%) [OR 1.15, 95% CI 0.29–4.64, $p = 0.54$] Incidence of air leaks was similar between preterm infants treated with T-piece and those treated with SIB: 99/1456 (7%) vs. 28/506 (6%), [OR 1.25, 95% CI 0.81–1.92, $p = 0.32$]
Bronchopulmonary dysplasia (BPD) 1 RCT (80 preterm infants <29 weeks gestation) and 1 quasi-RCT (sub-group of 195 VLBWI) ^{34,35} 1 Observational study: 1962 preterm infants 23–33 weeks gestation and birth weight 400–1499 g ³⁶	BPD was similar between infants treated with T-piece or SIB: 36/126 (36%) vs. 55/149 (28%), [OR = 0.69, 95% CI 0.41–1.14, $p = 0.15$] BPD was significantly decreased in infants treated with T-piece compared to those treated with SIB: 691/1456 (47%) vs. 308/506 (61%) [OR 0.58, 95% CI 0.47–0.71, $p < 0.001$]
Intubation rate in DR 1 Quasi-RCT (sub-group of 37 preterm infants <34 weeks gestation) and 1 RCT (80 preterm infants <29 weeks gestation) and 1 quasi-RCT (sub-group of 195 VLBWI) ^{34,35,37} 1 Observational study: 1962 preterm infants 23–33 weeks gestation and birth weight 400–1499 g ³⁶	Intubation in DR was similar between infants treated with T-piece or SIB: 76/153 vs. 107/178 [OR 0.68, 95% CI 0.44–1.06, $p = 0.09$] Intubation in DR was significantly lower in preterm infants treated with T-piece compared to those treated with SIB: 782/1456 (54%) vs. 340/506 (67%) [OR 0.57, 95% CI 0.46–0.70, $p < 0.001$]

Intubation in delivery room

All neonates. Two RCTs involving 1117 neonates (preterm and term infants) reporting rates of intubation in the DR were included in the meta-analysis. The pooled estimate showed a statistically significant reduction in intubation rate in DR in infants treated with TPR compared to those treated with SIB: 92/551 (17%) vs. 134/566 (24%) [OR 0.55, 95% CI 0.41–0.74, $p = 0.02$].

Preterm infants. Two RCTs involving 275 preterm infants reporting rates of intubation in the DR were included in the meta-analysis. The pooled estimate did not show a statistically significant difference in rate of intubation between preterm infants treated with TPR or SIB: 76/153 (50%) vs. 107/178 (60%) [OR 0.68, 95% CI 0.44–1.06, $p = 0.09$].

Rates of intubation in DR were reported in one observational study of 1962 preterm infants with 23–33 weeks gestation and birth weight 400–1499 g. The rate of intubation was significantly lower in preterm infants treated with TPR compared to those treated with SIB: 782/1456 (54%) vs. 340/506 (67%) [OR 0.57, 95% CI 0.46–0.70, $p < 0.001$].

Bronchopulmonary dysplasia

All neonates. BPD was reported in one RCT of 1027 neonates. There were no significant differences between infants treated with TPR or SIB: 28/511 (5%) vs. 44/516 (8%) [OR = 0.62, 95% CI 0.38–1.02, $p = 0.06$].

Preterm infants. Two RCTs involving 275 preterm infants reporting rates of BPD were included in the meta-analysis. The pooled estimate did not show a statistically significant difference in incidence of BPD between preterm infants treated with TPR or SIB: 36/126 (36%) vs. 55/149 (28%) [OR = 0.69, 95% CI 0.41–1.14, $p = 0.15$].

BPD was reported in one observational study of 1962 preterm infants with 23–33 weeks gestation and birth weight 400–1499 g. BPD was significantly decreased in preterm infants treated with TPR compared to those treated with SIB: 691/1456 (47%) vs. 308/506 (61%) [OR 0.58, 95% CI 0.47–0.71, $p < 0.001$].

DISCUSSION

The purpose of this scoping review was to look for very recent, high-grade evidence from clinical trials on the question whether respiratory support of newborn infants at birth would best be provided by either the SIB or a TPR. Based on a previous SR, which formed the basis of the 2015 ILCOR NLS CoSTR on this topic, an additional two studies were found that were not included in the previous meta-analysis. The four studies, three RCTs and one observational study, differed regarding the studied populations (two studies included term and preterm infants, two studies were in preterm infants only) and reported different primary outcomes. By adding the data from the new RCT to the existing meta-analysis, no significant differences for overall mortality were found between groups. Further outcomes, including pneumothorax rate

and incidence of BPD, were also not significantly different. The single observational study showed fewer intubations in the DR, less BPD and higher rates of survival to discharge. However, in the evidence synthesis from RCTs, no change in the already known lack of statistically significant differences between the devices regarding outcome measures such as survival to discharge were found. However, the CIs surrounding these pooled estimates still leave the possibility of clinically relevant risk and benefit for these important outcomes.

This scoping review was commissioned as a priority by the ILCOR neonatal taskforce. Recently, expanded research activities in the field of neonatal resuscitation practice and devices deemed an up-to-date literature review necessary. Performance of a scoping review was given preference over a SR in line with recent methodological advances in the field of evidence review and synthesis, where scoping reviews are utilized to survey current literature and as a potential precursors to full new SR. Depending on the outcome of the scoping review, a full SR would need to be performed in order to guide the most recent ILCOR recommendations concerning the use of these devices.

With regards to the methodological quality of the review, this scoping review was guided from the outset by the specific methodological framework and the Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for scoping reviews (PRISMA-ScR), ensuring scientific rigour in search and reporting of clinical evidence.³⁷ We are particularly confident that the structured search of the electronic databases OVID Medline, PubMed, Embase, and Cochrane as performed by a professional medical librarian (LC) was comprehensive. The qualitative review of the evidence was done by two clinical scientists with expertise in SR (D.T. and C.C.R.) and any ambiguities were resolved by discussion. The individual data from the four available clinical trials was overall regarded as solid, with the caveat that one of the four studies was an observational study. The total number of included infants in the meta-analysis of 2889 patients is substantial, particularly for reviews of newborn infants. However, we acknowledge the disparate nature of the studied populations (term and preterm), and that the primary outcomes of the included studies differed from the outcomes of interest of the present review. In the original studies, the outcomes of interest were reported as secondary outcomes. Therefore, whenever indicated, data were pooled in order to achieve sufficient patient numbers to assess statistical significance. The use of predictive modelling regards the question whether the only ongoing, small RCT, investigating differences of PPV duration between use of TPR or SIB in 50 preterm patients, would sway the already observed trend towards benefit of TPR over SIB, was beyond this scoping review. Such questions could be addressed in a full SR.

The format of a scoping review proved helpful as a precursor to a new SR on this topic. Our results confirm the relevance of current evidence from observational and RCT data and indicate a shift in signal towards use of TPR over SIB, particularly in the preterm population. The scoping review, however, did not allow for extensive literature search of non-English publication. This would be within the domain of a new full SR. In our review, in line with scoping review methodology, some of the outcomes were presented as pooled results in order to show the size of available (aggregate) data from identified studies.³⁷ We need to caution clinicians against changing their clinical practice based on the results of scoping reviews like ours. The scoping reviews' methodology lacks the strength of a formal SR, which, as mentioned, includes an even more rigorous literature search, formal risk of bias assessments and GRADE analysis.³⁸ Therefore, scoping reviews are regarded unsuitable for meta-analysis.³⁹

Strengths and limitations

The strengths of this scoping review include the strategy of the literature search, specific inclusion and exclusion criteria chosen

by a group of international experts on neonatal resuscitation (the ILCOR neonatal taskforce), and complete data extraction and analysis.

The limitations of this review are that the risk of bias and quality of the included studies were not assessed because this was a scoping review rather than an SR and the inclusion criteria limited to publications with an English language abstract. All the studies identified in this review reported primary outcomes different from those identified by the ILCOR NLS taskforce for this review. A further limitation was the heterogeneity of the study populations, that is, some studies included neonates of all gestational ages, while others included only preterm infants defined using different gestational age or birth weight cut-offs.

CONCLUSIONS

This scoping review, based on the 2015 ILCOR NLS CoSTR, found two additional studies, one observational study and one RCT.^{35,36} Thus, a total of four clinical studies could now be included in the data analysis. Studies differed regarding the investigated populations (two studies included term and preterm infants, two studies were in preterm infants only) and reported outcomes. Adding the RCT data to the existing meta-analysis, no significant differences for overall survival at discharge and air leak were found between groups. Further, difference in short- and long-term outcomes like intubation in the DR and incidence of BPD were not statistically significant, but there was a signal in favour of TPR. The single observational study showed a trend towards fewer intubations in the DR, less BPD and higher rates of survival to discharge.

Data from a substantial number of additional patients reported in one RCT and one large observational study suggest improved survival and less need for intubation and BPD with TPR use, particularly among preterm infants. These findings justify a new SR on the use of TPR and SIB during newborn resuscitation/stabilization. New evidence favouring the use of TPR warrants reconsideration of the topic in the next iteration of ILCOR guidance.

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AUTHOR CONTRIBUTIONS

C.C.R. and D.T. planned and coordinated the literature review, both independently assessed and graded the literature. D.T. performed the data analysis. C.C.R. and D.T. drafted the initial manuscript. P.G.D. and G.M.W. provided input in the data analysis and gave expert opinion on the interpretation of the findings. J.W.J. and M.H.W. led the consensus process (ILCOR), which led to the formulation of the research question and commission of the scoping review. All authors contributed to the final completion of the manuscript.

ADDITIONAL INFORMATION

The online version of this article (<https://doi.org/10.1038/s41390-020-1005-4>) contains supplementary material, which is available to authorized users.

Competing interests: The authors declare no competing interests.

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REFERENCES

1. Vento, M. & Saugstad, O. D. Resuscitation of the term and preterm infant. *Semin. Fet Neonat. Med.* **15**, 216–222 (2010).
2. Weiner, G. M., Zaichkin, J., Kattwinkel, J. & Ades, A. in *Textbook of neonatal resuscitation* 7th edn (eds Weiner, G. M., Zaichkin, J., Kattwinkel, J. & Ades, A.) (Elk Grove Village, 2016).
3. Björklund, L. J. et al. Manual ventilation with a few large breaths at birth compromises the therapeutic effect of subsequent surfactant replacement in immature lambs. *Pediatr. Res.* **42**, 348–55 (1997).
4. Jobe, A. H. & Ikegami, M. Mechanisms initiating lung injury in the preterm. *Early Hum. Dev.* **53**, 81–94 (1998).
5. Jobe, A. H. Mechanisms of lung injury and bronchopulmonary dysplasia. *Am. J. Perinatol.* **33**, 1076–8 (2016).
6. Perlman, J. M. et al. Part 7: Neonatal Resuscitation: 2015 International Consensus on Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science With Treatment Recommendations. *Circulation* **132**(Suppl. 1), S204–41 (2015).
7. Wyllie, J. et al. European Resuscitation Council Guidelines for Resuscitation 2015: Section 7. Resuscitation and support of transition of babies at birth. *Resuscitation* **95**, 249–63 (2015).
8. Escobedo, M. B. et al. 2019 American Heart Association Focused Update on Neonatal Resuscitation: an update to the American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. *Circulation* **10**, e922–e930 (2019).
9. Resuscitation Council UK. *Newborn Life Support* 4th edn, ISBN: 9781 903812 33 4 (2016).
10. Roehr, C. C., O’Shea, J. E., Dawson, J. A. & Wyllie, J. P. Devices used for stabilisation of newborn infants at birth. *Arch. Dis. Child Fetal Neonatal Ed.* **103**, F66–F71 (2018).
11. O’Donnell, C. P., Davis, P. G. & Morley, C. J. Positive pressure ventilation at neonatal resuscitation: review of equipment and international survey of practice. *Acta Paediatr.* **93**, 583–8 (2004).
12. O’Donnell, C. P., Davis, P. G. & Morley, C. J. Use of supplementary equipment for resuscitation of newborn infants at tertiary perinatal centres in Australia and New Zealand. *Acta Paediatr.* **94**, 1261–5 (2005).
13. Iriondo, M. et al. A survey of neonatal resuscitation in Spain: gaps between guidelines and practice. *Acta Paediatr.* **98**, 786–91 (2009).
14. Roehr, C. C. et al. Delivery room management of very low birth weight infants in Germany, Austria and Switzerland—a comparison of protocols. *Eur. J. Med. Res.* **15**, 493–503 (2010).
15. Trevisanuto, D. et al. Changes over time in delivery room management of extremely low birth weight infants in Italy. *Resuscitation* **85**, 1072–6 (2014).
16. Trevisanuto, D. et al. Delivery room management of extremely low birthweight infants shows marked geographical variations in Italy. *Acta Paediatr.* **103**, 605–11 (2014).
17. Charles, E., Hunt, K., Murthy, V., Harris, C. & Greenough, A. UK neonatal resuscitation survey. *Arch. Dis. Child Fetal Neonatal Ed.* **104**, F324–F325 (2019).
18. Hooper, S. B., Siew, M. L., Kitchen, M. J. & te Pas, A. B. Establishing functional residual capacity in the non-breathing infant. *Semin. Fetal Neonatal Med.* **18**, 336–43 (2013).
19. Siew, M. L. et al. Positive end-expiratory pressure enhances development of a functional residual capacity in preterm rabbits ventilated from birth. *J. Appl. Physiol.* **2009**, 1487–93 (1985).
20. Martherus, T. et al. Supporting breathing of preterm infants at birth: a narrative review. *Arch. Dis. Child Fetal Neonatal Ed.* **104**, F102–F107 (2019).
21. Hawkes, C. P., Ryan, C. A. & Dempsey, E. M. Comparison of the T-piece resuscitator with other neonatal manual ventilation devices: a qualitative review. *Resuscitation* **83**, 797–802 (2012).
22. Finer, N. N., Rich, W., Craft, A. & Henderson, C. Comparison of methods of bag and mask ventilation for neonatal resuscitation. *Resuscitation* **49**, 299–305 (2001).
23. Bennett, S., Finer, N. N., Rich, W. & Vaucher, Y. A comparison of three neonatal resuscitation devices. *Resuscitation* **67**, 113–8 (2005).
24. Tracy, M. B., Halliday, R., Tracy, S. K. & Hinder, M. K. Newborn self-inflating manual resuscitators: precision robotic testing of safety and reliability. *Arch. Dis. Child Fetal Neonatal Ed.* **104**, F403–F408 (2019).
25. Hinder, M., McEwan, A., Drevhammer, T., Donaldson, S. & Tracy, M. B. T-piece resuscitators: how do they compare? *Arch. Dis. Child Fetal Neonatal Ed.* **104**, F122–F127 (2019).
26. Roehr, C. C. et al. Manual ventilation devices in neonatal resuscitation: tidal volume and positive pressure-provision. *Resuscitation* **81**, 202–5 (2010).
27. Kelm, M., Proquitté, H., Schmalisch, G. & Roehr, C. C. Reliability of two common PEEP-generating devices used in neonatal resuscitation. *Klin. Padiatr.* **221**, 415–8 (2009).
28. Thio, M. et al. Delivery of positive end-expiratory pressure to preterm lambs using common resuscitation devices. *Arch. Dis. Child Fetal Neonatal Ed.* **104**, F83–F88 (2019).
29. Rafferty, A. R. et al. The accuracy of delivery of target pressures using self-inflating bag manometers in a benchtop study. *Acta Paediatr.* **105**, e247–51 (2016).
30. Hartung, J. C. et al. Time to adjust to changes in ventilation settings varies significantly between different T-piece resuscitators, self-inflating bags, and manometer equipped self-inflating bags. *Am. J. Perinatol.* **31**, 505–12 (2014).
31. Dawson, J. A. et al. Oxygenation with T-piece versus self-inflating bag for ventilation of extremely preterm infants at birth: a randomized controlled trial. *J. Pediatr.* **158**, 912–918 (2011).
32. Szyld, E. et al. Delivery Room Ventilation Devices Trial Group. Comparison of devices for newborn ventilation in the delivery room. *J. Pediatr.* **165**, 234–239 (2014).
33. Arksey, H. & O’Malley, L. Scoping studies: towards a methodological framework. *Int. J. Soc. Res. Methodol.* **8**, 19–32 (2005).
34. Munn, Z., Stern, C., Aromataris, E., Lockwood, C. & Jordan, Z. What kind of systematic review should I conduct? A proposed typology and guidance for systematic reviewers in the medical and health sciences. *BMC Med. Res. Methodol.* **18**, 5 (2018).
35. Guinsburg, R. et al. T-piece versus self-inflating bag ventilation in preterm neonates at birth. *Arch. Dis. Child Fetal Neonatal Ed.* **103**, F49–F55 (2018).
36. Thakur, A. et al. T-piece or self inflating bag for positive pressure ventilation during delivery room resuscitation: an RCT. *Resuscitation* **90**, 21–4 (2015).
37. Tricco, A. C. et al. PRISMA Extension for Scoping Reviews (PRISMA-ScR): checklist and explanation. *Ann. Intern. Med.* **169**, 467–473 (2018).
38. Puhan, M. A. et al. A GRADE Working Group approach for rating the quality of treatment effect estimates from network meta-analysis. *BMJ* **349**, g5630 (2014).
39. Considine, J. et al. Chest compression components (rate, depth, chest wall recoil and leaning): a scoping review. *Resuscitation* **146**, 188–202 (2020).