

QUESTION

Should Supraglottic airways vs. face mask be used for PPV among newborn infants 34 0/7 weeks' or more gestation during resuscitation immediately after birth?

POPULATION:	PPV among newborn infants 34 0/7 weeks' or more gestation during resuscitation immediately after birth
INTERVENTION:	supraglottic airways
COMPARISON:	face mask
MAIN OUTCOMES:	Failure to improve with device; Endotracheal intubation during resuscitation; Chest compressions during resuscitation; Adrenaline administration during resuscitation; Time to heart rate > 100 bpm; Duration of positive-pressure ventilation; Admission to NICU; Air leak during initial hospital stay; Soft tissue injury; Survival to hospital discharge; Neurodevelopmental impairment at >= 18 months;
SETTING:	Delivery room or any other place of birth.
PERSPECTIVE:	
BACKGROUND:	<p>At birth, successful transition requires the newborn to rapidly complete multiple physiologic changes, including lung aeration, airway liquid clearance, and the initiation of pulmonary gas exchange. Although most term and late preterm newborns require no assistance, approximately 5% of term newborns require positive-pressure ventilation (PPV) immediately after birth to support successful transition. Effective ventilation of the newborn's lung is the single most important component of neonatal resuscitation.</p> <p>During neonatal resuscitation, face masks and endotracheal tubes are the most frequently used interfaces, but both have limitations. Proficiency using a face mask rapidly declines after training. Furthermore, the efficacy of face mask ventilation may be compromised by leak around the mask or upper airway obstruction resulting in inadequate tidal volumes. Achieving proficiency in endotracheal intubation requires training and experience. Even with training, neonatal intubation is associated with low first attempt success rates and adverse events. Supraglottic airways (SGAs) have been used for many years as alternative interfaces for providing routine PPV in the operating room and for the management of difficult airways in adults, children, and neonates outside the delivery room. The SGA is a flexible airway tube attached distally to a small, soft, elliptical mask. The tube and mask are inserted orally and advanced into the hypopharynx without laryngoscopy or other instruments. Once properly inserted, the mask fits over the laryngeal inlet and the proximal end of the airway tube is connected to a PPV device. Variations on the SGA design include devices with a pre-curved airway tube and devices with or without an inflatable cuff/rim around the mask. Given the importance of effective PPV and the limitations of using either a face mask or endotracheal tube, the ILCOR NLS Task Force prioritized evaluation of SGAs for PPV. In 2015, the NLS Task Force conducted a systematic review focused on using an SGA compared with endotracheal intubation as the secondary device for PPV if initial ventilation with a face mask failed. For this review, the Task Force aimed to compare the use of an SGA with a face mask as the initial device for administering PPV during resuscitation immediately after birth and to determine if use of an SGA would decrease the probability of failing to improve with initial PPV.</p>
CONFLICT OF INTERESTS:	<p>One author (GMW) was co-author of one of the included observational studies. He was excluded from bias assessment of this study.</p> <p>One author (DT) was co-author of 3 included randomized trials and both included observational studies. He was excluded from bias assessment of these studies.</p> <p>Both acknowledged their potential intellectual conflicts of interest and participated in the Task Force discussion of the consensus on science and treatment recommendations</p>

ASSESSMENT

Problem

Is the problem a priority?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<input type="radio"/> No <input type="radio"/> Probably no	In this review, 14% of infants who received PPV immediately after birth failed to improve and 6% went on to receive endotracheal intubation. A more effective interface, such as a supraglottic airway, could	Establishing effective, spontaneous breathing is critical for successful transition at birth, including lung aeration and

<ul style="list-style-type: none"> <input type="radio"/> Probably yes <input checked="" type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know 	<p>improve short- and long-term outcomes for newborn infants who received PPV.</p>	<p>perfusion, and oxygenation. Newborn infants who have apnoea or ineffective breathing are given positive pressure ventilation (PPV) to facilitate establishment of breathing and to prevent ischaemic injury and cardiac arrest. This occurs in about 5% of all births. Endotracheal intubation is an advanced resuscitation skill not available to many first responders. Therefore, a simple and effective oropharyngeal interface is required to deliver PPV. Face masks are used most commonly, but tidal volumes are frequently inadequate due to mask leak, and delivery of gas flow to the lungs may be limited by upper airway obstruction or glottic closure, which is common in neonatal apnoea.</p>
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Desirable Effects

How substantial are the desirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Trivial <input type="radio"/> Small <input checked="" type="radio"/> Moderate <input type="radio"/> Large <input type="radio"/> Varies <input type="radio"/> Don't know 	<p>For every 10 infants who initially received PPV by supraglottic airway, compared with a face mask, one fewer infant failed to improve in response to PPV. For every 20-25 infants who initially received PPV by supraglottic airway, compared with a face mask, one infant avoided endotracheal intubation. The average time until the newborn's heart rate was greater than 100 bpm was 65 s shorter and the duration of PPV was nearly 20 s shorter with a supraglottic airway. Although these are clinically important benefits, the overall desirability of effects was judged to be moderate, given that few data were available for the critical outcome of survival at hospital discharge and no data were available for the critical outcome of neurodevelopmental impairment.</p>	

Undesirable Effects

How substantial are the undesirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Large <input type="radio"/> Moderate <input type="radio"/> Small <input type="radio"/> Trivial <input type="radio"/> Varies <input checked="" type="radio"/> Don't know 	<p>Although no difference in harm was identified, including air leak or soft tissue injury, when comparing the supraglottic airway and face mask, the available evidence was insufficient to make a judgement about undesirable effects. Overall, the rate of adverse events was very low, raising concern about incomplete ascertainment, particularly as most of the included studies did not report on methods for ascertaining and classifying adverse events.</p>	<p>Adverse effects should be assessed more closely in future studies. Some adverse effects reported by children and adults, such as sore throat, are difficult to assess in neonates.</p>

Certainty of evidence

What is the overall certainty of the evidence of effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
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<ul style="list-style-type: none"> ○ Very low ● Low ○ Moderate ○ High ○ No included studies 	<p>There was moderate certainty evidence of benefit for the important outcome of failure to improve with the assigned device but low certainty of evidence of benefit for the important outcomes of endotracheal intubation during resuscitation, time to heart rate > 100 bpm, and duration of positive pressure ventilation. Among outcomes for which there was no statistically significant effect, the certainty of evidence was either very low (air leak, admission to NICU) or low (survival to hospital discharge, chest compressions during resuscitation, adrenaline administration during resuscitation, soft tissue injury). We assessed imprecision in relation to the optimal information size (OIS), calculated for each outcome. Imprecision was judged to be serious for all outcomes except for duration of PPV. Thus, the overall certainty of evidence of was judged to be low.</p>	
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Values

Is there important uncertainty about or variability in how much people value the main outcomes?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> ○ Important uncertainty or variability ○ Possibly important uncertainty or variability ○ Probably no important uncertainty or variability ● No important uncertainty or variability 	<p>We included key outcomes relating to clinical improvement on receipt of PPV and prevention of short and long-term morbidity. We limited outcomes to those that were previously judged to be critical or important by an expert panel, and thus are likely to influence healthcare providers to use one device in preference to another.</p>	<p>Outcome ratings were adopted from the following publication: Strand ML, Simon WM, Wyllie J, Wyckoff MH, Weiner G. Consensus outcome rating for international neonatal resuscitation guidelines. Arch Dis Child Fetal Neonatal Ed. 2020;105(3):328-30.</p>

Balance of effects

Does the balance between desirable and undesirable effects favor the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> ○ Favors the comparison ○ Probably favors the comparison ○ Does not favor either the intervention or the comparison ● Probably favors the intervention ○ Favors the intervention ○ Varies ○ Don't know 	<p>Infants appear to be more likely to improve with PPV and less likely to require endotracheal intubation when PPV is provided by a supraglottic airway compared with face mask. Effect sizes were moderately large. However, the overall certainty of evidence was low to moderate and few or no data were available for several critical outcomes (survival to hospital discharge, neurodevelopmental impairment, adrenaline during resuscitation) and important outcomes (air leak during initial hospital stay, time to HR > 100 bpm). Furthermore, there was concern about incomplete ascertainment of adverse effects.</p>	<p>The balance of desirable and undesirable effects could be different in different clinical settings.</p>

Resources required

How large are the resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

<ul style="list-style-type: none"> ○ Large costs ○ Moderate costs ○ Negligible costs and savings ○ Moderate savings ○ Large savings ○ Varies ● Don't know 	<p>The included studies did not provide any cost data.</p>	<p>Given that about 5% of all newborns receive PPV and that ventilation equipment needs to be widely available in birthing environments, the cost of supraglottic devices is an important consideration. Costs may vary by device and location. If supraglottic devices can be reused, then costs may be similar to face masks.</p>
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Certainty of evidence of required resources

What is the certainty of the evidence of resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> ○ Very low ○ Low ○ Moderate ○ High ● No included studies 	<p>The included studies did not provide any cost data.</p>	

Cost effectiveness

Does the cost-effectiveness of the intervention favor the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> ○ Favors the comparison ○ Probably favors the comparison ○ Does not favor either the intervention or the comparison ○ Probably favors the intervention ○ Favors the intervention ○ Varies ● No included studies 	<p>The included studies did not provide any cost-effectiveness data.</p>	

Equity

What would be the impact on health equity?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> Reduced <input type="radio"/> Probably reduced <input type="radio"/> Probably no impact <input checked="" type="radio"/> Probably increased <input type="radio"/> Increased <input type="radio"/> Varies <input type="radio"/> Don't know 	<p>Adverse outcomes may be reduced, especially in settings where access to tracheal intubation is limited. The included studies were predominately undertaken in low resource settings, where resuscitation was largely initiated by midwives or primary providers. The supraglottic airway was able to be used after a short duration of training. This review has demonstrated the feasibility and potential benefit in such settings. It should be noted that supraglottic airways were not routinely available in many of the settings in which the studies were conducted, and acquisition of the device was supported by a grant or the device was provided by the manufacturer.</p>	<p>Cost and availability of supraglottic airways will influence the extent to which potential benefits are realised and whether health equity is increased or decreased.</p>

Acceptability

Is the intervention acceptable to key stakeholders?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> No <input type="radio"/> Probably no <input type="radio"/> Probably yes <input checked="" type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know 	<p>Once health providers became aware and were trained to use the supraglottic airway, it appeared to be an acceptable method for providing PPV.</p>	

Feasibility

Is the intervention feasible to implement?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> <input type="radio"/> No <input type="radio"/> Probably no <input type="radio"/> Probably yes <input checked="" type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know 	<p>The included studies have demonstrated that it is feasible to use a supraglottic airway to commence PPV after birth.</p>	

SUMMARY OF JUDGEMENTS

PROBLEM	JUDGEMENT						
	No	Probably no	Probably yes	Yes		Varies	Don't know
DESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Large	Moderate	Small	Trivial		Varies	Don't know
CERTAINTY OF EVIDENCE	Very low	Low	Moderate	High			No included studies

	JUDGEMENT						
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability			
BALANCE OF EFFECTS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	Probably favors the intervention	Favors the intervention	Varies	Don't know
RESOURCES REQUIRED	Large costs	Moderate costs	Negligible costs and savings	Moderate savings	Large savings	Varies	Don't know
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	Moderate	High			No included studies
COST EFFECTIVENESS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	Probably favors the intervention	Favors the intervention	Varies	No included studies
EQUITY	Reduced	Probably reduced	Probably no impact	Probably increased	Increased	Varies	Don't know
ACCEPTABILITY	No	Probably no	Probably yes	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	Probably yes	Yes		Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention ○	Conditional recommendation against the intervention ○	Conditional recommendation for either the intervention or the comparison ○	Conditional recommendation for the intervention ●	Strong recommendation for the intervention ○
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CONCLUSIONS

Recommendation

Where resources and training permit, we suggest that a supraglottic airway may be used in place of a face mask for newborn infants 34 0/7 weeks' or more gestation receiving intermittent positive-pressure ventilation during resuscitation immediately after birth.

Justification

- Although “failure to improve with device” was variously defined by authors, and studies often allowed cross-over to the alternative device if the newborn failed to improve with the assigned device, there was a strong inverse association between the use of a supraglottic airway and risk of endotracheal intubation. This may reflect a greater likelihood of achieving effective ventilation using the supraglottic airway. Given that the interventions were not blinded, and ability to intubate in the largest trial was dependent on physician availability, there are risks of differential co-interventions and other biases. Furthermore, optimal information size was not achieved for any of the critical or important pre-specified outcomes except duration of positive-pressure ventilation. Therefore, further trials are needed before stronger recommendations can be made about use of a supraglottic airway as the initial device for positive-pressure ventilation.
- Although the training provided was incompletely documented in several studies and no study compared the effectiveness of different training programs, successful insertion of the supraglottic airway was high among midwives and primary providers despite apparently short duration training using a manikin.
- While the individual studies had limited power to establish the safety of the supraglottic airway, there were a relatively large number of newborns reported across all studies and very few adverse events reported.
- Neither the cost of supplying supraglottic airways in the delivery room nor the cost-effectiveness of providing positive-pressure ventilation with a supraglottic airway compared with a face mask has been studied. In several studies, the device was provided as part of the study. The availability of resources and economic considerations may influence the decision whether to use a supraglottic airway or face mask. Given the large number of infants worldwide who receive positive-pressure ventilation after birth, it is important to evaluate the cost-effectiveness of the supraglottic airway as the initial device for positive-pressure ventilation.

Subgroup considerations

No data were reported to perform subgroup analyses by gestational age (term vs. late preterm).

For the outcome “failure to improve”, the only outcome with sufficient data to perform a subgroup analysis based on device design (cuffed device vs. uncuffed (i-Gel™) device), there was no evidence of interaction ($p = 0.29$, $I^2 = 10\%$).

Implementation considerations

Within the context of research trials, use of an SGA in the delivery room appears to be feasible even in resource limited settings. Despite the relatively large number of newborns enrolled in published trials, the certainty of evidence remains low. Implementation will remain dependent upon training requirements and resource utilization.

Monitoring and evaluation

As the recommendation is weak and is based on low certainty evidence, continued monitoring of the safety and efficacy of SGAs for initial PPV immediately after birth is recommended.

Research priorities

The training requirements to achieve and maintain competency with supraglottic airway insertion, including different types of device.

The effectiveness and safety of supraglottic airways as the initial device for positive-pressure ventilation in high resource settings.

The effectiveness and safety of supraglottic airways compared with face masks during chest compressions.

The effectiveness and safety of supraglottic airways compared with face masks for newborns with orofacial anomalies.

The effectiveness and safety of different supraglottic airway designs.

The effectiveness and safety of supraglottic airways for positive-pressure ventilation among newborns less than 34 weeks' gestation.

The resource utilization and cost-effectiveness of using supraglottic airways compared with face masks as the initial device for positive-pressure ventilation in different settings.