WORKSHEET for Evidence-Based Review of Science for Emergency Cardiac Care

Worksheet Authors:       Date Submitted for Review:
Gary M. Weiner, MD       1 November 2009

Clinical Question:
For neonates requiring positive pressure ventilation (P), is the laryngeal mask (I) an effective alternative to mask or endotracheal ventilation (C) for improving outcome (O)? (achieving stable vital signs and reducing the need for subsequent endotracheal intubation)?

Is this question addressing an intervention/therapy, prognosis or diagnosis?
Intervention/therapy

State if this is a proposed new topic or revision of existing worksheet:
Revision of an existing worksheet

Conflict of Interest Specific to this Question:
Do any of the authors listed above have conflict of interest disclosures relevant to this worksheet?
No.

Search Strategy:

Databases searched:
Medline (OVID), Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials, EMBASE, AHA Endnote master library, review references from retrieved articles, forward search all included controlled studies using OVID “cited by” function, use “find similar” OVID function for all included controlled studies.

OVID (7/15/09):
1 laryngeal mask.mp. or exp Laryngeal Masks/ (4016)
2 laryngeal mask$.tw. (3133)
3 infant, newborn.mp. or exp Infant, Newborn/ (426479)
4 1 or 2 (4026)
5 4 and 5 (179)

EMBASE (7/13/09):
1 ‘laryngeal mask’/syn OR ‘laryngeal mask airway’/syn OR ‘laryngeal mask’ (5840)
2 ‘newborn’/syn OR ‘neonate’/syn or ‘neonatal’ (499727)
3 1 and 2 (209)

Cochrane Database of Systematic Reviews (7/24/09):
laryngeal mask.mp. (title, abstract, full text, keyword, or caption text) (10)

Cochrane Central Register of Controlled Trials (7/24/09):
1 laryngeal mask.mp. or exp Laryngeal Masks/ (816)
2 laryngeal mask$.tw. (753)
3 infant, newborn.mp. or exp Infant, Newborn/ (9578)
4 1 or 2 (816)
5 3 and 4 (6)

AHA EndNote X1 Master Library (7/24/09):
‘laryngeal mask’ as textword in abstract (267)
**Inclusion and Exclusion Criteria:**

**Inclusion Criteria:**
1. Controlled clinical studies (randomized, quasi-randomized, non-randomized) describing a laryngeal mask used for positive pressure ventilation compared with either facemask ventilation or endotracheal intubation among human neonates (≤28 days of life or ≤ 44 weeks post-conceptual age) requiring resuscitation due to any cause.
2. Controlled animal and mechanical model studies (randomized, quasi-randomized, non-randomized) describing a laryngeal mask used for positive pressure ventilation compared with either facemask ventilation or endotracheal intubation in a resuscitation model approximating a human neonate (≤28 days of life or ≤ 44 weeks post-conceptual age).
3. Meta-analyses or systematic reviews including a minimum of 2 controlled clinical studies (randomized, quasi-randomized, non-randomized) describing a laryngeal mask used for positive pressure ventilation compared with either facemask ventilation or endotracheal intubation among human neonates (≤28 days of life or ≤ 44 weeks post-conceptual age) requiring resuscitation due to any cause.
4. Case series describing a laryngeal mask used for positive pressure ventilation among human neonates (≤28 days of life or ≤ 44 weeks post-conceptual age) requiring resuscitation due to any cause that include a minimum of 10 subjects.
5. Eligible controlled trials and meta-analyses were reviewed without language restrictions. Observational studies were only reviewed if they were published in English.

**Exclusion Criteria:**
1. Observational studies (case reports/case series) without appropriate comparison groups that include less than 10 subjects or were not published in English. Small (< 10 subject) observational studies, published in English, describing a laryngeal mask airway used for neonatal resuscitation are included in the section titled “Additional References- Case Series and Case Reports”.
2. Studies describing the laryngeal mask used for resuscitation among non-neonatal humans or animal models.
3. Studies describing neonatal subjects combined with older infants where insufficient details are provided to independently assess the outcome of the neonatal subgroup.
4. Studies describing the laryngeal mask used for administering anesthesia, administering surfactants, as a conduit for bronchoscopy, or as conduit for endotracheal intubation.
5. Studies describing the laryngeal mask used electively for ventilation during surfactant administration.
6. Duplicate publications of the same subjects (only most recent publication included).
7. Unpublished studies, studies published only in abstract form, letters to the editor, clinical guidelines and review articles without original data.

**Number of articles/sources meeting criteria for further review:**

The titles and abstracts were scanned to identify potentially relevant references for secondary review. A total of **59** potentially relevant references were identified:
- OVID → 54 potentially relevant references
- Embase → 3 additional references
- AHA Endnote Library → 1 additional reference
- Cochrane → no additional references for further review (already identified by Ovid search)
- Reviewing references from included searches, forward search and “find similar” → no additional references
- One additional reference (Feroze, 2008) was identified by another ILCOR reviewer (Dr. Enrique Udaeta) during a Google Scholar™ search. The publishing journal (The Professional
Medical Journal-Pakistan) is not indexed in either Embase or Medline.

The full text of each potentially relevant reference was reviewed for inclusion and exclusion criteria. In total, 9 references met inclusion criteria and 50 references were excluded. Twenty additional references that were excluded because they were small case series, single case reports, or letters to the editor are included in the section titled “Additional References-Case Series and Reports.”

### Summary of evidence

#### Evidence Supporting Clinical Question

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#### Level of evidence

A = Return of spontaneous circulation  
B = Survival of event  
C = Survival to hospital discharge  
D = Intact neurological survival  
E = Other endpoint  

*Italicics = Animal studies*

*Trevisanuto 2004 is a two-part study (LOE 2 case-control and LOE 4 case series)*  
*Zanardo 2004 includes a subset of patients reported in Trevisanuto 2004 with a different hypothesis and a unique control group*
### Evidence Opposing Clinical Question

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**Level of evidence**

- **A** = Return of spontaneous circulation
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### REVIEWER’S FINAL COMMENTS AND ASSESSMENT OF BENEFIT / RISK:

#### Discussion:

**Background:**

The laryngeal mask is a small elliptical mask with an inflatable rim connected to an airway tube. The mask is inserted orally using the operator’s index finger and is guided along the hard palate without instruments to the hypopharynx. Once the device is inserted, the rim is inflated and the mask sits with its lumen facing the laryngeal opening while the rim conforms to the contours of the hypopharynx occluding the esophagus with a low-pressure seal. The airway tube includes an adaptor that is attached to a positive pressure device. A large body of literature describes the laryngeal mask used for pediatric patients during operative anesthesia, to facilitate diagnostic bronchoscopy, as a guide to facilitate tracheal intubation, and a rescue device for difficult airways (Brimacombe 1997, Grein 2005, Lopez-Gil 1996, Mora 2006, Trevisanuto 2004). It is the initial device recommended by the American Society of Anesthesiologists when both facemask ventilation and direct laryngoscopy are unsuccessful (American Society of Anesthesiologists Task Force on Management of the Difficult Airway, 2003).

During neonatal resuscitation, the laryngeal mask may be considered as an alternative to facemask ventilation, an alternative to endotracheal intubation (“secondary airway”), or as a rescue airway when both facemask ventilation and endotracheal intubation have been unsuccessful (“rescue airway”).

In 2005, the ILCOR Consensus on Science and Treatment Recommendations (CoSTR) recommended the laryngeal mask as a rescue airway during neonatal resuscitation if bag-mask ventilation was unsuccessful and tracheal intubation was unsuccessful or not feasible. There was insufficient evidence to recommend the laryngeal mask as a primary airway during neonatal resuscitation or in the setting of meconium stained amniotic fluid, chest compressions, or for the delivery of emergency medications into the trachea. At that time, there was no evidence directly comparing the laryngeal mask with bag-mask ventilation as the primary airway for neonatal resuscitation. The best available evidence consisted of two large case series describing the laryngeal mask used for delivery room resuscitation (primary airway), a single randomized trial comparing the laryngeal mask with endotracheal intubation (secondary airway), and 13 case reports describing resuscitation with the laryngeal mask when both face-mask ventilation and intubation were unsuccessful (rescue airway).

Additional evidence published since the 2005 CoSTR review includes: two additional randomized

**Primary Airway**

Since the 2005 CoSTR statement, two additional randomized controlled trials have compared the laryngeal mask with a facemask device for delivery room resuscitation (LOE 1 Singh, 2005; LOE 1 Feroze, 2008). Singh (Singh, 2005) randomized 50 neonates receiving positive pressure ventilation after cesarean section delivery to resuscitation with either a laryngeal mask or facemask. The overall success with ventilation was similar between the laryngeal mask and bag-mask ventilation (24/25 vs. 22/25). The laryngeal mask was inserted successfully on the first attempt in 20/25 (80%) while three subjects required two or three attempts. Consistent with previous case reports, the laryngeal mask was placed quickly (median 10.0 seconds, range 7-32 seconds). The laryngeal mask group had resolution of subjective cyanosis (“pink up”) faster than the facemask group (33.33 sec vs. 44.52 sec). Despite three insertions, effective ventilation could not be achieved for one infant using the laryngeal mask and endotracheal intubation was required. Effective ventilation could not be achieved for three infants in the facemask group; two of these infants were resuscitated with an endotracheal tube. One infant with a cleft lip and palate could not be ventilated with a facemask and could not be intubated after two attempts. This infant was successfully resuscitated with a laryngeal mask. No complications were described, however, the duration of follow up is not explicitly stated. While not specifically stated, it appears that the treatment assignment was not concealed from the individual(s) assigning outcomes. The authors did not describe how the sample size was determined and it appears likely that the study lacked sufficient power to find a clinically significant difference in the primary outcome measure (successful ventilation) or the requirement for subsequent endotracheal intubation.

Feroze (Feroze, 2008) randomized 75 neonates (> 1.5 kg) with an Apgar score < 4 “at birth” to receive positive pressure ventilation using either a facemask, endotracheal tube, or laryngeal mask as the primary airway device. The published paper lacks important details about recruitment, randomization, and baseline characteristics of the subjects in the study and the data reported are very incomplete. The authors state that 24/25 (96%) subjects randomized to LMA placement were successfully resuscitated compared with 80% of those assigned to facemask ventilation and 90% of those assigned to endotracheal intubation. The average time required for LMA placement was 9 ± 1.4 seconds compared with 9.5 seconds for endotracheal tube placement. No details are provided about the subjects that were not successfully resuscitated with their assigned device. Despite the limitations, these two randomized trials suggest that, with appropriate training, the laryngeal mask may be an effective alternative to either facemask ventilation or endotracheal intubation as the primary airway for neonatal resuscitation. These findings are consistent with evidence from larger observational studies.

The largest body of evidence evaluating the laryngeal mask as a primary airway for neonatal resuscitation comes from three observational studies (LOE 4 Paterson 1994; LOE 4 Gandini 1999; LOE 4 Trevisanuto 2004) describing a total of 220 newborns. Two case series, reported by Paterson and Gandini, included 125 subjects (Patterson n = 21, Gandini n = 104, birth weight range 1000-4460 gm) and were included in the previous CoSTR review. In these series, the laryngeal mask was successfully placed on the first attempt in all subjects and effective ventilation achieved in 20/21 and 103/104 subjects respectively. The time required for placement ranged from approximately 8-10 seconds. Each series included one newborn that did not respond to either laryngeal mask ventilation or subsequent endotracheal intubation. Most recently, Trevisanuto (Trevisanuto, 2004) reported a 2-part study that was not included in the previous CoSTR statement. The first part is a case series (LOE 4) describing 95 newborns resuscitated in the delivery room with a laryngeal. The physician resuscitators completed a manikin-based training program and then placed the laryngeal mask under supervision in 10 patients in the operating room. Resuscitators could choose to use the laryngeal mask in place of a facemask, at their discretion, among newborns >/= 34 wks gestation and/or >/= 2000 grams birth weight with apnea or bradycardia (<100 bpm) at birth. The laryngeal mask was not considered an option if newborns were in "cardiac arrest", required chest compressions or tracheal drugs, had "severe fetal distress" or a prenatally diagnosed contraindication (e.g. meconium stained fluid,
diaphragmatic hernia, major anomaly). The laryngeal mask was placed successfully and effective ventilation was achieved in 94/95 newborns (99%). Effective ventilation was not achieved in one infant (2570 gm, 36 weeks EGA) who was found to have a tension pneumothorax. Two additional series (LOE 5 Gandini 2004; LOE 5 Micaglio 2006) describe laryngeal mask placement by 115 healthcare providers in neonatal manikin models following brief (15-minute) training sessions with neonatal intubation manikins. All insertions were successful and the time required for insertion was short (range 5-22 seconds), however, it is not clear that successful insertion in a manikin model adequately represents success in a human newborn during resuscitation. In summary, three case series have described the laryngeal mask used for resuscitation as the primary airway among 220 term or late preterm newborns with a combined success rate of 217/220 (98.6%), however, the lack of a control group prevents direct comparisons with facemask ventilation.

The second part of Trevisanuto’s study (LOE 2 Trevisanuto 2004) is a retrospectively assembled cohort study comparing a subset of the 95 infants resuscitated with a laryngeal mask (n=74) with 74 gestational age-matched infants resuscitated with a facemask. The choice of which device to use was at the physician's discretion using the same eligibility criteria described above. Effective ventilation was achieved in 73/74 (99%) of those resuscitated with a laryngeal mask compared with 70/74 (94%) resuscitated with a facemask. Four newborns that did not respond to facemask ventilation were successfully resuscitated with a laryngeal mask. There were no differences in the demographic characteristics of the two groups, their hospital course, or outcome measures (length of stay, admission to NICU, primary diagnosis, Apgar score). Although there were no apparent confounders, it is possible that that subjects assigned to the facemask device were more severely depressed at birth. A subset of infants in this study are the subjects of another retrospectively assembled cohort study (LOE 2 Zanardo 2004). In this study, newborns delivered by elective cesarean section at term are compared with the next vaginally delivered newborn. In a sub-analysis, newborns resuscitated with a laryngeal mask (n=43) were compared with newborns resuscitated using an endotracheal tube, rather than a facemask, as the primary airway (n=18). Overall, newborns resuscitated with a laryngeal mask had better Apgar scores and required less respiratory support after delivery. It is reasonable to assume, however, that infants resuscitated with an endotracheal tube were felt to be sicker at birth. Potential cofounders were not described by the authors and were not controlled for. Both of these cohort studies are limited by their retrospective design, lack of randomization, and potential for selection bias.

The consistent results from two randomized controlled trials, three large case series, and two retrospective cohort studies provide good evidence that the laryngeal mask may be used as an alternative to a facemask or endotracheal tube as the primary airway for positive pressure ventilation during neonatal resuscitation among newborns weighing more than 2000 grams. There is limited evidence, however, to evaluate its use for newborns weighing < 2000 grams or delivered < 34 weeks gestation.

Secondary Airway

At the time of the 2005 CoSTR review, Esmail’s (Esmail 2002) study comparing the laryngeal mask with endotracheal intubation (ETT) as a secondary airway was the only randomized controlled trial evaluating a laryngeal mask during neonatal resuscitation. Forty newborns were randomized to laryngeal mask placement (n=20) or ETT (n=20) if their heart rate remained < 100 beats/minute following one minute of positive pressure ventilation by facemask. Successful placement following the first attempt was similar using either the laryngeal mask (17/20) or ETT (18/20). The average time for insertion was remarkably short for both interventions. There was a clinically insignificant difference favoring endotracheal intubation (10 seconds vs. 7.5 seconds, mean difference 2.5 seconds; 95% CI 1.27-3.73 seconds, p<0.05). The course of heart rate improvement, color change, Apgar scores, and time to spontaneous respirations were similar in both groups. There was no statistically significant difference in airway trauma between groups (6/20 laryngeal mask vs. 3/20 ETT). Esmail’s study was limited by the absence of details describing the randomization method, failure to describe the sample size calculation, and the use of anesthesiologists rather than pediatricians as the resuscitators in all cases. The resuscitators had substantially better success performing endotracheal intubation than has been reported by other investigators and this may have biased the study against the laryngeal mask.

Since the 2005 CoSTR review, there has been no additional evidence to compare the laryngeal mask
with endotracheal intubation as a secondary airway. Feroze (LOE 1 Feroze, 2008) found that the laryngeal mask compared favorably with endotracheal intubation as the primary airway, however, endotracheal intubation is infrequently used as the primary airway. Although Singh’s randomized controlled trial has limitations, it does suggest that success with the laryngeal mask and endotracheal intubation may be similar among experienced operators for establishing effective ventilation if attempts with a facemask have been unsuccessful. The laryngeal mask has not been evaluated, however, during the administration of chest compressions or for airway suction with meconium stained fluid. There is very little evidence indicating whether emergency medications can be administered through the laryngeal mask.

### Rescue Airway

The most frequently reported use of the laryngeal mask among neonates and infants is for rescue airway management when both facemask ventilation and endotracheal intubation have been unsuccessful. The search strategy for this review identified 11 case reports describing a total of 13 newborns in whom a laryngeal mask was used as a lifesaving rescue device (Baraka 1995, Brimcombe 1995, Brimacombe 1999, Bucx 2003, Denny 1990, Fernandez-Jurado 2002, Fraser 1999, Gandini 2003, Leal-Pavey 2004, Trawoger 1999, Trevisanuto 2005). Other reports describe the laryngeal mask used for anesthesia or as a conduit to guide endotracheal intubation among newborns with difficulty Airways in the operating room. Based on these reports, a relatively strong class of recommendation can be made for attempting laryngeal mask placement during resuscitation when effective ventilation cannot be achieved with a facemask and endotracheal intubation is unsuccessful. Although the level of evidence from a case report may be considered weak, the non-invasive nature of the laryngeal mask in comparison with the alternative (tracheostomy), the consistent positive results, and the practical difficulties of designing a randomized controlled trial in this unpredictable emergency situation make it unlikely that a randomized controlled trial will ever be completed to address this question.

### Acknowledgements:

None

### Citation List:

**Included Studies:**


**Comment:** (LOE 1, Fair, Supportive, No comment regarding industry funding)

*To date, the only neonatal randomized controlled trial directly comparing the LMA with endotracheal intubation as a secondary airway during resuscitation. The method of randomization is not clear. While not specifically stated, it can be inferred that the randomization list was not concealed and that the individual(s) assigning outcomes were not blinded to the treatment group. It is not clear if all patients that entered the trial were accounted for at the conclusion because patient flow is not explicitly described. It is not explicitly stated if the outcomes were analyzed with the "intent to treat" principle. The operator in all cases appears to be an anesthesiologist. It is not clear if the results of this study can be generalized to pediatrician resuscitators given the operators’ high success rate (90%) with endotracheal intubation. Other studies have shown that pediatrician resuscitators have a much lower success rate with endotracheal intubation and that intubation, when successful, takes much longer than 7.5 seconds. This may have biased the study against the LMA. Two subjects in the LMA group and 1 subject in the ETT group had evidence of trauma to the epiglottis requiring treatment with corticosteroids.*

*This study was identified from the AHA Endnote library and was available on-line in electronic format in 2004. It is not indexed in either Ovid or Embase and no longer appears available on-line from any website. Attempts to contact the author from the contact information provided in the manuscript were not successful.*

**Comment:** (LOE 1, Poor, Supportive, No comment regarding industry funding)

This reference was identified by another ILCOR reviewer (Dr. Enrique Udaeta) using a Google Scholar ™ search. The publication is not indexed in either Embase or Medline and did not appear in the search strategy described above. The authors state that a convenience sample of neonates undergoing C-Section were randomized into three treatment groups. The timing and method of randomization were not stated and it is not known if the randomization list was concealed. It is surprising that in a 20-week period, 75 neonates required positive pressure ventilation after a cesarean section delivery. The inclusion criteria are based on birth weight (> 1.5 kg), however, it is not clear how the investigators would have known the birth weight before intervention was required. While not specifically stated, it can be inferred from the text that the individual(s) assigning outcomes were not blinded to the treatment group. It is not clear if all patients that entered the trial were accounted for at the conclusion because details about recruitment, eligibility, randomization and patient flow are not described. It is not explicitly stated if the outcomes were analyzed with the "intent to treat" principle. It is not clear if the treatment groups were similar at the start of the trial (no data provided) and only delivery room outcomes were described. No follow up data were provided. The data are reported in both tabular and graphic format, however, they are very incomplete. The authors described a plan for statistical comparisons between the three groups in the methods section, however, these comparisons and their results were never reported. The resuscitator in all cases is a second year resident in anesthesia under the supervision of a consultant anesthetistologist. Their training in neonatal resuscitation and the treatment algorithm that they followed is not described.

The authors report that 24/25 (96%) of those assigned to the LMA were successfully resuscitated, compared with 90% in the ETT group and 80% in the facemask group. The authors state "better results were achieved using size one LMA", however, this difference would not be statistically significant if the authors used the chi-square test as indicated in the methods. They state that the average time for insertion was 9 seconds (LMA) and 9.5 seconds (ETT) and that the LMA took "1-2" attempts at insertion compared with "2-3" attempts for endotracheal intubation. They state that the LMA was used when neonates could not be ventilated using either a facemask or endotracheal tube but provide no details about these cases.

Overall, this paper has multiple methodologic and reporting flaws and provides only modest supporting evidence that experienced users may have equivalent success using the LMA compared with either facemask or endotracheal intubation as the primary airway during neonatal resuscitation.


**Comment:** (LOE 5, Poor, Supportive, No comment regarding industry funding).

A case series describing 80 health care workers with various professional backgrounds who received 15 minutes of training before attempting to place an LMA into a neonatal manikin. While all insertions were successful and the mean time to insertion was extremely short (range 5-16 seconds), it is not clear that LMA placement in this manikin model adequately represents success during resuscitation in vivo. This study is similar to Lavies (Lavies, 1993) and Micaglio (Micaglio, 2006).


**Comment:** (LOE 4, Good, Supportive, No comment regarding industry funding).

Case series describing one investigator’s experience attending 689 deliveries and placing the LMA in 104 neonates requiring resuscitation over a 5-year period. An LMA was inserted if positive pressure ventilation (PPV) was required (HR < 100 bpm or apnea) for neonatal resuscitation. Neonates delivered through meconium stained fluid underwent laryngoscopy before PPV and were excluded if there was evidence of meconium aspiration. If adequate chest expansion was not obtained after 2 insertion attempts, either facemask or tracheal intubation was attempted. Of the 689 deliveries attended, 130 required PPV, 26 had meconium stained fluid with evidence of aspiration and were excluded, 104 met inclusion criteria (75 normal birthweight, 29 low birthweight, 6 weighed 1000-1500 grams, the smallest was 1000 grams). The LMA was successfully inserted by this single operator on the first attempt in all
104. The average time to chest expansion was 10 seconds, average time to achieve HR > 100 bpm was 13 seconds (normal BW) and 14 seconds (LBW). The average time until LMA removal was less than 1 minute in both groups (42 seconds). The longest that the LMA was left in place was 6.8 minutes. Six neonates resuscitated with the LMA ultimately required tracheal intubation or nasal CPAP for respiratory distress syndrome. One neonate did not respond to ventilation through the LMA and subsequently failed to respond to endotracheal intubation as well. There were no complications reported.

This report is the largest single case series using the LMA as the primary device for PPV during neonatal resuscitation.


Comment: (LOE 5, Poor, Supportive, No comment regarding industry funding). This study compares success using two different models of the laryngeal mask among 35 healthcare workers with different backgrounds who received 15 minutes of training and practice before placing the device in a neonatal manikin model. The "Pro-Seal" LMA mask is a modification that allows a tighter seal to the hypopharynx and gastric drainage through an additional tube. Participants were allowed 3 attempts for successful placement. The first attempt success rate was slightly higher using the "Pro-Seal" LMA compared with the "Classic LMA" but the insertion time was slightly longer (neither difference clinically significant). The study does not include a comparison between the laryngeal mask and a bag-mask device or endotracheal intubation but is included as a "case series" because it provides some evidence to evaluate the ability of providers to place an LMA. While all participants successfully placed each laryngeal mask (92-97% first attempt success rate) and the mean time to insertion was short (range 6-22 seconds), it is not clear that LMA placement in this manikin model adequately represents success during resuscitation in vivo.


Comment: (LOE 4, Good, Supportive, No comment regarding industry funding) Case series describing LMA placement as the primary airway, instead of bag-mask ventilation, in the delivery room for 21 newborn receiving positive pressure ventilation. Newborns only included if one of 3 investigators was available to attend the delivery. Excluded infants with oropharyngeal anomalies, those requiring chest compressions, and known congenital anomalies. Infants with thick meconium staining and birth depression underwent tracheal intubation and suction prior to LMA placement. Investigators had placed 24 LMAs in the operating room before elective surgery prior to starting this delivery room resuscitation study. The investigators attended 93 deliveries and resuscitated 21 newborns. One infant was depressed at birth; an LMA was placed but the HR did not improve. An ETT was placed, chest compressions administered, and epinephrine delivered through the ETT. This subject died at 6 hours of age and was excluded from the data analysis. All remaining subjects (n=20) had LMA placed on first attempt without difficulty. Birth weight ranged 2235 gm - 4460 gm. Mean (range) time for LMA insertion was 8.6 sec (7-12) and duration of PPV 80 sec (30-300). One infant had a pneumothorax diagnosed at 90 minutes. No infant had clinical complications at 2 days.

This was the first large case series describing the LMA used as an alternative to bag-mask ventilation for delivery room resuscitation.


Comment: (LOE 1, Fair, Supportive, No comment regarding industry funding) To date, the only neonatal randomized controlled trial directly comparing the LMA with facemask ventilation as the primary airway during resuscitation. The method of randomization is not clear. While not specifically stated, it can be inferred that the randomization list was not concealed and that the individual(s) assigning outcomes were not blinded to the treatment group. It is not clear if all patients that entered the trial were accounted for at the conclusion because patient flow is not explicitly described. It is not explicitly stated if the outcomes were analyzed.
with the "intent to treat" principle. Although it is not explicitly stated, it appears that the operator in all cases was an anesthesiologist. The authors describe statistical analyses in the methods, however, the analyses are not described in the results section. A total of 50 patients were randomized, however, the authors do not explain how they determined the sample size (no power analysis described).

Overall success with ventilation appears similar between the LMA and facemask ventilation (24/25 vs 22/25). LMA placement was successful on the first attempt in 20/25 (80%), 3 others had the LMA placed on the 2nd or 3rd attempt. The LMA was placed quickly (median 10.0 seconds, range 7-32 seconds) similar to the experience described by Paterson and Gandini. The experience of the operators using an LMA is not described, however, the methods section states that five practice insertions of the LMA were done before the study began. The time to "pink up" appears faster in the LMA group (33.33 sec vs 44.52 sec). Despite 3 insertions, one infant could not be ventilated with the LMA and endotracheal intubation was performed. Following airway suction through the tracheal tube, the infant was successfully ventilated. Three infants in the facemask group could not be effectively ventilated. Two infants required endotracheal intubation. One infant with a cleft lip and palate could not be ventilated with a facemask and could not be intubated after two attempts. This infant was successfully resuscitated with an LMA. No complications were described, however, the duration of follow up is not explicitly stated.


**Comment:** (LOE 2, Fair; LOE 4, Good, Supportive, No comment regarding industry funding)

This study is presented in two parts. The first part is a case series (LOE 4) describing 95 newborns resuscitated in the delivery room with an LMA at a single institution (University of Padova, Italy) in 2000 by ten physicians. The physicians had completed a manikin training program as part of a 2-day Neonatal Resuscitation Program (AAP/AHA) course and then had placed the LMA in 10 patients undergoing operative procedures under the supervision of an anesthesiologist. Although not specifically stated, it appears that the physicians were either attending neonatologists, pediatric residents, or neonatology fellows. Newborns were eligible for resuscitation with an LMA if they were >/= 34 wks gestation and/or >/= 2000 grams birth weight, had apnea or bradycardia (<100 bpm) at birth. They were not eligible if they were in "cardiac arrest", required chest compressions or tracheal drugs, or had "severe fetal distress" or a prenatally diagnosed contraindication (e.g. meconium stained fluid, diaphragmatic hernia, major anomaly). The LMA was placed successfully and provided effective ventilation in 94/95 newborns (99%). The LMA did not provide effective ventilation in one infant (2570 gm, 36 weeks EGA) who was found to have a tension pneumothorax. Five infants required prolonged ventilation (> 15 minutes) and the LMA was replaced with an endotracheal tube.

The second part of the study is a non-randomized, retrospectively matched comparison (LOE 2) between 74 infants resuscitated with an LMA and 74 infants resuscitated with a facemask. The choice of equipment used by the resuscitator (LMA vs. facemask) was at the physician's discretion with the same eligibility criteria described above. The LMA provided effective ventilation in 73/74 (99%) neonates and the facemask provided effective ventilation in 70/74 (94%). All 4 infants that failed facemask ventilation were successfully resuscitated with an LMA. There were no differences in the demographic characteristics of the two groups or outcome measures (length of stay, admission to NICU, primary diagnosis, Apgar score). The author's indicate in Table 1 that the LMA was successful in all 74 infants, however, the text indicates that the LMA was not successful in one infant that required endotracheal intubation. The author's table indicates a lower "failure" rate with the LMA, however, when corrected for the infant that required tracheal intubation, there is no difference between the groups.

A portion of the patients included in this study (those delivered in 2000) are also reported in Zanardo, 2004.


**Comment:** (LOE 2, Fair, Supportive, No comment regarding industry funding)

This retrospectively assembled cohort study compares infants delivered by elective cesarean section at term (cases) with a matched group delivered vaginally during a 3-year period at a single institution. The authors identified infants from each group that received positive pressure ventilation for delivery room resuscitation. In addition, the
authors compared the infants resuscitated in both groups with an LMA to those resuscitated with an ETT. At the author's institution, the LMA is used as the primary device for PPV in place of a fac-mask. Infants delivered by elective cesarean section without labor were more likely to receive positive pressure ventilation at birth (OR 1.26). In total, the LMA was used for resuscitation in 43 infants and was "successful" in 42/43. The authors comparisons of Apgar scores, NICU admission, and requirement for mechanical ventilation between the LMA and ETT resuscitated infants (n=18) are subject to significant selection bias because the resuscitating physician presumably selected the ETT as the primary airway device for sicker infants. Although the authors state that AAP/NRP guidelines for resuscitation were followed, an ETT is not the recommended primary airway device except among infants with diaphragmatic hernias. It is not clear why the resuscitator would have chosen intubation rather than LMA or facemask ventilation and limits the ability to generalize these results to other institutions.

The patients resuscitated by LMA in this study are also included in the larger study reported by Trevisanuto, 2004. This study compares the subjects to a unique control group.

Additional References: Case Series and Case Reports


Reason for Exclusion: Letter to the editor describing a single patient, LMA as a conduit for intubation in OR
Comment: 3-wk old with micrognathia, anesthetized for PDA ligation in OR, 3.0 mm ETT placed over fiberoptic bronchoscope in OR. The patient was unstable after OR and the ETT and LMA (deflated) were left in place for 8 days. There was no apparent injury when the oropharynx was examined following removal of the LMA.


Reason for Exclusion: Single case report, LMA used as a conduit for bronchoscopic intubation
Comment: This case describes the LMA placed following unsuccessful direct laryngoscopy and rigid bronchoscopy during an EXIT (ex utero intrapartum treatment) procedure at 37 weeks gestation (2075 gm) for a fetus with a known difficult airway (dysgnathia complex). The the fetal head was delivered through a hysteroscopy with intact placental circulation and the size-1 LMA placed. A fiberoptic bronchoscope, loaded with two 3.0 mm tracheal tubes, was placed through the LMA and the delivery was completed. A tracheostomy was placed 4 hours after delivery.


Reason for Exclusion: Letter to the editor, single case report
Comment: Brief letter describing a 3-day old, 3.2 kg, full-term male with Pierre-Robin who developed airway obstruction and cyanosis in the hospital. He remained severely desaturated and bradycardic despite bag-mask ventilation with an oral airway with poor chest rise and gastric distension. Endotracheal intubation was unsuccessful by the anesthesia team. A size-1 LMA was inserted easily and successfully resuscitated the infant. No details regarding skill level of the resuscitators, circumstances leading up to the event, or adverse outcomes. Supports using the LMA for newborns with difficult airways during resuscitation. (Rescue Airway)


Reason for Exclusion: Single case report, letter to the editor
Comment: Brief letter describing an 800 gm, 24 wk EGA newborn delivered in a rural hospital (Australia) distant from skilled neonatal resuscitators and without small neonatal endotracheal tubes. Failed bag-mask ventilation. Unconventionally managed with a 14-gauge venous catheter placed through the vocal cords because there were no small endotracheal tubes available. An attempt at ETT was made when a pediatrician arrived at 1 hour of age, but was complicated by bradycardia. A size-1 LMA with an un-inflated cuff was successfully placed and epinephrine
was instilled through the tube resulting in successful ventilation and resuscitation. The infant died at 5 hours. This is the only reported case of epinephrine instillation through a LMA during neonatal resuscitation and the smallest reported neonate successfully ventilated with a LMA. No details regarding the experience or training of the pediatrician that attempted ETT and placed the LMA. (Rescue Airway)


Reason for Exclusion: Letter to the editor, single case report
Comment: Brief letter to the editor describing a 3.25 kg term neonate with respiratory distress (pneumonia?) who developed apnea and oxy-hemoglobin desaturation un-responsive to bag-mask ventilation during helicopter transport. Endotracheal intubation was not attempted because of physical environment limitations in the helicopter. A pediatric registrar inserted a size-1 LMA and the infant "pinned up rapidly" with positive pressure ventilation. The physician had successfully placed an LMA on one previous occasion. The LMA was removed after he became vigorous but was placed again when apnea recurred later during the flight. (Rescue Airway)


Reason for Exclusion: Single case report
Comment: This case report describes a 10 day old with Treacher Collins syndrome that was resuscitated with a LMA after other measures were unsuccessful. Airway obstruction recurred after the LMA had been left in place for 4 days. The medical team and parents decided to withdraw support. After the infant's death, fiberoptic laryngoscopy showed edema of the arytenoids with no other evidence of trauma or significant edema. The cause of airway obstruction with the LMA in place was not identified. Similar problems, however, have been identified with prolonged LMA use in an animal model (see Brietzke SE, Ann Otol Rhinol Laryngol 110(9); 2001). (Rescue Airway)


Reason for Exclusion: Letter to the editor, single case report
Comments: Brief letter describing a 2.75 kg, full-term female with Pierre-Robin with airway distress successfully resuscitated in the delivery room using a size-1 LMA after bag-mask ventilation and ETT failed. After initial resuscitation, she was managed with a NP airway and tongue tie, but developed airway distress again on DOL 3 and was successfully managed with a LMA after unsuccessful attempts at ETT. In the operating room, ETT with laryngoscopy was again unsuccessful as well as an attempt to place an intubating bougie blindly through the LMA. A tracheostomy was performed while anesthesia was administered through the LMA. No details about the skills and training of the delivery room resuscitators. (Rescue Airway)


Reason for Exclusion: Single case report
Comments: Preterm (35 wk, 1560 gm) with micrognathia who required resuscitation on the fourth day of life due to desaturation and bradycardia associated with myoclonus and apnea. The infant was resuscitated with a bag-mask device but couldn't be intubated by either the NICU staff or a pediatric anesthesiologist (> 3 attempts). A size-1 LMA was placed and positive pressure ventilation continued for 44 hours with a ventilator. The cuff was deflated every 12 hours. The infant did not require sedatives or muscle relaxants while receiving ventilation through the LMA. At 44 hours, an oro-tracheal tube was placed through the LMA using a fiberoptic bronchoscope and an intubating bougie. (Rescue Airway)


Reason for Exclusion: Small case series (2 subjects)
Comments: Case report describing 2 newborns (both 35 weeks EGA, 2.8 kg and 2.9 kg) on the first day of life with laryngotracheo-esophageal clefts that could not be effectively ventilated with a bag-mask or endotracheal tube. A size-1 LMA was successfully placed in both infants and achieved adequate ventilation during transport from their referring hospitals to a tertiary care center. No details are provided regarding the training or experience of the operator placing the LMA. The authors speculated that the shape of the LMA prevented it from sliding into the esophagus and, therefore, provided better ventilation than an endotracheal tube in the setting of a laryngotracheo-esophageal cleft. Both infants ultimately died of respiratory failure (2 days of age, 11 days of age). (Rescue Airway)


Reason for Exclusion: Letter to the editor, single case report

Comments: Brief letter to the editor further describing one of the subjects in Fraser's case report (Fraser, 1999 [A]). This 35-week gestation infant with a laryngotracheo-esophageal cleft was managed with a LMA and high frequency oscillator ventilation for 10 hours. The authors report that there was adequate chest wall movement without excessive leak around the cuff. This is the only reported case of the LMA used with a high frequency oscillator ventilator. Ultimately, the medical staff and family elected to withdraw support because of the complexity of his multiple anomalies.


Reason for Exclusion: Letter to the editor, single case report

Comments: Letter to the editor describing a 3.3 kg, 38 wk EGA with antenatally diagnosed severe retrognathia and cleft-palate suggestive of Pierre-Robin sequence. At birth the infant had "complete" airway obstruction. A size-1 LMA was "easily" placed in the delivery room. It is not stated if bag-mask ventilation or endotracheal intubation were attempted. The LMA was removed after the infant was transferred to the nursery but had to be replaced immediately secondary to respiratory distress. CPAP was applied to the LMA and was maintained for 4 days. The cuff was deflated every 6 hours. The infant then needed a nasopharyngeal tube for 1 month. (Rescue Airway)


Reason for Exclusion: Published only as letter to the editor

Comments: Brief letter describing a comparison between endotracheal intubation and LMA placement among 7 midwives and 4 pediatric residents using an intubating mannequin. Found that all subjects were able to place the LMA, but 4/7 midwives and 1/4 residents could not intubate the mannequin. Not clear how success was determined with the LMA, how much time was allowed for a single attempt, how many attempts were permitted. Not clear that success with the mannequin is equivalent to success during a live resuscitation. See larger manikin training study (Gandini, 2004).


Reason for Exclusion: Single case report

Comment: This case report describes a newborn (2.3 kg, 36-week gestation) with micrognathia, high arched palate and cleft tongue that required resuscitation in a rural hospital delivery room. Face-mask ventilation was initiated but was felt to be ineffective and the pediatrician attending the delivery was unable to place an endotracheal tube despite multiple attempts and was advised to place an LMA by the hospital anesthesiology provider. The attending pediatrician had never placed an LMA in a live patient. The anesthesia provider was not available to come to the bedside and verbally coached the pediatrician who successfully placed the LMA on the first attempt and immediately achieved effective ventilation. The patient was transferred with the LMA to a tertiary facility where a tracheostomy was performed. (Rescue Airway)

**Reason for Exclusion:** Letter to the editor  
**Comments:** Letter to the editor describing placement of the size-1 ProSeal LMA (PLMA), a modified LMA with gastric drainage, in a series of 12 newborns requiring delivery room resuscitation. Subjects weights ranged from 2.13-4.20 kg with gestational age ranging from 35-41 weeks. The laryngeal mask was placed successfully in all cases using the provided introducer and effective ventilation was achieved in all infants. Insertion time ranged from 10-25 seconds. The experience and training of the operators placing the PLMA is not described, however, based on previous publications it can be inferred that the operators already had significant experience placing an LMA. The PLMA may allow the resuscitator to use higher ventilating pressures because of its ability to drain/vent gastric contents.


**Reason for Exclusion:** Single case report  
**Comment:** This case report describes a 36 week, 2.8 kg male with an omphalocele that had persistent difficulty with ventilation and oxygenation both before and after surgical repair despite placement of an endotracheal tube. On the 2nd day of life, he had worsening oxygenation and hypercarbia, the endotracheal tube was removed and replaced with a size-1 LMA which resulted in improved ventilation and decreased air leak. Bronchoscopy through the LMA revealed a type IV laryngotracheo-esophageal cleft and ventilation through the LMA was continued as he was taken to the OR for repair.


**Reason for Exclusion:** Single case report, letter to the editor  
**Comments:** Letter to the editor describing a term (39 week gestation) male, 2300 gm, with mandibular hypoplasia, glossoptosis, and contractures who was cyanotic and bradycardic in the delivery room. He remained bradycardic despite bag-mask ventilation and endotracheal intubation was unsuccessful. A size-1 LMA was placed while the tongue was held with a Magill forcep. Positive pressure ventilation was continued through the LMA for 3 hours while diagnostic tests completed. Multiple anomalies were identified and the family elected to withdraw support. At autopsy, he had a micro-larynx and pharyngo-esophageal cleft. There was no trauma noted from the LMA. *(Rescue Airway)*


**Reason for Exclusion:** Small case series (2 subjects)  
**Comments:** This case series describes 2 newborns (36 weeks EGA/2.61 kg and 41 weeks EGA/2.37 kg) resuscitated with a size-1 LMA in the delivery room after bag-mask ventilation was found to be ineffective and endotracheal intubation was unsuccessful. The first infant was found to have choanal atresia. The referring physician placed the LMA. The report does not describe if this physician had previous experience or training in LMA placement. The transport team physician removed the LMA and successfully placed an orotracheal tube. The second infant had severe mandibular hypoplasia. Following delivery, bag-mask ventilation was ineffective and orotracheal intubation was unsuccessful. The resuscitator placed a nasopharyngeal tube without improvement in ventilation. A size-1 LMA was placed at 5 minutes of age and effective ventilation was achieved. No details were provided about the resuscitators previous experience or training in LMA placement. The transport team was also unable to place an orotracheal tube and transported the infant to a tertiary care center with the LMA in place. A nasotracheal tube was placed in the operating room over a fiber-optic bronchoscope by an otorhinolaryngologist at the tertiary care center. *(Rescue Airway)*


**Reason for Exclusion:** Letter to the editor, single case report
Comment: This case report describes a size-1 LMA used in conjunction with an intravenous catheter (placed orally through the glottis) for emergency airway management during cardiopulmonary resuscitation in a 3-day old (1188 gm) infant with subglottic stenosis. The infant was under anesthesia in the operating room undergoing jenjunectomy when the 2.0 mm ETT was accidently dislodged and re-intubation attempts had been unsuccessful. While an emergency tracheostomy was being prepared, an 18 gauge intravenous catheter was placed orally into the glottis to stent it open and ventilation was continued with the LMA. This is clearly an unusual case and describes a procedure that would be performed only by practitioners with advanced airway skills and additional equipment.


Reason for Exclusion: Single case report
Comment: The infant in this case (2.9 kg, 40 weeks EGA) had acute airway distress associated with Pierre-Robin sequence. She had been intubated twice in the newborn period with significant difficulty and complications. After her second extubation attempt, an LMA was placed electively and she was maintained in a prone position breathing spontaneously through the LMA for 6 days. The LMA was removed each day to relieve pressure on the mucosa of the hypopharynx and to assess her work of breathing. The infant in this case did not receive positive pressure ventilation through the LMA and did not require "resuscitation" at the time of its placement.


Reason for Exclusion: Duplicate report of same patients (Zanardo, Fetal Diagn Ther 2004, #54), no additional data regarding LMA

Additional References:


Reason for Exclusion: Practice guideline, no original data
Comment: Algorithm developed, primarily for anesthetized patients, by the American Society of Anesthesiologists Task Force on Management of the Difficult Airway, updated from the original version in 1992, following a systematic review. The ASA states that the algorithm is intended for patients of all ages. The LMA is recommended as the initial airway device if facemask ventilation and direct laryngoscopy are unsuccessful. Based on their review of 32 studies (including all age groups), the first attempt success rate with difficult airways is estimated at 90%.


Reason for Exclusion: Review article, no original data or subjects described


Reason for Exclusion: Systematic review describing < 2 randomized controlled trials
Comments: This systematic only considered randomized or quasi-randomized studies comparing the LMA with either bag-mask ventilation or endotracheal intubation for neonatal resuscitation. Observational studies were excluded. The authors identified a single RCT (Esmail, 2002) and concluded that there was insufficient evidence to compare the safety or efficacy of the LMA with bag-mask ventilation or endotracheal intubation. Based on supportive case series and the low likelihood that a randomized controlled trial could ever be performed to evaluate the LMA as a rescue airway, they recommended that the LMA be considered for resuscitation when both bag-mask ventilation and endotracheal intubation are unsuccessful.

**Reason for Exclusion:** Non-neonatal, OR use for anesthesia
**Comment:** This is the largest published pediatric case series describing LMA placement by trainee anesthesiologists for operative anesthesia in 1400 consecutive children. The reader cannot be absolutely certain how many of the subjects were neonates from the available data, however, 245 patients had a size-1 LMA (recommended for infants < 5kg) placed and their outcomes are separately reported. The size-1 LMA had the highest "problem" rate (22.4%). There are no details describing exactly what kind of problems were encountered. Overall, fewer problems were noted with increasing experience.


**Reason for Exclusion:** Systematic review with less than two randomized controlled trials.
**Comments:** Similar conclusions to the Cochrane Systematic Review (Grein, 2005)


**Reason for Exclusion:** Review article, no original data or subjects described