QUESTION

NLS 5341 Supraglottic airway devices compared to tracheal tubes for neonatal resuscitation	
POPULATION:	Newborn infants receiving intermittent positive pressure ventilation immediately after birth
INTERVENTION:	Supraglottic airway devices
COMPARISON:	Tracheal tubes
MAIN OUTCOMES:	Successful ventilation with device; First attempt successful insertion; Time to successful insertion; Adverse events; Survival to discharge;
SETTING:	Any location immediately after birth
PERSPECTIVE:	Patient/individual (primary), Society/population (secondary)
BACKGROUND:	Ventilation of the newborn infant's lungs is the single most important component of neonatal resuscitation, and determining the most effective interface for administering assisted ventilation is a clinical and research priority. During neonatal resuscitation, tracheal tubes are most frequently used as a back-up or secondary device after ventilation attempts with a face mask have failed. However, achieving proficiency in tracheal intubation requires significant training and experience. Even with training, neonatal intubation is associated with prolonged procedure times, multiple attempts, and adverse events. The ILCOR Neonatal Life Support Task Force identified the comparison of ventilation with a supraglottic airway device (SGAD) compared with a tracheal tube (TT) as a priority for review. The topic was last reviewed in 2015 for a systematic review of the comparison of an SGAD vs. TT as the secondary device if initial ventilation with a face mask failed. The Consensus on Science and Treatment Recommendation (CoSTR) that resulted from that review was based on a single randomized trial enrolling 40 patients. In 2025, the literature search for an evidence update (NLS 5341) of this topic identified 2 systematic reviews published since the last ILCOR systematic review that included evidence from 3 additional randomized trials and one observational study.
CONFLICT OF INTERESTS:	Gary Weiner is a co-author on an observational study and was excluded from study selection and bias assessment for this study.[1]

ASSESSMENT

Problem

Is the problem a priority?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ● Yes ○ Varies ○ Don't know	When a newborn infant requires resuscitation, it is usually because of respiratory failure and ineffective gas exchange. Therefore, establishing effective ventilation of the newborn infant's lungs is the single most important component of neonatal resuscitation.[2] Failure to achieve effective ventilation is the most common reason that newborn infants receive chest compressions in the delivery room (DR).[3] During neonatal resuscitation, tracheal tubes are most frequently used as a back-up or secondary device after ventilation attempts with a face mask have failed. An international registry study found that 4.3% of all newborn infants will receive	With the increased emphasis on non-invasive ventilation for respiratory support among preterm infants, changes in staffing, and changes in training programs, opportunities to acquire and maintain proficiency in tracheal intubation are decreasing.[10] In North America, less than half of neonatology trainees achieve procedural competence,

	non-invasive ventilation with a face mask and nearly 25% of these infants will undergo intubation and subsequent invasive ventilation.[4] However, achieving proficiency in tracheal intubation requires significant training and experience. Even with training, neonatal intubation is associated with prolonged procedure times, multiple attempts to achieve success, and adverse events.[5] Insertion of an SGAD may be an effective alternative to tracheal intubation. Supraglottic airway devices have been shown to be effective alternatives to face mask ventilation and as airway rescue devices when tracheal intubation is not successful.[6, 7] They may require less training to achieve insertion proficiency and fewer attempts to achieve a successful airway than tracheal intubation.[8] However, SGADs are infrequently used.[9] Determining the most effective interface for administering assisted ventilation when face mask ventilation fails is a clinical and research priority.	defined as 80% overall success within 2 attempts, at the conclusion of training.[11] Anatomic variations among newborn infants or unanticipated congenital anomalies, may result in a "difficult airway" situation where the infant cannot be oxygenated with a face mask or intubated ("Can't oxygenate, Can't intubate"). In a large cohort study including 2009 tracheal intubations, approximately 14% of tracheal intubations attempted in 10 academic neonatal intensive care units (NICU) in North America met the definition of a "difficult airway".[12] Failure to intubate, or performing multiple unsuccessful attempts, may result in serious complications including airway injury, severe oxygen desaturation, brain injury, or death. Identifying an effective alternative for tracheal intubation in this situation is also a priority.

Desirable Effects

How substantial are the desirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Trivial ○ Small ○ Moderate ○ Large ○ Varies ● Don't know	The available evidence from the included 4 small, randomized trials suggests that both SGAD insertion and tracheal intubation are effective. The summary effect estimates for important and critical outcomes, including successful ventilation, first-attempt insertion success, time to device placement, and survival to discharge are very close to 1.0 (null effect). However, the confidence intervals surrounding the absolute risk differences for most outcomes are potentially within the range including the minimally important difference (MID) for both benefit and harm.	Contemporary studies indicate that first-attempt tracheal intubation success during clinical practice (40-60%) is substantially lower than the success rates reported in the included randomised trials (94%). Registry data from the NEAR4NEOS multi-center collaborative demonstrated that only 46% of DR intubations were successful at the first attempt.[5, 13] First attempt success (DR and NICU) varied by provider experience (25% pediatric trainee, 52% neonatology trainee, 64% neonatologist). A report from 4 neonatal units in the United Kingdom demonstrated 53% overall first attempt intubation success with 31% of delivery room intubations requiring 3 or more attempts.[14] The probability of first attempt success increased with operator experience. Similar data (62% first attempt success) were reported from Australia in a single center study of intubations in the NICU.[15] Again, the probability of first attempt success increased with operator seniority. In this study, the occurrence of adverse events increased with the number of attempts required for successful intubation.

Outcomes	Nº of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with tracheal tubes	Risk difference with Supraglottic airway devices
Successful ventilation with device	238 (4 RCTs)	⨁⨁◯◯ Low	**RR 0.98** (0.93 to 1.03)	974 per 1,000	**19 fewer per 1,000** (from 68 fewer to 29 more)
Successful ventilation with device	52 (1 non-randomised study)	⨁◯◯◯ Very low	**OR 2.33** (0.14 to 39.82)	938 per 1,000	**30 more per 1,000** (from 100 fewer to 160 more)[d]
First attempt successful insertion	188 (3 RCTs)	⨁⨁◯◯ Low	**RR 0.98** (0.91 to 1.06)	946 per 1,000	**19 fewer per 1,000** (from 85 fewer to 57 more)
Time to successful insertion	(3 RCTs)	⨁⨁◯◯ Low	-	-	MD **0.51 seconds lower** (1.05 lower to 0.04 higher)
Survival to discharge	68 (1 RCT)	⨁⨁◯◯ Low	**RR 1.03** (0.95 to 1.12)	969 per 1,000	**29 more per 1,000** (from 48 fewer to 116 more)

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **MD:** mean difference; **OR:** odds ratio; **RR:** risk ratio

These findings suggest that tracheal intubation success in clinical practice is strongly dependent on operator skill and context, and that the high tracheal intubation success rates reported in the included randomised trials, which primarily included anesthesiologists, may not reflect clinical experience during resuscitations performed by other health care professionals. In contrast, randomized trials of SGAD insertion during neonatal resuscitation, including studies conducted in low-resource settings with basic health care providers, have reported similar high first-attempt insertion success rates following brief training.[16, 17]

In the setting of a difficult airway, when tracheal intubation is not successful, an SGAD may be successful. After introducing the SGAD to medical personnel in Japan with a 60-minute course, Mizumoto reported successful rescue ventilation using an SGAD among 7 infants in “cannot ventilate, cannot intubate” situations during a 12-month interval.[18] Similar case reports have described successful ventilation with an SGAD during neonatal resuscitation when face mask ventilation and tracheal intubation were unsuccessful.[19-21] When face mask ventilation and tracheal intubation are unsuccessful, insertion of an SGAD is the first recommended step in the American Society of Anesthesiologists Practice Guidelines for Management of the Difficult Airway.[22] Similarly, the European Society of Anaesthesiology and Intensive Care and British Journal of Anaesthesia joint guidelines recommend insertion of an SGAD in neonates and infants for rescue oxygenation and ventilation when tracheal intubation fails.[23]

Undesirable Effects

How substantial are the undesirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

○ Large ○ Moderate ○ Small ○ Trivial ○ Varies ● Don't know	A small total number of adverse events were described in the included randomized trials (9 adverse events in the SGAD group and 7 adverse events in the TT group), and the methods used to identify adverse events were inconsistently reported, thereby limiting confidence in the summary effect estimate. Imprecision in the effect estimate includes the possibility of important benefit or harm with either device (RR 1.22, 95% CI 0.50 to 3.00). The available evidence was insufficient to make a judgement about undesirable effects.	The NEAR4NEOS multicenter registry reported that at least one adverse event occurred in 17% of DR intubations, severe adverse events occurred in 5% of DR intubations, and severe oxygen desaturation occurred in 31% of DR intubations.[5] The overall frequency of adverse events associated with tracheal intubation in the included randomized trials is similar to the adverse event rate described in the NEAR4NEOS registry study; however, the frequency of severe oxygen desaturation may be underestimated. For SGADs, there are no registry data available for comparison. If the first attempt success reported in the included trials is greater than found in clinical practice, as noted above, the undesirable effects associated with tracheal intubation may be underestimated.

Adverse events	108 (2 RCTs)	⊕⊕◯◯ Low	**RR 1.22** (0.50 to 3.00)	135 per 1,000	**30 more per 1,000** (from 67 fewer to 269 more)

Certainty of evidence

What is the overall certainty of the evidence of effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Very low ● Low ○ Moderate ○ High ○ No included studies	The certainty of evidence was assessed as low for each critical and important outcome due to risk of bias (ROB) and imprecision. ROB was judged to be serious for all outcomes. Imprecision was judged to be serious for all outcomes except for time to successful insertion. In addition, the certainty of evidence is low due to inconsistent reporting of adverse events.	

Values

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

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Important uncertainty or variability ○ Possibly important uncertainty or	The prioritization of critical and important outcomes was made according to a consensus of international neonatal resuscitation experts or by Task Force consensus.[24]	

variability ○ Probably no important uncertainty or variability ● No important uncertainty or variability		

Balance of effects

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

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ 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	The available evidence shows that most effect estimates are very close to null effect, with confidence intervals including both potential benefit and harm. The balance of effects does not clearly favor either the intervention or comparison.	Because the probability of first attempt success and adverse events associated with tracheal intubation has been shown to vary based on operator experience, the balance of desirable and undesirable effects could vary depending on clinical setting and provider experience.[5, 14, 15]

Resources required

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Large costs ○ Moderate costs ○ Negligible costs and savings ○ Moderate savings ○ Large savings	The included studies did not evaluate the resources required to train clinicians or to use either SGADs or tracheal tubes during neonatal resuscitation.	Tracheal tubes and SGADs are typically single use, disposable devices. Tracheal intubation additionally requires purchase and maintenance of laryngoscopes. The resources required to train clinicians to become proficient in neonatal tracheal intubation are uncertain. A recent scoping review identified multiple studies utilizing self-directed learning, didactic education, simulation training, and supervised clinical practice with duration of training ranging from a single 5-minute episode to one

○ Varies ● Don't know		month of repeated supervised clinical practice.[25] The effectiveness of short duration (< 60 minute) training was unclear as some studies reported improved outcomes while others did not, and many studies only reported outcomes measured in simulation rather than clinical settings. One study reported that tracheal intubation skills demonstrated in simulation did not transfer to the clinical environment.[26] Evidence from randomized trials comparing SGAD with face mask ventilation suggest that fewer resources and time may be required to teach SGAD insertion. Two studies completed in low resource settings with a range of health providers, including physicians, nurse anesthetists, and midwives utilized the Helping Babies Breathe curriculum with an additional module for SGAD insertion.[16, 17] Participants practiced insertion with a high fidelity manikin and were required to demonstrate 3 successful insertions in a manikin prior to clinical use. In both studies, participants were very successful (96% and 100%, respectively) inserting the device and achieving effective ventilation during neonatal resuscitation. The successful ventilation rate with the SGAD in these studies was similar to the success rate described in the present review.

Certainty of evidence of required resources

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

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Very low ○ Low ○ Moderate ○ High ● No included studies	The included studies did not evaluate the resources required to train clinicians or to use either SGADs or tracheal tubes during neonatal resuscitation.	

Cost effectiveness

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

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ 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	No included studies evaluated the cost-effectiveness of SGAD insertion or tracheal intubation during neonatal resuscitation.	In some settings, tracheal tubes may be more cost-effective because the necessary equipment and supplies are already routinely purchased and maintained. Purchasing and maintaining SGADs, which may be used infrequently only as rescue devices, may be less cost-effective. However, in low-resource settings, neither laryngoscopes, tracheal tubes, nor SGADs may be routinely available.

Equity

What would be the impact on health equity?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Reduced ○ Probably reduced ○ Probably no impact ○ Probably increased ○ Increased ○ Varies ● Don't know	No included studies evaluated the impact of SGAD insertion or tracheal intubation on health equity.	In low-resource settings, equipment and personnel trained in either SGAD insertion or tracheal intubation are often limited. The resources necessary to provide ongoing care to infants requiring advanced resuscitation may be limited. An intervention that requires fewer resources for training and can be successfully implemented by providers with limited skills may improve health equity, particularly in settings with the highest burden of critically ill newborns who require assisted ventilation.[16, 17]

Acceptability

Is the intervention acceptable to key interest-holders?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

○ No ○ Probably no ● Probably yes ○ Yes ○ Varies ○ Don't know	No included study evaluated the acceptability of the SGAD use compared with tracheal intubation by key interest-holders.	Both SGAD and tracheal tubes are included in major international neonatal resuscitation training programs in North America and Europe.[27, 28] However, a survey of Neonatal Resuscitation Program instructors and participants in the United States (n=5,809 respondents) demonstrated that few (12%) had ever placed an SGAD during newborn resuscitation and one-third reported that SGADs are not available in their local setting.[9] The most commonly cited barrier to SGAD use was insufficient experience using the device. A similar survey completed in Europe including 858 health professionals from 42 countries showed that few had placed an SGAD in a newborn infant (23%); however, they perceived the device to be less difficult to insert than a TT and less invasive.[29] A survey of all tertiary neonatal units in Australia and New Zealand (n=29) found that one-third did not have SGADs available and only 40% felt their staff had adequate competency to insert an SGAD.[30] Although clinicians may have less familiarity with the SGAD, health care providers with less experience may find them an acceptable alternative to tracheal intubation due to their ease of use. After a brief (60 minute) training course with a manikin for Japanese healthcare providers without any previous experience using an SGAD, Mizumoto reported widespread introduction of the SGAD (38/51 institutions) including general hospitals without consistent pediatric coverage, obstetric clinics, and midwifery homes.[18]

Feasibility

Is the intervention feasible to implement?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ● Probably yes ○ Yes ○ Varies ○ Don't know	No included study evaluated the feasibility of implementing SGD use compared with tracheal intubation during neonatal resuscitation.	Randomized trials comparing SGAD and face mask ventilation among health care professionals in limited resource settings suggested that it is feasible to implement SGAD use among a range of health providers.[16, 17]

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
PROBLEM	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
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

○	○	●	○	○

CONCLUSIONS

Recommendation

1. Depending on resources and training, when ventilation with a face mask is not successful or not feasible, we suggest inserting either an appropriately sized supraglottic airway device or an appropriately sized tracheal tube. (Conditional recommendation, low certainty of evidence)

2. If face mask ventilation is not effective and tracheal intubation is not feasible or not successful, we recommend inserting an appropriately sized supraglottic airway device. (Implementation consideration)

Remarks

Justification

In making this recommendation for newborn infants requiring assisted ventilation when face mask ventilation is not successful or not feasible, the Task Force considered that both tracheal intubation and insertion of a supraglottic airway device were very successful interventions. In a small number of randomized trials, the summary effect estimates for critical and important outcomes were near the null threshold suggesting little difference between the two interventions. However, the certainty of evidence for key outcomes was low due to serious risk of bias and imprecision. The confidence intervals around key outcomes included the possibility of both harm and benefit for both interventions. Indirect evidence suggests that introduction of supraglottic airway devices as an alternative to tracheal intubation is likely acceptable and feasible.[17, 18, 31] International neonatal resuscitation training programs already include these devices.[28, 32] The cost, resources, equity, and safety of either intervention were not directly assessed in the included studies.

Indirect evidence from registry studies suggests that successful insertion on the first attempt for tracheal intubation in clinical practice may be overestimated by the included studies.[5, 14, 15]

In the setting of a difficult airway, when ventilation with a face mask fails to achieve an adequate response and tracheal intubation is not successful or not feasible ("Cannot oxygenate, cannot intubate"), international guidelines consistently recommend a supraglottic airway device as the initial adjunctive airway device.[22, 23]

Subgroup considerations

No data for the planned subgroup analyses were available.

Implementation considerations

Implementation of either SGAD insertion of tracheal intubation requires appropriate training, equipment, and monitoring. The lack of SGADs appropriately sized with demonstrated effectiveness for very preterm infants may limit their use in this population.

Monitoring and evaluation

We recommend ongoing evaluation of the rates of successful device insertion, successful insertion at the first attempt, time to successful insertion, time until effective ventilation achieved, and adverse events with both devices.

Research priorities

Future studies to compare insertion of an SGAD vs. tracheal intubation among newborn infants being resuscitated immediately after birth are needed to evaluate:

· Efficacy, effectiveness and safety in decreasing the time until effective ventilation achieved

· Efficacy, effectiveness, and safety among preterm infants < 34 weeks' gestation or < 2000 g birthweight

· Training and resource requirements to achieve and maintain proficiency with SGAD insertion and tracheal intubation among health care professionals with varying levels of experience

· Feasibility, cost-effectiveness, and impact on health equity of widespread SGD implementation

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