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[Intervention Review]

Laryngeal mask airway versus endotracheal tube for percutaneous dilatational tracheostomy in critically ill adults

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ABSTRACT

Background

Percutaneous dilatational tracheostomy (PDT) is one of the most common bedside surgical procedures performed in critically ill adults, on intensive care units (ICUs), who require long-term ventilation. PDT is associated with relevant life-threatening complications: Cuff rupture or accidental extubation may lead to hypoxia, aspiration or loss of airway. Puncture of the oesophagus, or creating a false passage during dilatation or replacement of the tracheostomy tube, can lead to pneumothorax or emphysema. Wound infections may occur which can cause mediastinitis, especially after creation of false passage or in early tracheotomized post-sternotomy patients after cardiac surgery. During the procedure, the patient's airway can be secured with an endotracheal tube (ETT) or a laryngeal mask airway (LMA). This is an updated version of the review first published in 2014.

Objectives

To assess the safety and effectiveness of LMA versus ETT in critically ill adults undergoing PDT on the ICU.

Search methods

We searched the following databases to 9 January 2018: Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE and Embase. We searched for reports of ongoing trials in the metaRegister of Controlled Trials (mRCT). We handsearched for relevant studies in conference proceedings of five relevant annual congresses. We contacted study authors and experts concerning unpublished data and ongoing trials. We searched for further relevant studies in the reference lists of all included trials and of relevant systematic reviews.

Selection criteria

We included randomized controlled trials (RCTs) that compared use of laryngeal mask airways versus endotracheal tubes in critically ill adults undergoing elective PDT in the ICU, without injuries to or diseases of the face or neck. We imposed no restrictions with regard to language, timing or technique of PDT performed.

Data collection and analysis

Two review authors independently assessed the eligibility and methodological quality of each study and carried out data extraction. Our primary outcomes were all-cause mortality, procedure-related mortality and tally of participants with one or more serious adverse events.

Where possible, we combined homogeneous studies for meta-analysis. We used Cochrane's 'Risk of bias' tool and used GRADE to assess the quality of evidence for key outcomes.

Main results

We included nine RCTs in this review involving 517 participants.

Studies had a high or unclear risk of bias. The main reason for this was low methodological quality or missing data, even after study authors were contacted. Study size was generally small, with a minimum of 40, and a maximum of 73 participants.

In one study (40 participants), three deaths in the LMA group and two deaths in the ETT group were reported, although none of the deaths were related to the procedure (very low-quality evidence).

Five studies (281 participants) reported on procedure-related deaths, stating that no procedure-related death occurred at all (very low-quality evidence).

It is uncertain whether there is a difference in the number of people experiencing one or more serious adverse event(s) between LMA and ETT (risk ratio (RR) 0.86, 95% confidence interval (CI) 0.41 to 1.80; 467 participants, 8 studies, very low-quality evidence).

The duration of the procedure may be shorter in the LMA group (mean difference (MD) -1.46 minutes, 95% CI -1.92 to -1.01 minutes; 6 studies, 324 participants, low-quality evidence).

However failure of procedure, as allocated by randomization, requiring conversion to any other procedure, may be higher in the LMA group (RR 2.82, 95% CI 1.22 to 6.52; 8 studies, 439 participants, low-quality evidence).

We did not find any clear evidence of a difference between ETT and LMA groups for all other outcomes. Only one study provided follow-up data for late complications related to the intervention, showing no clear evidence of benefit for any treatment group.

Authors' conclusions

Evidence on the safety of LMA for PDT is too limited to allow conclusions to be drawn on either its efficacy or safety compared with ETT. Although the LMA procedure may shorten the period during which the airway is insecure, it may also lead to higher conversion rates. Also, late complications have not been investigated sufficiently. These results are primarily based on single-centre trials with small sample sizes, and therefore the level of evidence remains low. Studies with low risk of bias focusing on late complications and relevant patient-related outcomes are necessary for definitive conclusions on safety issues related to this procedure. The dependency of the successful placement of a LMA on the type of LMA used should also be further assessed.

There are two studies awaiting classification that may alter the conclusions once assessed.

PLAIN LANGUAGE SUMMARY

Laryngeal mask airway versus endotracheal tube for percutaneous dilatational tracheostomy in critically ill adults

Review question

We compared different ways of securing patients' airways so that the patients can continue to be ventilated during planned opening of the trachea. This procedure is needed for adults hospitalized for a length of time in an intensive care unit (ICU) and continuing to require artificial ventilation. The use of a laryngeal mask airway was compared with the existing endotracheal tube in terms of the safety and effectiveness of the procedure.

Background

Critically ill adults in an ICU often require mechanical ventilation to help them to breathe. Initially they are ventilated using an endotracheal tube (ETT) placed in the trachea (windpipe). Patients receiving long-term ventilation may require a tracheostomy with the breathing tube placed directly into the trachea to avoid damage to the trachea and larynx by the ETT. An opening in the neck and trachea (tracheostoma) is created and a tracheostomy tube is then inserted into this opening to ventilate the patient. This procedure is known as percutaneous dilatational tracheostomy (PDT) and is one of the most common interventional bedside procedures performed in the ICU. PDT uses a cannula to puncture through the skin to reach the trachea, followed by widening (dilatation) of this access to place a tracheostomy tube in the trachea.

PDT enters a critical stage when the tracheal cannula is inserted and the previous means of breathing, through the ETT, is loosened in the trachea and then removed. Several complications can occur at this stage.

The ETT can be damaged and the patient may not receive sufficient oxygen, the contents from the stomach may enter the lungs causing a severe lung infection, the oesophagus may be damaged, and air may get into the space between the lungs and the chest wall, or tissues in the chest may become inflamed.

A laryngeal mask airway (LMA) is often used for general anaesthesia and can also be used during PDT. It is secured in the throat and does not have to be withdrawn during the PDT, although the seal of the LMA is not as effective as that of an ETT.

Study characteristics

The evidence is current to January 2018. We included nine randomized controlled trials (517 participants). The trials included between 40 and 73 participants.

Key results

Although use of the LMA procedure may shorten the period during which the airway is insecure, the procedure is more likely to have to be changed.

Only one small study of 40 participants reported the number of people who died from any cause during their stay in hospital, without any difference between treatment groups. No deaths were caused by the procedure itself in the five studies (281 participants) that reported this outcome. Eight studies reported the number of participants with one or more serious adverse events, showing no clear evidence of a benefit for a laryngeal mask airway or endotracheal tube (467 participants). Serious adverse events that occurred were irregular rhythm of the heart beat, low blood oxygen concentrations, accidental displacement of the ETT or LMA, damage of parts of the ETT, minor bleeding and reflux of swallowed food into the airways. Neither method was superior in terms of preventing any adverse event.

The duration of the procedure was clearly shorter in the laryngeal mask group, by well over a minute (6 studies, 324 participants). This benefit was associated with a higher risk of needing to change over to a different procedure (8 studies, 434 participants). Longer-term complications were not sufficiently investigated.

Quality of the evidence

We judged the quality of evidence to be very low or low because we could not obtain important information on the methods used to conduct these studies. We had serious concerns about study limitations, the small number of participants in the studies and the variation in findings within and between studies (imprecision). Most studies were limited in reporting on patient relevant outcomes. The first study was published in 2002 and techniques have improved over time since then.

SUMMARY OF FINDINGS

Summary of findings for the main comparison. Laryngeal mask airway (LMA) compared to endotracheal tube (ETT) for percutaneous dilatational tracheostomy in critically ill adults

LMA compared to ETT for percutaneous dilatational tracheostomy in critically ill adults

Patient or population: critically ill adults undergoing percutaneous dilatational tracheostomy
Setting: general or neurosurgical intensive care units in Germany, India, Italy, Spain, UK, Turkey
Intervention: LMA
Comparison: ETT

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Nº of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with ETT	Risk with LMA				
All-cause mortality during hospital stay	In the LMA group, three of 20 participants (15%) died. In the ETT group, two of 20 participants (10%) died. According to the study author, none of these deaths was related to the procedure.		-	40 (1 RCT)	⊕⊕⊕⊕ Very low ^a	
Procedure-related mortality during procedure or follow-up during hospital stay	Study population		-	281 (5 RCTs)	⊕⊕⊕⊕ Very low ^b	Not estimable. No event occurred in any study providing information
	See comment	See comment				
Tally of participants with one or more serious adverse event(s) during procedure or within 24 hours after procedure	Study population		RR 0.86 (0.41 to 1.80)	467 (8 RCTs)	⊕⊕⊕⊕ Very low ^c	Serious adverse events were: arrhythmia, desaturation, skin emphysema, accidental extubation, cuff puncture of ETT, displacement of LMA, minor bleeding and gastric distension with regurgitation
	173 per 1000	149 per 1000 (71 to 311)				
Duration of procedure (minutes)		MD 1.46 lower (1.92 lower to 1.01 lower)	-	324 (6 RCTs)	⊕⊕⊕⊕ Low ^d	The mean duration with ETT ranged from 5.9 to 26.65 minutes
Failure of procedure, requiring conversion to any other procedure	Study population		RR 2.82 (1.22 to 6.52)	439 (8 RCTs)	⊕⊕⊕⊕ Low ^e	
	28 per 1000	78 per 1.000 (34 to 180)				

***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; **ETT:** endotracheal tube; **LMA:** laryngeal mask airway; **MD:** mean difference; **RCT:** randomized controlled trial; **RR:** risk ratio.

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect

Moderate certainty: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

Low certainty: our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect

Very low certainty: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect

^aThis outcome was downgraded three levels to very low-quality of evidence due to serious concerns about study limitations and very serious concerns about imprecision. The study of [Fernandez-Ortega 2005](#) enrolled participants with an assigned number. Odd numbers correspond to LMA, and pairs to partial withdrawal of endotracheal tube. The study author stated that the list of randomly generated numbers was not visible/accessible for study staff enrolling participants before procedure of randomization. However, this sequence generation has a high risk of making treatment allocation very obvious to study staff.

^bThis outcome was downgraded three levels to very low-quality of evidence due to very serious concerns about study limitations and imprecision. Three studies providing information on procedure-related mortality had at least one aspect of a high risk of bias concerning random sequence generation ([Fernandez-Ortega 2005](#)), allocation concealment ([Fernandez-Ortega 2005](#); [Linstedt 2010](#)), incomplete outcome data ([Dosemeci 2002](#)), or blinding of outcome assessment ([Linstedt 2010](#)). Only five studies provided explicit information that no procedure-related death occurred.

^cThis outcome was downgraded three levels to low-quality of evidence due to very serious concerns about study limitations and imprecision. Three studies providing information on tally of participants with 1 or more serious event(s) had at least one aspect of a high risk of bias concerning random sequence generation ([Fernandez-Ortega 2005](#)), allocation concealment ([Fernandez-Ortega 2005](#); [Linstedt 2010](#)), incomplete outcome data ([Dosemeci 2002](#)), or blinding of outcome assessment ([Linstedt 2010](#)).

^dThis outcome was downgraded two levels to low-quality of evidence due to very serious concerns about study limitations. Four studies providing information on duration of procedure had at least one aspect of a high risk of bias concerning random sequence generation ([Fernandez-Ortega 2005](#)), allocation concealment ([Fernandez-Ortega 2005](#); [Linstedt 2010](#)), incomplete outcome data ([Dosemeci 2002](#); [Gründling 1998](#)), or blinding of outcome assessment ([Linstedt 2010](#)).

^eThis outcome was downgraded two levels to low-quality of evidence due to very serious concerns about study limitations. Four studies providing information on failure of procedure requiring conversion had at least one aspect of a high risk of bias concerning random sequence generation ([Fernandez-Ortega 2005](#)), allocation concealment ([Fernandez-Ortega 2005](#); [Linstedt 2010](#)), incomplete outcome data ([Dosemeci 2002](#); [Gründling 1998](#)), or blinding of outcome assessment ([Linstedt 2010](#)).

BACKGROUND

Description of the condition

Critically ill patients on the intensive care unit (ICU) often require prolonged respiratory support, protection of their airway or prolonged tracheobronchial suction. This can be done by translaryngeal intubation or by tracheostomy. Translaryngeal intubation is the first choice for ventilating critically ill patients, and is often sufficient for short-term ventilation. Despite a limited body of evidence (Bishop 1985; Walz 1998), it is common practice to perform tracheostomy in 10% to 41% of all critically ill patients during their stay on the ICU (Arabi 2004; Azevedo 2013; Confalneri 2001; Esteban 2000; Hong 2008; Kuebler 2013). This is with the intent of avoiding complications associated with long-term translaryngeal intubation, such as subglottic stenosis or laryngeal damage (Mallick 2010). A tracheostomy may also be beneficial with regard to security of the airway, need for sedation, length of stay on the ICU or incidence of ventilator-associated pneumonia (Arabi 2004; Brook 2000; Griffiths 2005).

Tracheostomy was originally performed by surgeons in the operating theatre. In 1985, Ciaglia invented the so-called percutaneous dilatational tracheostomy (PDT) as a bedside surgical procedure (Ciaglia 1985). The original technique, and some variants have become widely accepted (Ciaglia 1985; Freeman 2000; Griggs 1990; Silvester 2006).

Besides numerous procedure-specific risks associated with performing PDT (Mallick 2010), evidence from a Cochrane Review indicates that PDT compared with surgical tracheostomy significantly decreased rates of wound infections and stomatitis (moderate-quality evidence) and unfavourable scarring (low-quality evidence) (Brass 2016). However no significant difference was found for the rates of procedure-related mortality or serious, life-threatening intraoperative adverse events.

Patients undergoing PDT are ventilated by a respirator with an endotracheal tube (ETT), that has a blocked cuff to ensure positive-pressure ventilation. After relevant tracheal structures (thyroid cartilage and tracheal cartilage rings) are identified as supported by endotracheal visualization via bronchoscopy, the ETT is withdrawn and the trachea is punctured with a needle usually between the second and third tracheal cartilage ring. After aspiration of air and visualization by the bronchoscope to ensure tracheal placement of the needle, a guidewire is placed in the trachea (Byhahn 2000a).

Dilatation of the trachea can be done by using several dilators, as originally described by Ciaglia, or a single dilator, through the Ciaglia Blue Rhino technique (Byhahn 2000b). Other variants include dilatation with grooved Howard-Kelly forceps (Griggs 1990), or via a guidewire passing the vocal cords for placement of the tracheal cannula (Fantoni 1997).

After dilatation, a tracheal cannula is placed and blocked in the airway; its position is verified by bronchoscopy. After the tracheal cannula has been correctly placed, the translaryngeal airway device is removed.

Description of the intervention

During PDT the operator and the person who takes care of the translaryngeal airway have to compete for the patient's airway. The PDT procedure requires withdrawal of the existing ETT until the

cuff is visible at the vocal cords. Therefore, it has an associated risk of hypoventilation or even loss of airway, given that cuff rupture, insufficient cuff deflation or accidental extubation can occur at an early stage of PDT. Also, aspiration of gastric contents may occur due to deflation of the cuff before readjustment has been described (Westphal 1998). Other imminent risks include damage to the dorsal tracheal wall caused by the puncture needle as the result of suboptimal visualization and injuries that occur during dilatation, leading to severe complications such as mediastinitis (Linstedt 2010; Westphal 2002).

Strategies used to reduce these procedure-related complications tend to prevent insufficiency of an endotracheal cuff and to improve visibility of anatomical structures by improving illumination of the trachea through the bronchoscope. This might be achieved by replacing the ETT with a supraglottic airway device such as a laryngeal mask airway (LMA) before beginning the PDT.

How the intervention might work

Supraglottic airway devices such as LMAs are accepted and used for a variety of surgical procedures that require assisted or controlled ventilation of a patient (Brimacombe 1995). A pilot study and a case series have suggested the use of LMAs for PDT to avoid loss of a sufficient airway, as occurs when ventilation is provided with an ETT (Dexter 1994; Lyons 1995). Use of a LMA prevents cuff rupture because the LMA cuff is placed above the vocal cords and therefore above the site of puncture. It is also not necessary to deflate the cuff during the procedure or to withdraw the supraglottic airway device.

Although the immediate risks of an ETT might be prevented, other serious adverse events may occur instead by using a LMA, such as, gastric insufflation due to possible insufficient sealment of the oesophagus, aspiration or even loss of airway (Westphal 1998).

Why it is important to do this review

Tracheostomy, besides placement of arterial and central venous catheters is one of the most common surgical procedures in critically ill patients requiring long-term ventilation (Arabi 2004; Azevedo 2013; Confalneri 2001; Esteban 2000; Hong 2008; Kollef 1999; Kuebler 2013). PDT is generally associated with life-threatening complications, such as hypoxaemia due to a loss of airway, possibly causing fatal cardiac arrest. The incidence rate of severe adverse procedure-related events in non-obese patients undergoing PDT is reported to be 3% to 18% (Ambesh 2002a; Ambesh 2002b; Byhahn 2005; Cattano 2006; Dosemeci 2002; Freeman 2000). Some of these trials indicate that complication rates may be twice as high in patients ventilated with ETT as in those ventilated with LMA, but heterogeneity is evident among published randomized controlled trials (RCTs).

Although replacement of an ETT with a LMA can improve the visibility of structures and prevent accidental damage to the ETT cuff, aspiration during replacement of the ETT may limit the pressure of ventilation during the procedure, leading to hypoventilation.

This Cochrane Review assesses the safety and effectiveness of LMA versus ETT in performance of PDT.

OBJECTIVES

To assess the safety and effectiveness of LMA versus ETT in critically ill adults undergoing PDT on the ICU.

METHODS

Criteria for considering studies for this review

Types of studies

We included randomized controlled trials (RCTs) comparing the use of laryngeal mask airway (LMA) versus endotracheal tube (ETT) for securing the airway during performance of percutaneous dilatational tracheostomy (PDT). We imposed no general restrictions concerning the time of follow-up and applied no language restrictions.

We excluded quasi-randomized trials (e.g. those using alternate treatment allocation or allocation by date of birth).

Types of participants

We included critically ill adult participants on intensive care units (ICUs) (no restriction by speciality) undergoing elective PDT, without injuries to or diseases of the face or neck.

Types of interventions

We included elective PDT in ICU participants without restriction regarding different techniques of PDT.

In most cases, long-term ventilated patients will have a nasogastric tube inserted before the procedure is performed. Different approaches can be used to manage these tubes. Nasogastric tubes have to be removed for correct placement of LMAs, with the possibility of replacement when a LMA with a gastric tube drainage channel is used. They can be left in situ, or removed when an ETT is used. We applied no restrictions regarding selection of studies, but assessed the management of nasogastric tubes.

Types of outcome measures

Primary outcomes

1. All-cause mortality during hospital stay
2. Procedure-related mortality during procedure or follow-up during hospital stay
3. Tally of participants with one or more serious adverse event(s), during procedure, or within 24 hours after procedure

Secondary outcomes

1. Duration of procedure (minutes)
2. Failure of procedure, as allocated by randomization, requiring conversion to any other procedure
3. Time to extubation after tracheostomy (days)
4. Length of ICU stay after tracheostomy (days)
5. Length of hospital stay after tracheostomy (days)

6. Specific serious adverse events
 - a. Fatal loss of airway during procedure
 - b. Non-fatal loss of airway during procedure
 - c. Cardiac arrest during procedure
 - d. Aspiration pneumonia (confirmed by bronchoscopy) within 24 hours after procedure
 - e. Mediastinitis within 24 hours after procedure
 - f. Any other serious adverse event, as reported by study authors

Search methods for identification of studies

Electronic searches

We identified RCTs through literature searching with systematic and sensitive search strategies as outlined in Chapter 6.4 of the *Cochrane Handbook for Systematic reviews of Interventions* (Higgins 2011). We did not apply restrictions to language or publication status.

We searched the following databases for relevant trials.

1. Cochrane Central Register of Controlled Trials (CENTRAL; 2018, Issue 1).
2. MEDLINE (Ovid SP, 1984 to 9 January 2018).
3. Embase (Ovid SP, 1988 to 9 January 2018).

We developed a subject-specific search strategy in MEDLINE and used that as the basis for the search strategies in the other databases listed. Where appropriate, the search strategy was expanded with search terms for identifying RCTs. All search strategies can be found in [Appendix 1](#).

We searched for reports of ongoing trials in the metaRegister of Controlled Trials (mRCT), using the terms 'percutaneous tracheostomy' and 'laryngeal mask' (www.controlled-trials.com).

The search strategy was developed in consultation with the Information Specialist.

Searching other resources

We handsearched for relevant studies in conference proceedings of the International Symposium on Intensive Care and Emergency Medicine (ISICEM), the Annual Congress of the European Society of Intensive Care Medicine (ESICM), the Annual Congress of the Society of Critical Care Medicine (SCCM), the American Thoracic Society (ATS) Annual Meeting, and the Annual Meeting of the American College of Chest Physicians (ACCP). We conducted the latest search on 12 January 2018.

We scanned the reference lists and citations of included trials and any relevant systematic reviews identified in the *Cochrane Database of Systematic Reviews* (CDSR) for further references to additional trials. When necessary, we contacted trial authors for additional information.

We contacted study authors and experts concerning unpublished data and ongoing trials.

Data collection and analysis

Selection of studies

Two review authors (RS, MB) independently screened for titles and abstracts of each reference identified by the search. We recorded

the selection process in sufficient detail to complete a PRISMA flow diagram (Moher 2009). We independently used a predefined standardized data extraction sheet (see Appendix 2), as described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We resolved disagreements between review authors on trial selection by discussion.

Data extraction and management

Two review authors (RS, MB) independently extracted data from each included study using a predefined data extraction sheet and quality assessment form designed for this review, and in accordance with the requirements of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011), (see Appendix 2).

We resolved disagreements between review authors by discussion.

RS contacted all first authors of relevant trials for additional information by sending an individualized missing data form.

Assessment of risk of bias in included studies

The same review authors who extracted the data (RS, MB), independently assessed trial quality using the Cochrane 'Risk of bias' tool, described in Chapter 8 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We considered the following domains, among others.

1. Was the treatment allocation adequately randomized with concealment of allocation?
2. Were the outcome assessors blinded?
3. Were the numbers of dropouts and non-evaluable participants stated for each trial arm, and was the dropout rate less than 10%?
4. Was the analysis by intention-to-treat (ITT)?
5. Were baseline characteristics similar in the two groups?
6. How was the trial funded?

We discussed disagreements and reached consensus.

With regard to selective reporting, we screened the trial databases ClinicalTrials.gov (clinicaltrials.gov), and International Standard Randomized Controlled Trial Number (ISRCTN; www.isrctn.com) for study protocols of all included studies.

We considered a trial as having low risk of bias if all domains were assessed as adequate. We considered a trial as having high risk of bias if one or more domains were assessed as inadequate or unclear.

We reported the 'Risk of bias' table as part of the 'Characteristics of included studies' table and presented a 'Risk of bias' summary, which details all judgements made for all studies included in the review.

Measures of treatment effect

We present binary outcomes as risk ratios (RRs). We planned to calculate number needed to treat for an additional beneficial outcome (NNTB), and number needed to treat for an additional harmful outcome (NNTH), when appropriate. We present numerical comparisons as differences between means. For all measures of effect, we reported 95% confidence intervals (CIs) and

corresponding P values. We calculated P values for the subtotal RR using the Fisher test to avoid spurious (non-) significance in studies with small sample sizes or low numbers of events. We considered $P < 0.05$ to be statistically significant. In cases of statistical significance calculated by the Fisher test, but with an insignificant confidence interval (CI) (including the RR of 1), we computed 95% CIs additionally by using the methods described by Miettinen 1985 (CI-M) to obtain an estimate of CIs that is closer to the exact CI.

Unit of analysis issues

The standard unit of analysis in the review is the participant. Since none of the identified studies was a cluster-randomized trial, and cross-over trials did not meet our inclusion criteria, we had no issues with units of analysis.

Dealing with missing data

RS contacted the first authors of trials reporting incomplete information to request the missing information. If the author of such a trial did not respond within four weeks, we (RS, MB, TW) assessed whether the data were missing at random or were not missing at random, by discussion. Consensus was achieved by discussion in all cases.

If we considered data to be missing at random, we ignored missing data and analysed only available data. If we considered data not to be missing at random, we imputed missing data with replacement values to create worst- and best-case scenarios from which to explore the robustness of our findings.

Assessment of heterogeneity

We investigated clinical and statistical heterogeneity. If clinical heterogeneity was obvious, we did not perform a meta-analysis. We investigated statistical heterogeneity using I^2 statistics (Higgins 2003). We further explored heterogeneity by performing subgroup analyses.

Assessment of reporting biases

We did not assess reporting bias visually using a funnel plot because we included fewer than 10 studies in this review (Egger 1997).

Data synthesis

We conducted a meta-analysis of trials and subgroups using a random-effects model. In the case of clinical heterogeneity, we did not perform a meta-analysis (see Subgroup analysis and investigation of heterogeneity). When combining small studies with binary outcomes, we used inverse variance to calculate the estimate (RR). We present data in the form of forest plots. We assumed statistical significance to correspond to an $\alpha < 0.05$. For outcome measures, we report 95% CIs.

Subgroup analysis and investigation of heterogeneity

In the case of sufficient data, we planned to explore procedure-associated factors such as the chosen technique of PDT (e.g. Ciaglia, Griggs, PercuTwist) or handling of nasogastric tubes, ventilator-associated factors such as ventilation mode (e.g. pressure controlled versus volume controlled), physician-related factors such as experience or patient-related factors such as duration of ventilation before tracheostomy.

Two clinically experienced review authors (RS, MB) independently judged clinical heterogeneity before meta-analyses. They considered the underlying population, selection of participants, severity of disease, concurrent treatment, settings and outcome measures. In the case of divergence, discussion was allowed with a final vote by the first review author.

We investigated statistical heterogeneity using the I^2 statistic. We defined substantial statistical heterogeneity as an I^2 statistic with a value greater than 50%. If extreme levels of heterogeneity existed between studies (I^2 statistic > 80%), we intended to report the results of these studies individually and to explore heterogeneity using subgroup analyses.

Sensitivity analysis

We planned to perform sensitivity analyses to explore the influence of study quality as assessed by the 'Risk of bias' table. Furthermore, we planned to investigate the influence of trial size, funding source and use of a fixed-effect model by performing a sensitivity analysis.

'Summary of findings' table and GRADE

We created a 'Summary of findings for the main comparison' table using the five GRADE criteria (risk of bias, inconsistency, indirectness, imprecision and publication bias) (Guyatt 2008), to assess the quality of evidence (high, moderate, low, very low) relating to the studies that contributed data to the comparisons for each of the following five outcomes.

1. All-cause mortality during hospital stay.
2. Procedure-related mortality during procedure or follow-up during hospital stay.
3. Tally of participants with one or more serious adverse event(s) during procedure or within 24 hours after procedure.

4. Duration of procedure (minutes).
5. Failure of procedure, requiring conversion to any other procedure.

Two review authors (RS, MB) independently assessed quality of evidence. Disagreements were discussed to reach consensus. When we identified an issue that we considered to be serious in each of the five GRADE criteria, we downgraded the quality of evidence by one level, and when we considered the issue to be very serious, we downgraded the quality of evidence by two levels. Whenever we decided to downgrade the quality of evidence from the default high quality, we justified our decisions and described the level of downgrade in the footnotes of the table. We developed the 'Summary of findings' table using a web-based version of [GRADEpro GDT](#), according to the methods and recommendations described in Section 8.5 and Chapter 12 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011).

RESULTS

Description of studies

Results of the search

We reran the search in January 2018. After removing 94 duplicates, we retrieved a total of 690 references by our electronic searches. Handsearching resulted in two references, assessment of the reference lists of relevant studies and reviews in 133 references and searches of additional trial databases in five references, leading to 830 references in total, as shown in [Figure 1](#). Contact with experts did not result in additional studies or ongoing trials. We excluded 814 references because the title, the abstract or both did not fulfil our inclusion criteria.

Figure 1. Study flow diagram.

We sought the full texts of the remaining 16 references belonging to 15 studies. We excluded four because they were not randomized

controlled trials (RCTs) ([Cattano 2006](#); [Pratt 2011](#)), or did not compare endotracheal tube (ETT) versus laryngeal mask airway

(LMA) for percutaneous dilatational tracheostomy (PDT) (Carron 2010; Girgin 2007). Of the remaining 11 studies, we transferred two (Demirkiran 2016; ISRCTN27187981), to the section [Studies awaiting classification](#). We contacted the first author of Demirkiran 2016 to confirm that this publication met our inclusion criteria but received no answer until completion of this update. We had received an answer from the principal investigator of ISRCTN27187981, indicating that the study found in the trial database was completed but the data were not yet analysed. The remaining publications consisted of 10 records of nine studies. We included nine RCTs with 517 participants in this update. Of those nine RCTs, we added one new study in the 2018 update of this review (Price 2014).

Dealing with missing data

We tried to contact all authors of all included publications by sending them an individualized missing data contact form via email. Authors of three studies answered our request (Fernandez-Ortega 2005; Linstedt 2010; Price 2014). All three authors provided additional information that we used in the analysis of these studies.

Included studies

We included one new study in this updated review (Price 2014).

In total we included nine studies (517 participants) in this update (Ambesh 2002; DiPietro 2006; Dosemeci 2002; Fernandez-Ortega 2005; Gründling 1998; Kaya 2006; Linstedt 2010; Price 2014; Turkmen 2006).

Designs

All nine included studies had a randomized controlled, parallel-group design.

Eight of the nine studies compared only LMA versus ETT (Ambesh 2002; DiPietro 2006; Dosemeci 2002; Fernandez-Ortega 2005; Gründling 1998; Linstedt 2010; Price 2014; Turkmen 2006). One study compared LMA versus ETT versus cuffed oropharyngeal airway (COPA) (Kaya 2006). The endotracheal group was handled as a control group.

Further details are provided in the [Characteristics of included studies](#) tables.

Sample size

The number of participants evaluated in the studies ranged from 40 to 73. Two studies included a sample size of fewer than 50 participants (Fernandez-Ortega 2005; Gründling 1998), and seven studies enrolled 50 or more participants (Ambesh 2002; DiPietro 2006; Dosemeci 2002; Kaya 2006; Linstedt 2010; Price 2014; Turkmen 2006). Further details are provided in the ['Characteristics of included studies'](#) tables.

Population

The included trials exclusively assessed critically ill participants (e.g. with head injury, neurological disease, multi-trauma, sepsis, acute respiratory failure and/or chronic obstructive pulmonary disease). Five studies explicitly excluded participants with injuries to or diseases of the face or neck (Ambesh 2002; DiPietro 2006; Dosemeci 2002; Gründling 1998; Kaya 2006).

Seven studies enrolled men and women, although in general they enrolled more men (n = 216, 66%) than women (n = 111, 34%), (Ambesh 2002; Dosemeci 2002; Fernandez-Ortega 2005; Gründling 1998; Kaya 2006; Linstedt 2010; Price 2014). Gender information was missing for three participants in Linstedt 2010 because of withdrawal of consent and for four participants in Dosemeci 2002 as the result of dropouts. Two studies did not provide gender information (DiPietro 2006; Turkmen 2006). Participants' ages ranged from 16 in Price 2014 to 90 years in Gründling 1998, with a mean age between 42.1 in Dosemeci 2002 and 65.9 years in DiPietro 2006. Further details are provided in the ['Characteristics of included studies'](#) tables.

Setting

All included studies took place in either general or neurosurgical intensive care units (ICUs). Six studies enrolled participants in Europe (DiPietro 2006; Fernandez-Ortega 2005; Gründling 1998; Linstedt 2010; Price 2014; Turkmen 2006), and three enrolled participants in Asia (Ambesh 2002; Dosemeci 2002; Kaya 2006). We found no RCTs conducted in either North America, South America, Africa or Australia. Turkey conducted the largest number of studies (n = 3). All studies except Price 2014 were single-centre trials.

Further details are provided in the ['Characteristics of included studies'](#) tables.

Interventions

In the intervention group, ETT was replaced by LMA. Pro-seal LMA was used in two studies (Fernandez-Ortega 2005; Kaya 2006). LMA Supreme was used in one study (Price 2014), LMA Classic and single-use LMA were used in one study (Linstedt 2010). Three studies used LMA #4 for women and LMA #5 for men (DiPietro 2006; Kaya 2006; Linstedt 2010). Ambesh 2002 used LMA #3 for women and LMA #4 for men. Fernandez-Ortega 2005 used LMA #4 or #5 for men and LMA #3 or #4 for women, adapted according to their weight. Three studies did not provide information on either the type or size of the laryngeal masks (Dosemeci 2002; Gründling 1998; Turkmen 2006).

PDT was performed in different ways. Ambesh 2002 and Price 2014 used Ciaglia's technique (Ciaglia 1985). DiPietro 2006 used Blue Rhino technique (Byhahn 2000b). Four studies (Dosemeci 2002; Fernandez-Ortega 2005; Linstedt 2010; Kaya 2006), used Griggs method (Griggs 1990). Two studies did not provide explicit information about the technique of PDT used (Gründling 1998; Turkmen 2006).

The studies described different methods of handling the nasogastric tube during the procedure. In Dosemeci 2002, the nasogastric tube was suctioned and was left in place. In four studies, the nasogastric tube was removed before the procedure was begun (Ambesh 2002; DiPietro 2006; Fernandez-Ortega 2005; Linstedt 2010). The remaining studies did not provide information about the handling of nasogastric tubes.

Further details are provided in the ['Characteristics of included studies'](#) tables and in the [Effects of interventions](#) section.

Outcomes

Only one study assessed all-cause mortality (Fernandez-Ortega 2005). In the LMA group, three of 20 participants (15%) died. In the ETT group, two of 20 participants (10%) died. According to the

study author, none of these deaths were related to the procedure (Fernandez-Ortega 2005).

Five studies, including 281 participants, assessed procedure-related mortality (Dosemeci 2002; Fernandez-Ortega 2005; Kaya 2006; Linstedt 2010; Price 2014). No studies reported any procedure-related mortality.

Eight studies reported serious adverse events or absence of such events (Ambesh 2002; DiPietro 2006; Dosemeci 2002; Fernandez-Ortega 2005; Kaya 2006; Linstedt 2010; Price 2014; Turkmen 2006). The serious adverse event rate ranged between 0% in Linstedt 2010 and 33% in Ambesh 2002 (mean 14.8%) in the LMA group, and between 0% in Kaya 2006 and 50% in Fernandez-Ortega 2005 (mean 17.3%) in the ETT group.

All of the studies apart from Turkmen 2006, reported on the failure of the procedure, requiring conversion to another procedure. The failure rate of the procedure ranged between 2.9% in Kaya 2006 and 32% in Price 2014 in the LMA group and between 0% in Ambesh 2002, DiPietro 2006, Dosemeci 2002, Fernandez-Ortega 2005, and Kaya 2006 and 10% in Linstedt 2010 in the ETT group.

In five studies (DiPietro 2006; Dosemeci 2002; Gründling 1998; Kaya 2006; Linstedt 2010), the trial authors stated that the duration of procedure time to establishment of a secure airway ranged between 4.5 minutes (Dosemeci 2002; Kaya 2006), and 11 minutes (Linstedt 2010), in the LMA group and between 5.9 minutes (Dosemeci 2002), and 13 minutes (Linstedt 2010), in the ETT group. The longest duration of procedure was described in Fernandez-Ortega 2005, with a mean time of 30.45 minutes in the LMA group and 26.65 minutes in the ETT group.

Only one study reported on the length of ICU stay after tracheostomy, with 7.7 (3.9) days in the LMA group versus 6.9 (3.5) days in the ETT group (Fernandez-Ortega 2005).

Further details are provided in the 'Characteristics of included studies' tables and the Effects of interventions section.

Excluded studies

We excluded four studies after assessing the full text; two because they were not RCTs (Cattano 2006; Pratt 2011), and two because they did not compare use of LMAs versus ETT for PDT (Carron 2010; Girgin 2007). Further details are provided in the 'Characteristics of excluded studies' tables.

Ongoing trials

We identified no ongoing trials in our search.

Studies awaiting classification

There are two studies awaiting classification (Demirkiran 2016; ISRCTN27187981).

We are unable to confirm whether Demirkiran 2016 is a RCT. For this reason we have classified it as 'awaiting classification'. We will process the study in the update of this review as soon as we receive information on the study design.

We identified one study as potentially eligible in the mRCT (ISRCTN27187981). We contacted the principal investigator, who confirmed that the study was completed, but stated that trial data had not yet been analysed completely, and that no publication yet exists. We will assess this study in the update of this review as soon as we receive any publication or preliminary data.

For further details, see the table 'Characteristics of studies awaiting classification'.

Risk of bias in included studies

Regarding the risk of bias in included studies, we looked at the following four possible sources of bias: generation of the randomization sequence, allocation concealment, blinding and dropouts. We did not formally assess evidence of publication bias. Further details are provided in the 'Characteristics of included studies' tables and the 'Risk of bias' tables for each study.

For a graphical summary of the risk of bias components, see Figure 2 and Figure 3.

Figure 2. Risk of bias graph.

Figure 3. Risk of bias summary.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)
Ambesh 2002	+	?	+	?	?	?	?
DiPietro 2006	+	?	+	?	?	?	?
Dosemeci 2002	?	?	-	?	?	?	?
Fernandez-Ortega 2005	-	-	+	+	?	?	?
Gründling 1998	?	?	-	?	?	?	?
Kaya 2006	?	?	+	?	?	?	?
Linstedt 2010	+	-	+	+	?	?	-
Price 2014	+	+	+	+	+	?	?
Turkmen 2006	?	?	?	?	?	?	?

Allocation

Sequence generation and allocation concealment

We were able to obtain contact addresses for all corresponding authors or at least one other author of the included studies. We used the same contact procedures as for other missing data to contact these authors to request further details on random sequence generation and allocation concealment, as procedures of randomization and concealment were missing or incomplete in most included studies.

Two study authors answered these questions ([Fernandez-Ortega 2005](#); [Linstedt 2010](#)).

In [Fernandez-Ortega 2005](#), participants were enrolled consecutively by number, with odd numbers assigning participants to the LMA group. The study author stated that the list of numbers was not accessible to study staff enrolling participants before randomization. However, this sequence generation confers high risk of making treatment allocation very obvious to study staff. After internal consensus was reached, we judged the risk of bias for sequence generation and allocation of concealment as high.

[Linstedt 2010](#) stated that the computer-generated randomization list was visible to study staff enrolling participants before randomization. We therefore judged the risk of bias as high.

The method of generation of the randomization sequence was described in four of the studies. [Gründling 1998](#) used envelopes to allocate participants to treatment groups. However, regarding sequence allocation or concealment of allocation, it was not stated whether those envelopes were sealed and opaque. [Ambesh 2002](#) used a computer-generated table of random numbers. However risk of bias concerning allocation of concealment was unclear. [DiPietro 2006](#) used stratified block randomization, and [Linstedt 2010](#) and [Price 2014](#) used a computer-generated randomization list. [Price 2014](#) used opaque sealed envelopes. [DiPietro 2006](#) provided no information on concealment of allocation. Three studies did not provide information on generation of random sequence nor on concealment of allocation ([Dosemeci 2002](#); [Kaya 2006](#); [Turkmen 2006](#)).

Further details are provided in the 'Risk of bias' tables in the [Characteristics of included studies](#) section.

Blinding

None of the studies was described as 'double-blind' or implied double-blinding. All participants were sedated or unconscious during the procedure. Blinding was not possible for physicians responsible for securing the primary airway. However, during performance of PDT under sterile conditions, the face of the participant had to be concealed by sterile blankets, making it possible to blind physicians performing PDT. Also, outcome assessors for non-imminent adverse events were able to be blinded.

Outcome assessors were described as blinded for some outcomes in one study ([Fernandez-Ortega 2005](#)). In the study of [Linstedt 2010](#), outcome assessors were not blinded. In all other studies, it remained unclear whether assessors were blinded ([Ambesh 2002](#); [DiPietro 2006](#); [Dosemeci 2002](#); [Gründling 1998](#); [Kaya 2006](#); [Turkmen 2006](#)).

Further details are provided in the 'Risk of bias' tables in the [Characteristics of included studies](#) section.

Incomplete outcome data

The overall rate of participant dropout in eight of the included studies was 2.25% (10/444) ([Ambesh 2002](#); [DiPietro 2006](#); [Dosemeci 2002](#); [Fernandez-Ortega 2005](#); [Gründling 1998](#); [Kaya 2006](#); [Linstedt 2010](#); [Price 2014](#)). Dropout rates varied from 0% ([Ambesh 2002](#); [DiPietro 2006](#); [Fernandez-Ortega 2005](#); [Kaya 2006](#); [Price 2014](#)), to 6.9% ([Gründling 1998](#)). [Turkmen 2006](#) provided no information on dropout rates.

Six of the included studies analysed data on an ITT basis ([Ambesh 2002](#); [DiPietro 2006](#); [Fernandez-Ortega 2005](#); [Kaya 2006](#); [Linstedt 2010](#); [Price 2014](#)). We regarded studies as having low risk of bias if analysis was truly an ITT analysis with complete outcome data for participants analysed in the randomly assigned groups, or if dropout rates were < 10% and data from dropouts were explicitly included in the ITT analysis.

We judged studies to have an unclear risk of bias if the total number of participants randomly assigned was unclear ([Turkmen 2006](#)), and to have a high risk of bias if participants who failed to be ventilated with LMA or ETT were dropped out in general ([Dosemeci 2002](#); [Gründling 1998](#)). Patients who were dropped out for failure of procedure as allocated by randomization were included in [Analysis 1.3](#).

Further details are provided in the 'Risk of bias' tables in the [Characteristics of included studies](#) section.

Selective reporting

We contacted the corresponding authors of included studies to request data on outcomes not reported in their publications. With regard to selective reporting, we screened the trial databases ClinicalTrials.gov and International Standard Randomized Controlled Trial Number (ISRCTN) to look for published protocols of included studies. However, we did not find a previously published study protocol for any included study except [Price 2014](#).

Three study authors responded and stated that all outcomes within their studies were reported ([Fernandez-Ortega 2005](#); [Linstedt 2010](#); [Price 2014](#)). We judged these studies to have a low risk of reporting bias. We judged all other studies to have an unclear risk of reporting bias.

Further details are provided in the 'Risk of bias' tables in the [Characteristics of included studies](#) section.

Other potential sources of bias

We investigated whether funding or significant differences in baseline characteristics between treatment groups were reported in included studies. Only [Price 2014](#) reported on sources of funding, leading to a judgement of low risk of bias. We judged all other studies to have an unclear risk of bias concerning funding. Two studies did not report gender distribution and we judged them to have an unclear risk of bias concerning differences in baseline characteristics ([DiPietro 2006](#); [Turkmen 2006](#)). All other studies showed no significant differences in any baseline characteristics between treatment groups.

Details of other aspects that are likely to impact external validity or that may be sources of other bias are mentioned in the 'Risk of bias' tables provided in the [Characteristics of included studies](#) section.

Effects of interventions

See: [Summary of findings for the main comparison](#) Laryngeal mask airway (LMA) compared to endotracheal tube (ETT) for percutaneous dilatational tracheostomy in critically ill adults

Primary outcomes of this review

A summary of results is presented in [Summary of findings for the main comparison](#).

1. All-cause mortality during hospital stay

Only [Fernandez-Ortega 2005](#) assessed all-cause mortality. In the LMA group, three of 20 participants (15%) died. In the ETT group, two of 20 participants (10%) died. According to the study author, none of these deaths was related to the procedure ([Fernandez-Ortega 2005](#)).

We downgraded this outcome by three levels to very low-quality evidence. This was due to serious concerns about study limitations and very serious concerns about imprecision. Fernandez-Ortega and colleagues enrolled participants with an assigned number. Odd numbers correspond to LMA, and pairs to partial withdrawal of endotracheal tube. Fernandez-Ortega and colleagues stated that the list of randomly generated numbers was not visible/accessible for study staff enrolling participants before procedure of randomization. However, this sequence generation has a high risk of making treatment allocation very obvious to study staff.

2. Procedure-related mortality during procedure or follow-up during hospital stay

Five studies, including 281 participants, explicitly stated that no procedure-related deaths had occurred ([Dosemeci 2002](#); [Fernandez-Ortega 2005](#); [Kaya 2006](#); [Linstedt 2010](#); [Price 2014](#)).

We downgraded this outcome three levels to very low-quality evidence. This was due to very serious concerns about study limitations and imprecision. Three studies providing information on procedure-related mortality had at least one aspect of a high

risk of bias concerning random sequence generation ([Fernandez-Ortega 2005](#)), allocation concealment ([Fernandez-Ortega 2005](#); [Linstedt 2010](#)), incomplete outcome data ([Dosemeci 2002](#)), or blinding of outcome assessment ([Linstedt 2010](#)). Only five studies provided explicit information that no procedure-related death occurred. No event occurred in any study providing information.

3. Tally of participants with one or more serious adverse event(s), during procedure, or within 24 hours after procedure

Eight studies, including 467 participants, reported on tally of participants with one or more serious adverse event(s) ([Ambesh 2002](#); [DiPietro 2006](#); [Dosemeci 2002](#); [Fernandez-Ortega 2005](#); [Kaya 2006](#); [Linstedt 2010](#); [Price 2014](#); [Turkmen 2006](#)).

Combining all eight studies in a forest plot revealed no statistically significant differences in the ETT versus LMA group for tally of participants with one or more serious adverse event(s): risk ratio (RR) 0.86, 95% confidence interval (CI) 0.41 to 1.80; 467 participants, [Analysis 1.1](#), $P = 0.529$, very low-quality evidence.

We downgraded this outcome three levels to very low-quality evidence. This was due to very serious concerns about imprecision and study limitations. Three studies providing information on tally of participants with one or more serious event(s) had at least one aspect of a high risk of bias concerning random sequence generation ([Fernandez-Ortega 2005](#)), or allocation concealment ([Fernandez-Ortega 2005](#); [Linstedt 2010](#)), incomplete outcome data ([Dosemeci 2002](#)), or blinding of outcome assessment ([Linstedt 2010](#)).

Secondary outcomes of the review

1. Duration of procedure (minutes)

Seven studies, including 372 participants, reported on duration of procedure ([DiPietro 2006](#); [Dosemeci 2002](#); [Fernandez-Ortega 2005](#); [Gründling 1998](#); [Kaya 2006](#); [Linstedt 2010](#); [Price 2014](#)).

Combining all seven studies in a forest plot revealed a statistically significant reduction in duration of procedure in the LMA group compared with the ETT group: mean difference (MD) -1.46 minutes, 95% CI -1.91 to -1.01; 372 participants, [Analysis 1.2](#), $P < 0.00001$ ([Figure 4](#)), low-quality evidence.

Figure 4. Forest plot of comparison: 1 LMA versus ETT, outcome: 1.2 Duration of procedure.

Footnotes

(1) SD: N/A

We downgraded this outcome two levels to low-quality evidence (see [Summary of findings for the main comparison](#)). This

was due to very serious concerns about study limitations. Four studies providing information on duration of procedure

had at least one aspect of a high risk of bias concerning random sequence generation (Fernandez-Ortega 2005), allocation concealment (Fernandez-Ortega 2005; Linstedt 2010), incomplete outcome data (Dosemeci 2002; Gründling 1998), or blinding of outcome assessment (Linstedt 2010).

2. Failure of procedure, as allocated by randomization, requiring conversion to any other procedure

Eight studies, including 439 participants, reported on failure of procedure, requiring conversion to any other procedure (Ambesh 2002; DiPietro 2006; Dosemeci 2002; Fernandez-Ortega 2005; Gründling 1998; Kaya 2006; Linstedt 2010; Price 2014). In the LMA

group, ventilation was not possible after placing a LMA in 10.4% (23/222) of all patients leading to successful reintubation and continuation of PDT with ETT (n = 17), abandonment of PDT (n = 2) or study exclusion (n = 4). In the ETT group, ventilation during procedure sometimes was not possible leading to successful tube change (n = 3), successful placement of LMA (n=2) and continuation of PDT or study exclusion (n = 1).

Combining all eight studies in a forest plot revealed a statistically significant increase in the LMA group for failure of procedure, requiring conversion to any other procedure: RR 2.82, 95% CI 1.22 to 6.52; 439 participants, Analysis 1.3, P = 0.02 (Figure 5), low-quality evidence.

Figure 5. Forest plot of comparison: 1 Laryngeal mask airway (LMA) versus endotracheal tube (ETT), outcome: 1.3 Failure of procedure, as allocated by randomization, requiring conversion.

Based on low-quality evidence NNTH is 14, 95% CI 8.2 to 33.0 for failure of procedure, requiring conversion to any other procedure when using LMA instead of ETT for PDT.

We downgraded this outcome two levels to low-quality evidence (see Summary of findings for the main comparison). This was due to very serious concerns about study limitations. Four studies providing information on failure of procedure, requiring conversion, had at least one aspect of a high risk of bias concerning random sequence generation (Fernandez-Ortega 2005), allocation concealment (Fernandez-Ortega 2005; Linstedt 2010), incomplete outcome data (Dosemeci 2002; Gründling 1998), or blinding of outcome assessment (Linstedt 2010).

3. Time to extubation after tracheostomy (days)

None of the included studies assessed time to extubation after tracheostomy.

4. Length of ICU stay after tracheostomy (days)

In Fernandez-Ortega 2005, no statistically significant reduction in the duration of ICU stay after tracheostomy was reported when the LMA group was compared with the ETT group: mean duration 7.7 ± 3.9 days (LMA) versus 6.9 ± 3.5 days (ETT); RR 0.80, 95% CI -1.66 to 3.26, 35 participants, P = 0.52.

5. Length of hospital stay after tracheostomy (days)

None of the included studies assessed length of hospital stay after tracheostomy.

6. Specific serious adverse events

All studies, except Gründling 1998, reported on one or more serious adverse event(s) including arrhythmia, desaturation, skin emphysema, accidental extubation, cuff puncture of ETT, displacement of LMA, minor bleeding and gastric distension with regurgitation.

6a Fatal loss of airway during procedure

Three studies explicitly stated that no fatal loss of airway occurred (Fernandez-Ortega 2005; Linstedt 2010; Price 2014).

6b Non-fatal loss of airway during procedure

Six studies assessed non-fatal loss of airway (Ambesh 2002; DiPietro 2006; Dosemeci 2002; Fernandez-Ortega 2005; Kaya 2006; Linstedt 2010). Non-fatal loss of airway was reported in five of the studies (Ambesh 2002; DiPietro 2006; Dosemeci 2002; Fernandez-Ortega 2005; Linstedt 2010).

Combining all six studies revealed no statistically significant differences in the LMA versus ETT group for non-fatal loss of airway: RR 0.49, 95% CI 0.13 to 1.88; 344 participants, Analysis 1.4, P = 0.30, low-quality evidence.

In contrast to results on the outcome of failure of procedure requiring any other procedure, non-fatal loss of airway occurred more frequently in the ETT group (3/174 participants (1.7%) in LMA group versus 10/170 participants (5.8%) in ETT group); RR 0.49, 95% CI 0.13 to 1.88; 344 participants, Fisher test P = 0.30).

The only study reporting on non-fatal loss of airway in the LMA group was [Ambesh 2002](#). Most of all cases of non-fatal loss of airway in the ETT group (6/10) occurred in the [Fernandez-Ortega 2005](#) study, which may explain the longer duration of procedure, as mentioned above.

6c Cardiac arrest during procedure

Three studies explicitly stated that no cardiac arrests occurred during the procedure ([Fernandez-Ortega 2005](#); [Linstedt 2010](#); [Price 2014](#)); no other studies reported on cardiac arrest.

6d Aspiration pneumonia (confirmed by bronchoscopy) within 24 hours after procedure

In [Linstedt 2010](#), no aspiration pneumonia (confirmed by bronchoscopy) was noted within 24 hours after procedure in any treatment group. No other studies reported on aspiration pneumonia (as confirmed by bronchoscopy) within 24 hours after procedure in any treatment group.

6e Mediastinitis within 24 hours after procedure

Two studies explicitly stated that no mediastinitis occurred within 24 hours after procedure ([Fernandez-Ortega 2005](#); [Linstedt 2010](#)). No other studies reported on mediastinitis within 24 hours after procedure.

6f Any other serious adverse event, as reported by study authors

Five studies reported on any other serious adverse events ([Ambesh 2002](#); [Dosemeci 2002](#); [Fernandez-Ortega 2005](#); [Kaya 2006](#); [Price 2014](#)).

In the LMA group, 14 participants had other serious adverse events, such as gastric distension with regurgitation ($n = 2$), tracheal stenosis ($n = 1$), minor bleeding ($n = 1$), arrhythmia ($n = 1$), desaturation ($n = 6$) and skin emphysema ($n = 1$). In the ETT group, 16 participants had other serious adverse events, such as cuff rupture or impaled tube ($n = 7$), difficult placement of a tracheal cannula ($n = 6$), minor bleeding ($n = 2$) or tracheal stenosis ($n = 1$).

Combining all five studies reporting on any other serious event revealed no statistically significant differences in the LMA versus ETT group for any other serious adverse events: RR 0.86, 95% CI 0.18 to 4.09; 271 participants, [Analysis 1.4](#), $P = 0.84$, low-quality evidence.

Results of these five trials showed substantial statistical heterogeneity ($I^2 = 61\%$).

DISCUSSION

Summary of main results

Primary outcomes

All-cause mortality during hospital stay

Only one study provided information on all-cause mortality on the ICU, showing no clear evidence of a difference between the two treatment groups ([Fernandez-Ortega 2005](#)). Because a small sample size was included and little information was given, we were not able to draw further conclusions. We rated quality of evidence to be very low due to serious concerns about study limitations and very serious concerns about imprecision.

Procedure-related mortality during procedure or follow-up during hospital stay

Only five studies explicitly stated that no procedure-related deaths occurred ([Dosemeci 2002](#); [Fernandez-Ortega 2005](#); [Kaya 2006](#); [Linstedt 2010](#); [Price 2014](#)). No other studies explicitly reported on procedure-related mortality. We rated quality of evidence to be very low due to very serious concerns about study limitations and imprecision.

Tally of participants with one or more serious adverse events, during procedure, or within 24 hours after procedure

Eight studies assessed tally of participants with one or more serious adverse event(s) during procedure or follow-up showing no significant difference between the LMA and ETT group. In [Fernandez-Ortega 2005](#), a significant risk reduction was reported in the LMA group. In three studies, a non-significant reduction in serious adverse events was noted in the LMA group ([Dosemeci 2002](#); [Linstedt 2010](#); [Turkmen 2006](#)). Whereas, two studies showed a non-significant risk increase in the LMA group ([Ambesh 2002](#); [Kaya 2006](#)).

When exploring this heterogeneity, we found that [Ambesh 2002](#) was the only study regularly using LMA #3 in women and LMA #4 in men. We asked all contact authors to provide information on participants' weight, as the participants in [Ambesh](#) and colleagues' study may have had lower weight than all other participants. [Ambesh 2002](#) reported on participants' body mass index (BMI), which was 22 ± 1.6 in the LMA group and 23 ± 1.8 in the ETT group. However, we only received a reply from one study author concerning participants' weight ([Fernandez-Ortega 2005](#)).

[Ambesh 2002](#) was the first RCT undertaken to explore this topic. As both LMA devices and PDT techniques have advanced, the results of [Ambesh](#) and colleagues' study may have a limited effect on daily practice. But even if the studies of [Ambesh 2002](#), [Kaya 2006](#) and [Price 2014](#) were excluded, the overall effect would be non-significant, as presented in the best-case scenario subgroup analysis: RR 0.54, 95% CI 0.24 to 1.01; 292 participants, $P = 0.06$, low-quality evidence. Also subgroup analyses of method of PDT comparing Ciaglia's technique and Griggs method revealed no significant differences between LMA and ETT. This is probably due to the small sample sizes. However an increase in the number of studies might lead to significant results. We rated quality of evidence to be low due to very serious concerns about study limitations.

Secondary outcomes

Duration of procedure

Seven studies provided information on duration of procedure ([DiPietro 2006](#); [Dosemeci 2002](#); [Fernandez-Ortega 2005](#); [Gründling 1998](#); [Kaya 2006](#); [Linstedt 2010](#); [Price 2014](#)), showing a significant mean reduction of duration of 1.46 minutes (95% CI reduction 1.91 to 1.01 minutes; 324 participants, $P < 0.00001$) ([Figure 4](#)), low-quality evidence.

In four studies, the mean duration of procedure was less than 10 minutes in both treatment groups ([DiPietro 2006](#); [Dosemeci 2002](#); [Gründling 1998](#); [Kaya 2006](#)). The mean duration of procedure in the study of [Linstedt 2010](#) was 11 and 13 minutes, possibly related to the study design, which focused on visibility of structures with assessments of visibility during the procedure. [Fernandez-Ortega](#)

2005 reported a mean duration between 26 and 30 minutes, which was four times longer than that reported in the other studies. We were not able to detect the reasons for this difference, which may be related to differences in the procedure performed, in the experience of the performing physicians or in defining the study period (e.g. including time of preoxygenation before performance of PDT).

Given the clinical relevance of this reduction, the procedure was shortened in the studies of DiPietro 2006, Dosemeci 2002 and Kaya 2006 by 13.6% to 36.6%. With regard to the critical phase of replacing an airway in intensive care participants with very limited capacities to compensate for hypoventilation, we judged this reduction to be clinically relevant. When Fernandez-Ortega 2005 was excluded from a sensitivity analysis, combining all other studies led to a significant mean reduction of duration of 1.48 minutes (95% CI reduction 1.98 to 1.02 minutes; 284 participants, $P < 0.00001$, low-quality evidence). We rated quality of evidence to be low due to very serious concerns about study limitations.

Failure of procedure, as allocated by randomization, requiring conversion to any other procedure

Eight studies assessed failure of procedure, as allocated by randomization, requiring conversion to any other procedure. There was a significant increase in the LMA group for failure of procedure requiring conversion to any other procedure (Ambesh 2002; DiPietro 2006; Dosemeci 2002; Fernandez-Ortega 2005; Gründling 1998; Kaya 2006; Linstedt 2010; Price 2014). Most of these outcomes occurred in the LMA group (23/222 participants (10.4%) versus 6/211 participants (2.8%) in the ETT group; RR 2.82, 95% CI 1.22 to 6.52; 439 participants, $P = 0.02$ (Figure 5), low-quality evidence). Only three studies reported on events in the control group (Gründling 1998; Linstedt 2010; Price 2014). In five of six cases, tracheostomy was successfully performed by reintubating the participant or by faster completion of the procedure intended to secure the participant's airway. One patient in the study of Gründling 1998 that could not be ventilated sufficiently during PDT was excluded from the study.

Most of those events occurred in the studies of Price 2014 ($n = 10$) and Ambesh 2002 ($n = 5$). Price 2014 used LMA Supreme compared to Linstedt 2010 using LMA classic and Fernandez-Ortega 2005 and Kaya 2006 using LMA ProSeal. There is some evidence from small RCTs that placing LMA ProSeal instead of LMA Supreme results in fewer manipulations necessary and higher seal pressure (Lopez 2011), but conflicting evidence also exists (Seet 2010). A recently published Cochrane Review compared ProSeal versus Classic LMA for positive pressure ventilation in adults undergoing elective surgery (Hoda 2017). Hoda and colleagues included eight randomized studies, involving a total of 829 participants. Hoda and colleagues stated that based on low-quality evidence, a ProSeal LMA makes a better seal than Classic LMA and may be more suitable for positive pressure ventilation (Hoda 2017). Since all studies reporting on failure of procedure, requiring conversion to any other procedure, reported on failure of placement of LMA, it is unlikely that the type of LMA used has significant influence on this outcome. However, Ambesh 2002, as described above, used smaller LMAs than any other included studies. This may explain the high event rate of unsuccessful placement of a LMA, in that achievement of pharyngeal sealment was more unlikely.

Also, use of LMA is limited due to several procedure-related contraindications like certain anatomical findings, obesity or lack

of experience of the operator. Since DiPietro 2006 reported an unsuccessful placement of LMA due to severe obesity, which can be regarded as a contraindication for placement of LMA, results might be limited because of invalid selection of patients. However, use of LMA during PDT is restricted to a smaller subgroup than PDT with ETT due to these procedure-related limitations. We rated quality of evidence to be low due to very serious concerns about study limitations.

Overall completeness and applicability of evidence

Due to a limited number of RCTs, with small sample sizes, we were not able to draw any conclusion on all-cause mortality or procedure-related mortality in this review. Evidence for other outcomes is limited and of low-quality. We were only able to identify studies conducted in Europe and Asia, although percutaneous dilatational tracheostomy (PDT), as well as use of laryngeal mask airways (LMAs), is not limited to these continents. We did not detect a single fatal adverse event in any of the included studies. The reason for this outcome could involve the small sample sizes of the studies. Another possible reason is publication bias. We were not able to assess publication bias visually by using a funnel plot because the number of studies was too small to allow valid results (Egger 1997). As the number of included studies in an update search will likely increase, we hope that we will be able to assess the risk of publication bias in an update search because we regard publication to have a significant impact on the validity of findings. As far as the study protocols have been presented, or procedures have been described sufficiently in the studies, they can be compared with daily practice by assessing monitoring, medication and techniques used. It is unclear in all except one study (Dosemeci 2002), how long participants were ventilated before the PDT was conducted. Limited evidence derived from observational studies (Carron 2010; Colice 1989; Santos 1994), suggests that long-term ventilation (> 7 days) increases the risk of laryngeal oedema, so the duration of ventilation before PDT might have an influence on outcomes, especially with regard to success rates of placement of a LMA for sufficient ventilation. Also, a Cochrane Review comparing early (< 10 days after tracheal intubation) versus late (> 10 days after tracheal intubation) tracheostomy showed lower mortality rates in the early as compared with the late tracheostomy group, although these findings are only based on moderate-quality evidence (Andriolo 2015). However, replacement of an ETT with a LMA requires experience in ventilating patients with supraglottic airways. Use of LMAs should be limited on ICUs to staff members who have gained previous experience in ventilating patients with LMAs.

Quality of the evidence

The quality of the included studies was variable. Random sequence generation had low risk of bias in four studies (Ambesh 2002; DiPietro 2006; Linstedt 2010; Price 2014), unclear risk of bias in four studies (Dosemeci 2002; Gründling 1998; Kaya 2006; Turkmen 2006), and high risk of bias in one study (Fernandez-Ortega 2005). Risk of bias concerning concealment of allocation was low in Fernandez-Ortega 2005 and Price 2014, high in Linstedt 2010 and unclear in the remaining included studies. We judged risk of bias due to incomplete outcome data to be high in two studies (Dosemeci 2002; Gründling 1998), as participants who were unable to ventilate by LMA were excluded from the study and from further analyses. Risk of bias was low in six studies (Ambesh 2002; DiPietro 2006; Fernandez-Ortega 2005; Kaya 2006; Linstedt 2010;

Price 2014), and unclear as the result of missing information in the remaining included studies. Risk of bias for selective reporting remained unclear in most of the studies because we received answers on our missing data contact forms from only three study authors (Fernandez-Ortega 2005; Linstedt 2010; Price 2014), and all of these studies were associated with low risk of bias for selective reporting. Blinding of outcome assessors was not described in most of the studies. Only Linstedt 2010 described that assessors were blinded for only some relevant outcomes, leading us to assume a high risk of bias in this study.

We downgraded the quality of evidence for all primary outcomes by three levels to very low-quality evidence, and all secondary outcomes mentioned in Summary of findings for the main comparison two levels to low-quality evidence, due to serious or very serious concerns about study limitations and/or imprecision.

Potential biases in the review process

For three studies (Fernandez-Ortega 2005; Linstedt 2010; Price 2014), we received additional information from the trial authors that moved some risk of bias domains from 'unclear' to 'low,' but in two studies (Fernandez-Ortega 2005; Linstedt 2010), risk of bias was set from 'unclear' to 'high' at least once. In all other studies, missing information led to unclear risk of bias, which may reflect underestimation of true risk of bias for some domains in some studies (e.g. some studies did not report on dropout rates at all, so we had to assume that dropout rates were zero, which may be untrue). Also, missing information on late complications might be caused by missing follow-up or selective reporting, which would limit our findings.

Agreements and disagreements with other studies or reviews

In 2011, Pratt and Bromilow (Pratt 2011a), published a critical literature appraisal for this clinical question following a search of Cochrane CENTRAL, which identified six RCTs, one cohort study (Sarkar 2010), seven case series studies and one retrospective study (Cattano 2006). The publication of Pratt 2011a identified all RCTs included in this review, except for three (Fernandez-Ortega 2005; Gründling 1998; Price 2014).

Pratt and Bromilow stated that replacing an ETT with a LMA before PDT can improve visibility of structures. Also, use of a bronchoscope is associated with less obstruction of the artificial airway because the lumina of LMAs are wider than those of ETTs. However, Pratt and Bromilow state that these advantages did not lead to fewer complications in the appraised RCTs because of small sample sizes and inconsistent follow-up among studies.

We agree with Pratt and Bromilow (Pratt 2011a), in nearly all aspects of their critical appraisal and support their final conclusion to not generally recommend routine use of LMA for PDT. However, by limiting the use of LMA to potentially low-risk patients (ventilated less than 7 days, with moderate ventilation parameters without increased risk for regurgitation; e.g. patients with ileus) for physicians who are experienced in the use of LMA combined with mandatory bronchoscopy, we regard placement of a LMA as the true alternative for securing airways during PDT.

AUTHORS' CONCLUSIONS

Implications for practice

Evidence on the safety of laryngeal mask airway (LMA) for percutaneous dilatational tracheostomy (PDT) is too limited to allow conclusions to be drawn on either its efficacy or safety compared with endotracheal tube (ETT). Although the LMA procedure may shorten the period during which the airway is insecure, it may also lead to higher conversion rates. As the result of small sample sizes, few events and lack of patient-relevant outcomes, the effect on patient safety, especially concerning late complications, is uncertain. There are two studies awaiting classification that may alter the conclusions once assessed.

Implications for research

Further studies comparing ETT and LMA in PDT should focus on patient safety in terms of acute and late complications, as well as all-cause mortality. Also, the method of PDT in patients with LMA should be investigated in multiarm trials. Investigators should report on duration of switch from ETT to LMA, associated complications and strategies that have or have not led to resolution of these problems. Studies investigating the amount of training necessary to rule out preventable adverse events should also be conducted. Investigation of risk factors for increased adverse events should identify patients suitable for PDT to confirm contraindications that are not yet evidence-based. The optimal primary airway (LMA or ETT) for this procedure might depend on certain risk profiles that have not yet been prospectively identified. As endpoints, such as all-cause mortality, will require a multifactorial design and a reasonable sample size to ensure sufficient power, multicentric approaches seem necessary for conducting significant studies.

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Strametz R, Pachler C, Kramer JF, Byhahn C, Siebenhofer A, Weberschock T. Laryngeal mask airway versus endotracheal tube for percutaneous dilatational tracheostomy in critically ill adult patients. *Cochrane Database of Systematic Reviews* 2014, Issue 6. [DOI: [10.1002/14651858.CD009901](https://doi.org/10.1002/14651858.CD009901)]

* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Ambesh 2002

Methods	This randomized, parallel-group study was conducted at a single centre in India.
Participants	<p>Investigators recruited 60 participants (30 in the intervention group; 30 in the control group) of both genders, 17 to 75 years of age, who received ventilatory support</p> <p>Demographics of included participants</p> <ol style="list-style-type: none"> 17 men and 13 women in ETT group; 19 men and 11 women in LMA group Mean age (range) in intervention group = 49 years (19 to 75 years) Mean age (range) in control group = 46 years (17 to 71 years) Disease status: COPD: ETT n = 7; LMA n = 6; ARF: ETT n = 8; LMA n = 10; Guillain-Barré syndrome: ETT n = 5; LMA n = 7; chest/abdominal trauma: ETT n = 3; LMA n = 2; stroke/head injury/coma: ETT n = 7; LMA n = 5 <p>Exclusion criteria of the trial</p> <ol style="list-style-type: none"> Unstable cervical spine Gross thyroid swelling Severe coagulopathies PEEP support > 5 cmH₂O
Interventions	<ol style="list-style-type: none"> In the intervention group, ETT was replaced with LMA #3 in women and LMA #4 in men, under cricoid pressure In the control group, ETT was withdrawn until the cuff was visible below the vocal cords. During the procedure, ETT was held by another person PDT was performed using Ciaglia's technique in both groups A night before PDT, nasogastric tube feeding was stopped. At start of the procedure, gastric contents were aspirated and nasogastric tube was removed before the procedure was begun
Outcomes	<ol style="list-style-type: none"> Serious adverse events: non-fatal loss of airway, extubation, displacement of LMA, gastric insufflation of air and regurgitation of gastric content, perforation of the cuff, impalement of ETT, intratracheal bleeding Failure of procedure, requiring conversion to any other procedure

Ambesh 2002 (Continued)

Notes	<p>The funding body was not declared; no declaration of interest was found.</p> <p>The first author was contacted for additional information and was sent an individualized missing data form, but did not reply.</p>
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Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomization was done using a computer-generated table of random numbers.
Allocation concealment (selection bias)	Unclear risk	No information was given on concealment of allocation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No dropouts were reported. ITT analysis was carried out.
Selective reporting (reporting bias)	Unclear risk	We contacted the corresponding author for additional outcome data but received no response within the time limit.
Other bias	Unclear risk	Funding body was not declared. No significant differences between ETT and LMA groups for baseline characteristics of participants
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants were sedated with midazolam (2 mg to 5 mg), sodium thiopental (200 mg to 300 mg), vecuronium (4 mg to 6 mg).
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	It was not stated whether outcome assessors were blinded.

DiPietro 2006

Methods	This randomized, parallel-group study was conducted at a single centre in Italy.
Participants	<p>Investigators recruited 60 participants (30 in the ETT group; 30 in the LMA group) of both genders, 18 to 75 years of age, in the inclusive period between January 2002 and June 2004, with prior written informed consent obtained</p> <p>Demographics of included participants</p> <ol style="list-style-type: none"> 1. Range = 18 to 75 years 2. Mean age in intervention group = 65.9 ± 12.3 years 3. Mean age in control group = 61.27 ± 15.95 years 4. Participants were presented with sepsis, pulmonary pathologies, neurological pathologies, polytrauma and non-traumatic and traumatic brain injuries (vascular) <p>Exclusion criteria of the trial</p> <ol style="list-style-type: none"> 1. Cervical spine instability 2. Extensive thyroid goitre 3. Serious alterations in coagulation 4. Participants requiring alveolar recruitment and elevated PEEP (> 12 cmH₂O)

DiPietro 2006 (Continued)

Interventions	<ol style="list-style-type: none"> 1. In the intervention group, ETT was replaced by LMA #4 for women and LMA #5 for men. 15 minutes before this procedure, 0.07 mg/kg of atropine was administered for the purpose of reducing secretions of the oropharynx 2. In the control group, ETT was replaced (size 8.5 for women and size 9 for men) before the beginning of the procedure in such a way that the point of the tube did not exceed the cricoid cartilage 3. PDT was performed using Blue Rhino technique in both groups
Outcomes	<ol style="list-style-type: none"> 1. Serious adverse event: non-fatal loss of airway 2. Duration of procedure 3. Failure of procedure requiring conversion to any other procedure
Notes	<p>The funding body was not declared; no declaration of interest was found.</p> <p>The first author was contacted for additional information and was sent an individualized missing data form, but did not reply.</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Participants were separated through computerized randomized sampling into 2 groups of 30.
Allocation concealment (selection bias)	Unclear risk	Participants were separated through computerized randomized sampling into 2 groups of 30. However, it was unclear whether randomization was concealed.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No dropouts were reported. ITT analysis was carried out.
Selective reporting (reporting bias)	Unclear risk	We contacted the corresponding author for additional outcome data but received no response within the time limit.
Other bias	Unclear risk	Funding body was not declared. Study authors provided no information on the sex of participants.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants were sedated (propofol 1.5 mg/kg to 2 mg/kg, fentanyl 2 µg/kg to 5 µg/kg, atracurium 0.5 mg/kg).
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	It was not stated whether outcome assessors were blinded.

Dosemeci 2002

Methods	This randomized, parallel-group study was conducted at a single centre in Turkey.
Participants	Investigators recruited 60 participants (30 in the ETT group; 30 in the LMA group) of both genders, 17 to 84 years of age, who required elective tracheostomy. Main indications for tracheostomy were prolonged endotracheal intubation and neurological impairment with an inability to protect the airway
Demographics of included participants	

Dosemeci 2002 (Continued)

1. 20 men and 10 women in ETT group; 19 men and 7 women in LMA group
2. Mean age (range) in intervention group = 42.1 ± 22.4 years (17 to 84 years)
3. Mean age (range) in control group = 47.1 ± 15 years (18 to 74 years)
4. Disease status: head injury: LMA group n = 8; ETT group n = 7; neurological disease: LMA group n = 6; ETT group n = 9; multi-trauma: LMA group n = 5; ETT group n = 3; sepsis and ARF: LMA group n = 4; ETT group n = 7; COPD: LMA group n = 3; ETT group n = 4

Exclusion criteria of the trial

1. Difficult tracheal intubation
2. Suspected pathology of the pharynx
3. Recent local radiation of the upper airway
4. Significant infection of the upper airway

Interventions	<ol style="list-style-type: none"> 1. In the intervention group, ETT was removed and was replaced with LMA 2. In the control group, the cuff of the ETT was deflated and was withdrawn until the cuff was visible at the vocal cords. The cuff was reinflated 3. PDT was performed using Portex one-step tracheostomy kits using a set of forceps 4. Nasogastric tube was suctioned and was left in place during the procedure
Outcomes	<ol style="list-style-type: none"> 1. Procedure-related mortality 2. Serious adverse events: non-fatal loss of airway, puncture of ETT cuff, extubation, tracheal stenosis, bleeding, difficult insertion of tracheostomy tube 3. Duration of procedure 4. Failure of procedure requiring conversion to any other procedure
Notes	<p>The funding body was not declared; no declaration of interest was found.</p> <p>The first author was contacted for additional information and was sent an individualized missing data form, but did not reply.</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Study authors did not provide information about this. We sought information but received no response.
Allocation concealment (selection bias)	Unclear risk	Study authors did not provide information about this. We sought information but received no response.
Incomplete outcome data (attrition bias) All outcomes	High risk	4 participants were lost to follow-up ($4/30 = 13.3\%$ in the intervention group, resulting in 56 participants evaluated (26 in the intervention group and 30 in the control group)) 2 participants (6.7%) dropped out because LMA could not be inserted. These events were not analysed in the LMA group as adverse outcomes.
Selective reporting (reporting bias)	Unclear risk	We contacted the corresponding author for additional outcome data but received no response within the time limit.
Other bias	Unclear risk	It was not stated how the trial was funded. No significant differences between ETT and LMA groups were noted in baseline characteristics of participants.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants were sedated with midazolam.

Dosemeci 2002 (Continued)

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	It was not stated whether outcome assessors were blinded.
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Fernandez-Ortega 2005

Methods	This randomized, parallel-group study was conducted at a single centre in Spain.	
Participants	<p>Investigators recruited 40 participants (20 in the ETT group; 20 in the LMA group) of both genders, 17 to 78 years of age; consecutive intubated adult patients in the ICU who required percutaneous tracheostomy</p> <p>Demographics of included participants</p> <ol style="list-style-type: none"> Median age: 55 years Mean age (range) in intervention group = 56.1 years (17 to 78 years) Mean age (range) in control group = 54.25 years (17 to 73 years) 67% of participants were men, 33% were women Mean weight in men = 76 kg (SD 5.8) Mean weight in women = 69 kg (SD 5.1) Disease status: low level of consciousness (48%), lung disease (25%), neuromuscular disease (20%), airway obstruction (7%) <p>Exclusion criteria of the trial</p> <ol style="list-style-type: none"> These were not reported 	
Interventions	<ol style="list-style-type: none"> In the intervention group, ETT was replaced with Pro-seal LMA #3 to 4 in women and LMA #4 to 5 in men In ETT group, ETT was laryngoscope-assisted partially withdrawn In LMA and ETT groups, nasogastric tube was not replaced. Before PDT, nasogastric tube was suctioned in both groups PDT was performed using guidewire/dilating forceps technique in both groups 	
Outcomes	<ol style="list-style-type: none"> All-cause mortality Serious adverse events: fatal loss of airway, non-fatal loss of airway, cardiac arrest during procedure, mediastinitis within 24 hours after procedure, extubation, torn cuff, bent guidewire, difficult insertion of tracheostomy tube Duration of procedure Failure of procedure requiring conversion to any other procedure Length of ICU stay after tracheostomy 	
Notes	<p>The funding body was not declared; no declaration of interest was found.</p> <p>The first author was contacted for additional information and sent an individualized missing data form, and gave additional information.</p>	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Participants were incorporated correlatively with an assigned number. Odd numbers correspond to LMA, and pairs to partial withdrawal of endotracheal tube.

Fernandez-Ortega 2005 (Continued)

Allocation concealment (selection bias)	High risk	Study author stated that the list of randomly generated numbers was not visible/accessible for study staff enrolling participants before procedure of randomization. However, this sequence generation has a high risk of making treatment allocation very obvious to study staff.
Incomplete outcome data (attrition bias) All outcomes	Low risk	All participants who were randomly assigned entered the trial. Nobody was excluded. ITT analysis was carried out.
Selective reporting (reporting bias)	Low risk	All outcomes were reported within the study, according to authors' responses.
Other bias	Unclear risk	Funding body was not declared. No significant differences in ETT versus LMA groups were noted for baseline characteristics of participants.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	It was not stated whether participants were sedated.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Outcome assessors were blinded to results of arterial blood gases and times of procedures.

Gründling 1998

Methods	This randomized, parallel-group study was conducted at a single centre in Germany.
Participants	<p>Investigators recruited 43 long-term intubated participants (22 in the ETT group; 21 in the LMA group) of both genders, 18 to 90 years of age, in the inclusive period between April 1996 and August 1996, who received elective percutaneous dilatational tracheostomy</p> <p>Inclusion criteria</p> <ol style="list-style-type: none"> 1. $\text{PaO}_2 > 100$ mmHg 2. $\text{PaCO}_2 < 45$ mmHg <p>(in participants with head injury < 35 mmHg) under intermittent positive-pressure ventilation (IPPV) with mean ventilation pressure < 25 mmHg and $\text{FiO}_2 = 1.0$</p> <p>Demographics of included participants</p> <ol style="list-style-type: none"> 1. 29 men and 14 women 2. Mean age (range) in intervention group = 49 years (19 to 90 years) 3. Mean age (range) in control group = 47 years (25 to 72 years) 4. Disease status: head injury: LMA group 5; ETT group 6; thorax trauma: LMA group 3; ETT group 1; poly-trauma: LMA group 3, ETT group 3; pancreatitis: LMA group 4; ETT group 3; peritonitis: LMA group 1; ETT group 3; pneumonia: LMA group 1; ETT group 4; brain tumour/bleeding: LMA group 2; ETT group 1; APACHE II score: LMA group 23 ± 5; ETT group 24 ± 6 <p>Exclusion criteria of the trial</p> <ol style="list-style-type: none"> 1. Intestinal obstruction 2. Last enteral ingestion < 6 hours 3. Haemorrhages of the mouth and nose 4. Unfavourable anatomical conditions

Gründling 1998 (Continued)

Interventions	<ol style="list-style-type: none"> 1. In the intervention group, ETT was replaced with LMA 2. In the control group, ETT was withdrawn until the cuff was visible at the vocal cords
Outcomes	<ol style="list-style-type: none"> 1. Duration of procedure 2. Failure of procedure requiring conversion to any other procedure
Notes	<p>The funding body was not declared; no declaration of interest was found.</p> <p>The first author was contacted for additional information and was sent an individualized missing data form, but did not reply.</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomization was done by sealed envelopes. It was not stated whether these envelopes were opaque.
Allocation concealment (selection bias)	Unclear risk	Randomization was done by sealed envelopes. It was not stated whether these envelopes were opaque.
Incomplete outcome data (attrition bias) All outcomes	High risk	2/21 (9.5%) dropouts were included in the intervention group, and 1/22 (4.5%) in the control group, resulting in 40 participants evaluated (19 in the intervention group and 21 in the control group). Dropouts in the LMA group also resulted from failure to place LMA (no ITT analysis).
Selective reporting (reporting bias)	Unclear risk	This was unknown. We contacted the corresponding author for additional outcome data but received no response within the time limit.
Other bias	Unclear risk	Funding body was not declared. No significant differences between ETT and LMA groups were noted for baseline characteristics of participants.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants were sedated with midazolam.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	It was not stated whether outcome assessors were blinded.

Kaya 2006

Methods	This randomized, parallel-group study was conducted at a single centre in Turkey.
Participants	<p>Investigators recruited 65 participants (30 in the ETT group; 35 in the LMA group) of both genders, 18 to 80 years of age, who received long-term intubation from the reanimation unit and the neurosurgical intensive care unit</p> <p>Demographics of included participants</p> <ol style="list-style-type: none"> 1. 22 men and 8 women in ETT group; 28 men and 7 women in LMA group 2. Mean age (range) in intervention group = 49.0 ± 17.4 years (18 to 79 years) 3. Mean age (range) in control group = 48.2 ± 17 years (18 to 80 years) 4. Disease status: APACHE II score in ETT group: 17.3 ± 5.1; in LMA group: 17.9 ± 8.1

Kaya 2006 (Continued)

Exclusion criteria of the trial

1. Local inflammation
2. Coagulopathy
3. Short-necked
4. Enlarged thyroid gland
5. Morbid obesity
6. Cervical trauma
7. Participants younger than 18 years old

Interventions	<ol style="list-style-type: none"> 1. In the intervention group, ETT was replaced with Pro-seal LMA. LMA #4 was used for women and LMA #5 for men 2. In the control group, ETT was withdrawn until the cuff was visible at the vocal cords 3. PDT was performed using Griggs method
Outcomes	<ol style="list-style-type: none"> 1. Procedure-related mortality 2. Serious adverse events: fatal loss of airway, non-fatal loss of airway, aspiration, minor bleeding, arrhythmia, skin emphysema, hypercapnia ($\text{CO}_2 > 45$ mmHg), oxygen saturation decreased to less than 96% 3. Duration of procedure 4. Failure of procedure requiring conversion to any other procedure
Notes	<p>The funding body was not declared; no declaration of interest was found.</p> <p>The first author was contacted for additional information and sent an individualized missing data form, but did not reply.</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Study authors did not provide information on this. We sought information but received no response.
Allocation concealment (selection bias)	Unclear risk	Study authors did not provide information on this. We sought information but received no response.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Analysis was carried out as ITT. No dropouts were reported.
Selective reporting (reporting bias)	Unclear risk	This was unknown. We contacted the corresponding author for additional outcome data but received no response within the time limit.
Other bias	Unclear risk	Funding body was not declared. No significant differences between ETT and LMA groups were noted for baseline characteristics of participants.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants were sedated with propofol 2 to 3 mg/kg, vecuronium 0.1 mg/kg and fentanyl 1 µg/kg, followed by propofol infusion 100 µg/kg/min.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	It was not stated whether outcome assessors were blinded.

Linstedt 2010

Methods	This randomized, parallel-group study was conducted at a single centre in Germany.
Participants	<p>Investigators recruited 66 participants (33 in the ETT group; 33 in the LMA group) of both genders</p> <p>Demographics of included participants</p> <ol style="list-style-type: none"> 18 men and 12 women in ETT group; 17 men and 16 women in LMA group Mean age (range) in intervention group = 55 ± 18 years (18 to 84 years) Mean age (range) in control group = 58 ± 15 years (18 to 77 years) Disease status: neurosurgery: ETT group n = 21; LMA group n = 25; trauma surgery: ETT group n = 2; LMA group n = 1; general surgery: ETT group n = 4; LMA group n = 6; medicine: ETT group n = 2; LMA group n = 1; neurology: ETT group n = 1, LMA group n = 0 For 3 participants in the control group, consent was withdrawn, resulting in 63 participants evaluated (33 in intervention group and 30 in control group) <p>Exclusion criteria of the trial</p> <ol style="list-style-type: none"> Difficult airway Potentially difficult endotracheal intubation Oxygenation index ($\text{PaO}_2/\text{fraction of inspired oxygen (FiO}_2\text{)} < 200$ mmHg (26 kPa) PEEP ≥ 15 mbar (15.3 cmH₂O)
Interventions	<ol style="list-style-type: none"> In the intervention group, LMA Classic (LMA Deutschland, Bonn, Germany) or single-use LMA (Solus, Teleflex, Medical, Kernen, Germany) was inserted behind the ETT. With the correct position of the LMA, the ETT was removed. LMA #4 was used for women and LMA #5 for men In the control group, first tracheal cartilage position was marked by palpation. The ETT (size 7.5 for men and size 7.0 for women) was positioned above the marked position. The ETT was held by an assistant PDT was performed using Griggs method (Portex Griggs-Set, Smiths Medical, Colonial Way, Watford, UK)
Outcomes	<ol style="list-style-type: none"> Procedure-related mortality Serious adverse events: fatal loss of airway, non-fatal loss of airway, cardiac arrest during procedure, aspiration, mediastinitis, damage to tracheal wall, damage to rear tracheal wall Duration of procedure Failure of procedure requiring conversion to any other procedure
Notes	<p>The funding body was not declared; no declaration of interest was found.</p> <p>The first author was contacted for additional information and sent an individualized missing data form, and gave additional information.</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomization was obtained by a computer-generated randomization list.
Allocation concealment (selection bias)	High risk	Computer-generated randomization list was visible/accessible to study staff enrolling participants before procedure of randomization
Incomplete outcome data (attrition bias) All outcomes	Low risk	ITT analysis was carried out. Three dropouts occurred because consent was withdrawn by relatives.

Linstedt 2010 (Continued)

Selective reporting (reporting bias)	Low risk	All outcomes were reported within studies, according to authors' responses.
Other bias	Unclear risk	Funding body was not declared. No significant differences between ETT and LMA groups were noted for baseline characteristics of participants.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants were sedated with sufentanil/midazolam.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Outcome assessors were not blinded.

Price 2014

Methods	This randomized, parallel-group study was conducted at three sites in the UK.
Participants	<p>Investigators recruited 50 participants (25 in the ETT group; 25 in the LMA group) of both genders, 16 to 83 years of age</p> <p>Demographics of included participants</p> <ol style="list-style-type: none"> 14 men and 11 women in ETT group; 13 men and 12 women in LMA group Mean age (range) in intervention group = 55 years (19 to 83 years) Mean age (range) in control group = 53 years (16 to 76 years) Disease status: APACHE II score in ETT group: 22 (8-41); in LMA group: 20 (10-31) <p>Exclusion criteria of the trial</p> <ol style="list-style-type: none"> Aged less than 18 years Patient or relative/welfare guardian refusal Treating clinician refusal
Interventions	<ol style="list-style-type: none"> In the Intervention group LMA Supreme was placed prior to PDT In the control group, ETT was withdrawn until the cuff was visible at the vocal cords PDT was performed using the Ciaglia single dilator technique under bronchoscopic guidance All patients in both groups had nasogastric tubes that were suctioned but left in situ during the procedure <p>There was no follow-up beyond the procedure itself.</p>
Outcomes	<p>Primary outcome measure</p> <p>Change in PaCO₂ levels between start of percutaneous tracheostomy procedure and completion of tracheostomy procedure</p> <p>Secondary outcome measures</p> <p>Measured during the procedure and immediately on completion of the procedure:</p> <ol style="list-style-type: none"> Desaturation less than 90% during procedure Repositioning of airway device during bronchoscopy Difficulty passing bronchoscope Repositioning of airway device during tracheostomy

Price 2014 (Continued)

5. loss of end-expiratory CO₂
6. Other complications
7. Duration of procedure

Notes	<p>ISRCTN23203142</p> <p>Funding body was declared:</p> <p>Edinburgh Anaesthesia Fund gave financial support and LMA Supremes were supplied free of charge by Intavent Ltd. UK</p> <p>Declaration of interest: "No competing interests declared"</p> <p>The first author was contacted for additional information and sent an individualized missing data form, and gave additional information.</p>
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Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomization was obtained by a computer-generated randomization list.
Allocation concealment (selection bias)	Low risk	Randomization was done by sealed opaque envelopes.
Incomplete outcome data (attrition bias) All outcomes	Low risk	ITT analysis was carried out
Selective reporting (reporting bias)	Low risk	Some outcomes assessed according to the protocol of the study (ISRCTN23203142) were not reported, but were provided on request.
Other bias	Low risk	Funding body was declared. No significant differences between ETT and LMA groups were noted for baseline characteristics of participants.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants were anaesthetised; no information is stated which drugs were used
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Outcome assessors were independent from staff performing PDT, but it was not stated whether they were blinded.

Turkmen 2006

Methods	This randomized, parallel-group study was conducted at a single centre in Turkey.
Participants	<p>Investigators recruited 73 participants (42 in the ETT group; 31 in the LMA group)</p> <p>Demographics of included participants</p> <ol style="list-style-type: none"> 1. Age of participants was not reported 2. Sex of participants was not reported 3. Disease status: critically ill participants 4. Unclear how many participants were lost to follow-up

Turkmen 2006 (Continued)

Exclusion criteria of the trial

1. These were not reported

Interventions	
Outcomes	1. Serious adverse events: not specified
Notes	The funding body was not declared; no declaration of interest was found. The first author was contacted for additional information and sent an individualized missing data form, but did not reply.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Study authors did not provide information about this. We sought information but received no response within the time limit.
Allocation concealment (selection bias)	Unclear risk	Study authors did not provide information about this. We sought information but received no response within the time limit.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Study authors did not provide information about this. We sought information but received no response within the time limit.
Selective reporting (reporting bias)	Unclear risk	This was unknown. We contacted the corresponding author for additional outcome data but received no response within the time limit.
Other bias	Unclear risk	It was not stated how the trial was funded. Study authors provided no information on the sex of participants.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	It was not stated whether participants were sedated.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	It was not stated whether outcome assessors were blinded.

Abbreviations and acronyms used in this table

APACHE: Acute Physiology and Chronic Health Evaluation

ARF: acute respiratory failure

COPD: chronic obstructive pulmonary disease

ETT: endotracheal tube

FiO₂: fraction of inspired oxygen

ICU: intensive care unit

ITT: intention-to-treat

LMA: laryngeal mask airway

PaCO₂: partial pressure of carbon dioxide in arterial blood

PaO₂: partial pressure of oxygen in arterial blood

PDT: percutaneous dilatational tracheostomy

PEEP: positive end-expiratory pressure

SD: standard deviation

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Carron 2010	This study did not compare ETT versus LMA for PDT, but researchers reported on the efficacy of LMA during PDT after short versus long tracheal intubation.
Cattano 2006	This study was not a randomized controlled trial.
Girgin 2007	This study did not compare ETT versus LMA for PDT, but researchers analysed the efficacy and safety of LMA versus COPA during PDT.
Pratt 2011	This study is not a randomized controlled trial.

Abbreviations and acronyms used in this table

COPA: cuffed oropharyngeal airway

ETT: endotracheal tube

LMA: laryngeal mask airway

PDT: percutaneous dilatational tracheostomy

Characteristics of studies awaiting assessment *[ordered by study ID]*

[Demirkiran 2016](#)

Methods	This trial was conducted in Turkey.
Participants	<p>Investigators recruited 50 participants (10 in the ETT group; 10 in the LMA group) of both genders</p> <p>Demographics of included participants</p> <ol style="list-style-type: none"> 5 men and 5 women in ETT group; 6 men and 4 women in LMA group Mean age (range) in intervention group = 58.47 ± 22.42 years Mean age (range) in control group = 58.61 ± 21.56 years <p>Exclusion criteria of the trial</p> <ol style="list-style-type: none"> These were not stated in publication
Interventions	ETT versus I Gel for tracheostomy
Outcomes	Total PDT time PaO ₂ /FiO ₂ ratio before and after procedure, PaO ₂ before and after procedure, MAP before and after procedure, leakage volume
Notes	<p>DOI: 10.1213/01.ane.0000492500.26426.09</p> <p>First author was contacted twice to confirm that this was a randomized controlled trial, but did not respond in time.</p>

[ISRCTN27187981](#)

Methods	This randomized controlled trial had a target number of 40 participants.
Participants	<p>Inclusive criteria of the trial</p> <ol style="list-style-type: none"> Intensive care unit patients <p>Exclusion criteria of the trial</p>

ISRCTN27187981 (Continued)

1. Not provided at time of registration

Interventions	ETT versus Pro-seal LMA for tracheostomy
Outcomes	1. Signs of aspiration 2. Duration 3. Blood gas at end of procedure
Notes	ISRCTN27187981 Principal investigator was contacted again via email for the update of the review. He stated that the study is completed, but data or final analysis are not yet available.

Abbreviations and acronyms used in this table

DOI: digital object identifier

ETT: endotracheal tube

FiO₂: fraction of inspired oxygen

LMA: laryngeal mask airway

MAP: mean arterial pressure

PaO₂: partial pressure of oxygen in arterial blood

PDT: percutaneous dilatational tracheostomy

DATA AND ANALYSES

Comparison 1. Laryngeal mask airway (LMA) versus endotracheal tube (ETT)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Tally of participants with 1 or more serious adverse events	8	467	Risk Ratio (M-H, Random, 95% CI)	0.86 [0.41, 1.80]
2 Duration of procedure	7	372	Mean Difference (IV, Random, 95% CI)	-1.46 [-1.91, -1.01]
3 Failure of procedure, as allocated by randomization, requiring conversion	8	439	Risk Ratio (M-H, Random, 95% CI)	2.82 [1.22, 6.52]
4 Specific serious adverse event	7		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
4.1 Non-fatal loss of airway	6	344	Risk Ratio (M-H, Random, 95% CI)	0.49 [0.13, 1.88]
4.2 Any other serious adverse event, as reported by study authors	5	271	Risk Ratio (M-H, Random, 95% CI)	0.86 [0.18, 4.09]

Analysis 1.1. Comparison 1 Laryngeal mask airway (LMA) versus endotracheal tube (ETT), Outcome 1 Tally of participants with 1 or more serious adverse events. **Analysis 1.2. Comparison 1 Laryngeal mask airway (LMA) versus endotracheal tube (ETT), Outcome 2 Duration of procedure.** **Analysis 1.3. Comparison 1 Laryngeal mask airway (LMA) versus endotracheal tube (ETT), Outcome 3 Failure of procedure, as allocated by randomization, requiring conversion.**

Analysis 1.4. Comparison 1 Laryngeal mask airway (LMA) versus endotracheal tube (ETT), Outcome 4 Specific serious adverse event.

APPENDICES

Appendix 1. Search strategies for CENTRAL, MEDLINE and Embase

Search strategy for CENTRAL, *The Cochrane Library*

#1 MeSH descriptor Tracheostomy explode all trees

#2 (pdt or tracheot* or tracheost*) or tracheostomy

#3 (#1 OR #2)

#4 MeSH descriptor Intubation, Intratracheal explode all trees

#5 MeSH descriptor Laryngeal Masks explode all trees

#6 ((larynx* near (tube* or mask*)) or LMA or (cuff* near oropharynx*) or COPA or ((supraglottic or epiglottic) near airway*) or (proseal or softseal or i-gel or (cobra near pl*)))

#7 (#4 OR #5 OR #6)

#8 (#3 AND #7)

Search strategy for MEDLINE (Ovid SP)

1. exp Tracheostomy/ or (pdt or tracheot* or tracheost*).ti,ab. or tracheostomy.sh.

2. exp Intubation, Intratracheal/ or exp Laryngeal Masks/ or ((larynx* adj2 (tube* or mask*)) or LMA or (cuff* adj3 oropharynx*) or COPA or ((supraglottic or epiglottic) adj3 airway*) or (proseal or softseal or i-gel or (cobra adj2 pl*))).mp.

3. 1 and 2

4. (randomized controlled trial or controlled clinical trial).pt. or randomized.ab. or placebo.ab. or drug therapy.fs. or randomly.ab. or trial.ab. or groups.ab.) not (animals not (humans and animals)).sh.

5. 3 and 4

Search strategy for Embase (Ovid SP)

1. exp tracheostomy/ or (pdt or tracheot* or tracheost*).ti,ab. or tracheostomy.sh.

2. exp endotracheal intubation/ or exp laryngeal mask/ or ((larynx* adj2 (tube* or mask*)) or LMA or (cuff* adj3 oropharynx*) or COPA or ((supraglottic or epiglottic) adj3 airway*) or (proseal or softseal or i-gel or (cobra adj2 pl*))).mp.

3. 1 and 2

4. (randomized-controlled-trial/ or randomization/ or controlled-study/ or multicenter-study/ or phase-3-clinical-trial/ or phase-4-clinical-trial/ or double-blind-procedure/ or single-blind-procedure/ or (random* or cross?over* or factorial* or placebo* or volunteer* or ((singl* or doubl* or trebl* or tripl*) adj3 (blind* or mask*))).ti,ab.) not (animals not (humans and animals)).sh.

5. 3 and 4

Appendix 2. Study selection, quality assessment and data extraction form

Laryngeal mask airway versus endotracheal tube for percutaneous dilatational tracheostomy in critically ill adults

Study selection, quality assessment and data extraction form

First author	Journal/Conference proceedings, etc	Year
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Study eligibility

RCT	Relevant participants	Relevant interventions	Relevant outcomes
	Critically ill participants on ICU (age 18 years and older)	Elective percutaneous dilatational tracheostomy (no restriction to certain technique)	<ul style="list-style-type: none"> ·All-cause mortality ·Procedure-related mortality ·Any serious adverse event ·Duration of procedure

(Continued)

- Failure of procedure requiring conversion to any other procedure
- Time to extubation after tracheostomy
- Length of ICU stay after tracheostomy
- Length of hospital stay after tracheostomy

Yes/No/Unclear	Yes/No/Unclear	Yes/No/Unclear	Yes/No/Unclear
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Do not proceed if any of the above answers is 'No.' If study is to be included in 'Excluded studies' section of the review, record below the information to be inserted into the 'Table of excluded studies.'

References to trial

Check other references identified in searches. If further references to this trial are identified, link the papers now and list below. All references to a trial should be linked under one study ID in RevMan.

Code each paper	Author(s)	Journal/Conference proceedings, etc	Year
	<i>Paper listed above</i>		
	<i>Further papers</i>		

Participant and trial characteristics

Participant characteristics

Further details

Age (mean, median, range, etc)

Sex of participants (numbers/%, etc)

Disease status/Type, etc (if applicable)

(Continued)

Other

Trial characteristics

Further details

Single centre/multicentre

Country/countries

How was participant eligibility defined?

How many people were randomly assigned?

Number of participants in each intervention group

Number of participants who received intended treatment

Number of participants who were analysed

Type of laryngeal mask used

Median (range) length of follow-up reported in this paper (state weeks, months or years, or not stated)

Handling of nasogastric tube

Time points when measurements were taken during the study

Time points reported in the study

Time points you are using in RevMan

Other

Methodological quality
Random sequence generation

State here method used to generate allocation and reasons for grading

Grade (circle)

Comment on allocation by review authors or included study

Low risk of bias (random)

quote concerning allocation

High risk of bias (e.g. alternate)

(Continued)

Unclear

Allocation concealment

State here method used to conceal allocation and reasons for grading	Grade (circle)
Comment on allocation concealment by review authors or included study quote concerning concealment of allocation	Low risk of bias
	High risk of bias
	Unclear

Blinding

Participant	Yes/No
Outcome assessor	Yes/No
Other (please specify)	Yes/No
Comment on blinding by review authors or included study quote concerning blinding	

Intention-to-treat

All participants entering trial
15% or less excluded
More than 15% excluded
Not analysed as 'intention-to-treat'
Unclear

Withdrawals

Were withdrawals described?	Yes/No/Unclear
Discuss if appropriate	

Data extraction

Outcomes relevant to your review

	Reported in paper (circle)
All-cause mortality	Yes/No
Procedure-related mortality	Yes/No
Serious adverse events	Yes/No
· Fatal loss of airway	Yes/No
· Non-fatal loss of airway	Yes/No
· Cardiac arrest during the procedure	Yes/No
· Aspiration (confirmed by bronchoscopy)	Yes/No
· Pneumonia within 24 hours after procedure	Yes/No
· Mediastinitis within 24 hours after procedure	Yes/No
· Any other serious adverse events as reported by study authors	Yes/No
Duration of procedure	Yes/No
Failure of procedure requiring conversion to any other procedure	Yes/No
Time to extubation after tracheostomy	Yes/No
Length of ICU stay after tracheostomy	Yes/No
Length of hospital stay after tracheostomy	Yes/No

For continuous data					
Code of paper	Outcomes (rename)	Unit of measurement	Intervention group		Control group
			n	Mean (SD)	n
	Duration of procedure	minute			
	Time to extubation after tracheostomy	days			
	Length of ICU-stay after tracheostomy	days			
	Length of hospital-stay after tracheostomy	days			

For dichotomous data

Code of paper	Outcomes (rename)	Intervention group (n) n = number of participants, not number of events	Control group (n) n = number of participants, not number of events
	All-cause mortality		
	Procedure-related mortality		
	Serious adverse events		
	Failure of procedure requiring conversion to any other procedure		

Other information which you feel is relevant to the results

Indicate if: any data were obtained from the primary author; if results were estimated from graphs etc; or calculated by you using a formula (this should be stated and the formula given). In general, if results not reported in paper(s) are obtained this should be made clear here to be cited in review.

Freehand space for writing actions such as contact with study authors and changes

References to other trials

Did this report include any references to published reports of potentially eligible trials not already identified for this review?

First author	Journal/Conference	Year of publication
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Did this report include any references to unpublished data from potentially eligible trials not already identified for this review? If yes, give list contact name and details

WHAT'S NEW

Date	Event	Description
9 January 2018	New search has been performed	<p>We added one new included study (Price 2014), and one new study is awaiting classification (Demirkiran 2016).</p> <p>Four authors (Johanna Kramer, Christoph Pachler, Christian Byhahn and Andrea Siebenhofer) left the team and one author (Martin Naoki Bergold) joined.</p> <p>We added the outcome, 'procedure-related mortality' to the 'Summary of findings' table.</p>
9 January 2018	New citation required and conclusions have changed	After inclusion of the Price 2014 study, the use of laryngeal mask airway is associated with statistically significant higher failure rates of the procedure leading to conversion.

CONTRIBUTIONS OF AUTHORS

Conceiving the review: Reinhard Strametz (RS)

Co-ordinating the review: RS

Undertaking manual searches: RS, Martin N Bergold (MB)

Screening search results: RS, MB

Organizing retrieval of papers: RS

Screening retrieved papers against inclusion criteria: RS, MB

Appraising quality of papers: RS, MB

Abstracting data from papers: RS, MB

Writing to authors of papers for additional information: RS

Providing additional data about papers: RS

Obtaining and screening data on unpublished studies: RS, MB

Managing data for the review: RS

Entering data into Review Manager (RevMan) ([Review Manager 2014](#)): RS

Handling RevMan statistical data: Tobias Weberschock (TW)

Performing other statistical analyses not using RevMan: TW

Interpreting data: RS, MB, TW

Making statistical inferences: RS, MB, TW

Writing the review: RS, MB, TW

Securing funding for the review: RS

Performing previous work that served as the foundation of the present study: Johanna Kramer, Christoph Pachler, Christian Byhahn, Andrea Siebenhofer

Serving as guarantor for the review (one review author): RS

Taking responsibility for reading and checking the review before submission: RS

DECLARATIONS OF INTEREST

Reinhard Strametz: none known

Martin N Bergold: none known

Tobias Weberschock: none known

SOURCES OF SUPPORT

Internal sources

- Wiesbaden Business School, RheinMain University of Applied Sciences, Wiesbaden, Germany.
Provision of infrastructure (e.g. Office, PC-/Web-Access)
- Evidence-Based Medicine Working Group, Institute for General Practice, Goethe University, Frankfurt am Main, Germany.
Provision of infrastructure (e.g. Database-Access)

External sources

- No sources of support supplied

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

We made the following differences to the protocol ([Strametz 2012](#)).

1. The search strategy was extended to handsearching of conference proceedings. This required more work than we originally anticipated; therefore Johanna Kramer joined the group of review authors for the 2014 review.
2. We identified four studies with at least one participant who was 16 or 17 years old ([Ambesh 2002](#); [Dosemeci 2002](#); [Fernandez-Ortega 2005](#); [Price 2014](#)) . After internal discussion, we decided to include these relevant studies because anatomical landmarks were very likely to be comparable with those of participants 18 years of age or older.
3. We did not perform subgroup analysis for airway devices, percutaneous dilatational tracheostomy (PDT) technique, handling of nasogastric tubes, ventilation mode, experience of physicians and duration of ventilation because information provided for most of the studies was incomplete.
4. We did not perform investigation of heterogeneity and sensitivity analysis because of unclear risk of bias in all studies, homogeneous trial sizes and missing information regarding funding.
5. We calculated P values for the subtotal risk ratio (RR) using the Fisher test to avoid spurious (non-) significance in studies with small sample sizes or low numbers of events. In cases of statistical significance calculated by the Fisher test, but with an insignificant confidence interval (CI) (including the RR of 1), we computed 95% CIs additionally by using the methods described by [Miettinen 1985](#) (CI-M) to obtain an estimate of CIs that is closer to the exact confidence intervals.

We made the following differences to the previous version of this review ([Strametz 2014](#)).

1. Four authors (Christoph Pachler, Johanna Kramer, Christian Byhahn and Andrea Siebenhofer) did not contribute to the 2018 update of this review and were removed from the list of authors.
2. Martin N Bergold joined the team of authors for the 2018 update of this review and provided substantive intellectual contributions that justify his inclusion as author.
3. We added the outcome, 'procedure-related mortality' for the 'Summary of findings' table.

INDEX TERMS

Medical Subject Headings (MeSH)

*Critical Illness; *Laryngeal Masks [adverse effects]; Dilatation [instrumentation]; Intubation, Intratracheal [adverse effects] [*instrumentation] [mortality]; Randomized Controlled Trials as Topic; Tracheostomy [adverse effects] [instrumentation] [*methods] [mortality]

MeSH check words

Adult; Humans