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Laryngeal mask airway versus endotracheal tube for percutaneous dilatational tracheostomy in critically ill adult patients (Review)

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

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ABSTRACT

Background

Percutaneous dilatational tracheostomy (PDT) is one of the most common bedside surgical procedures performed in critically ill adult patients on intensive care units (ICUs) who require long-term ventilation. PDT is generally associated with relevant life-threatening complications (e.g. cuff rupture leading to possible hypoxia or aspiration, puncture of the oesophagus, accidental extubation, mediastinitis, pneumothorax, emphysema). The patient's airway can be secured with an endotracheal tube (ETT) or a laryngeal mask airway (LMA).

Objectives

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

This review addresses the following research questions.

1. Is an LMA more effective than an ETT in terms of procedure-related or all-cause mortality?
2. Is an LMA safer than an ETT in terms of procedure-related life-threatening complications during a PDT procedure?
3. Does use of an LMA influence the conditions for performing a tracheostomy (e.g. duration of procedure)?

Search methods

We searched the *Cochrane Database of Systematic Reviews* (CDSR); the Cochrane Central Register of Controlled Trials (CENTRAL) 2013, Issue 6 (part of *The Cochrane Library*); MEDLINE (from 1984 to 27 June 2013) and EMBASE (from 1984 to 27 June 2013). We searched for reports of ongoing trials in the metaRegister of Controlled Trials (mRCT). 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) and the Annual Meeting of the American College of Chest Physicians (ACCP). We contacted study authors and experts concerning unpublished data and ongoing trials.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 identified in the *CDSR*. We reran the search in March 2017. Two potential new studies of interest were added to a list of 'Studies awaiting Classification' and will be incorporated into the formal review findings during the review update.

Selection criteria

We included randomized controlled trials (RCTs) that compared use of endotracheal tubes versus laryngeal mask airways in critically ill adult patients undergoing PDT on the ICU. 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. We resolved disagreements by discussion. Our primary outcomes were all-cause mortality, procedure-related mortality and tally of participants with one or more serious adverse events. When available, we reported on our secondary outcomes, which included duration of the procedure, failure of the procedure requiring conversion to any other procedure, time to extubation after tracheostomy, length of ICU stay after tracheostomy, length of hospital stay after tracheostomy and any other serious adverse events. When possible, we combined homogeneous studies for meta-analysis. We used the risk of bias tool of The Cochrane Collaboration to assess the internal validity of all included studies in six different domains.

Main results

We included in this review eight RCTs involving 467 participants. There are three studies awaiting classification

The included trials exclusively assessed critically ill participants (e.g. with head injury, neurological disease, multi-trauma, sepsis, acute respiratory failure (ARF) and/or chronic obstructive pulmonary disease (COPD)). Internal validity was considerably low in studies with 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. Only one study (40 participants) reported on overall mortality, showing no clear evidence of a difference between treatment groups (risk ratio (RR) 1.5, 95% confidence interval (CI) 0.28 to 8.04, Fisher test P value 1.0, low-quality evidence). Four studies (231 participants) reported that no procedure-related deaths occurred with any intervention. Seven studies reported the numbers of participants with adverse events, showing no clear evidence of benefit of either LMA or ETT during PDT (RR 0.73, 95% CI 0.35 to 1.52, P value 0.41, low-quality evidence). The tally of participants in included studies with adverse events ranged from 0% to 33% in the LMA group and from 0% to 50% in the ETT group. However, the duration of the procedure was significantly shorter in the LMA group (mean difference (MD) -1.46 minutes, 95% CI -1.92 to -1.01 minutes, 324 participants, P value ≤ 0.00001 , low-quality evidence). No clear evidence of a difference between ETT and LMA groups was found 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 its efficacy or safety compared with ETT. Although the LMA procedure is shorter because of optimal visual conditions, its effect on especially late complications has not been investigated sufficiently. Studies focusing on late complications and relevant patient-related outcomes are necessary for definitive conclusions on safety issues related to this procedure.

PLAIN LANGUAGE SUMMARY

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

Critically ill adult patients in intensive care units (ICUs) often require mechanical respiration. Initially, patients are ventilated using an endotracheal tube (ETT). However, patients receiving long-term ventilation often also require a tracheostomy. This procedure involves creating an opening in the neck and trachea, making it possible to circumvent the upper respiratory tract. A tracheostomy tube is then inserted into this opening. The aim of this procedure is to minimize complications such as scarred constrictions in the upper section

of the trachea or damage to the larynx. In 1985, percutaneous dilatational tracheostomy (PDT) was established as a bedside procedure and is now one of the most common surgical procedures performed on the ICU.

PDT enters a critical stage when the tracheal cannula is inserted and the former breathing device removed, as the cuff of the ETT that tightens the trachea has to be unblocked while the ETT is being withdrawn. During this phase, several complications may occur, such as accidental extubation, cuff rupture or aspiration of gastric contents. Studies have therefore investigated the usefulness of so-called laryngeal mask airways (LMAs) during PDT. This device is frequently used for general anaesthesia and, because it is blocked in the pharynx, it does not have to be withdrawn during PDT. This procedure is generally achieved without difficulty. Nevertheless, the seal of the LMA is not as effective as that of a blocked ETT and in a worst-case scenario may fail. For this reason, clinical studies have been performed to explore the use of LMA versus ETT with regard to effectiveness and safety in patients undergoing PDT.

The evidence is current to June 2013. We included eight randomized controlled trials (467 participants). All studies included between 40 and 73 participants. The internal validity of the studies was rather low because we could not obtain important information on the methods used to conduct these studies. Only one study reported the number of people who died, and the results were too uncertain for researchers to determine how use of ETT or LMA affected mortality. No procedure-related death was reported for any intervention. Some studies showed that fewer adverse events occurred when ETT was used and some reported fewer adverse events in the LMA group. Overall, neither method was superior in terms of preventing adverse events. However, the procedure was shorter when an LMA was used.

Use of an LMA may or may not reduce complication rates. On the basis of the limited number of patients investigated in clinical trials, it is not possible for researchers to draw any conclusions as to which procedure is superior in terms of the likelihood of occurrence of mortality and adverse events. However, use of LMA seems to shorten the duration of the procedure with improved visibility conditions for the physician, and this shortens the period during which the airway is insecure. This should be taken into account when critically ill patients require PDT. Additional studies may provide useful information and enable firm conclusions on the relative safety of LMA compared with ETT.

We reran the search in March 2017. We will deal with the two studies of interest when we update the review. In total there are three studies awaiting classification.

SUMMARY OF FINDINGS FOR THE MAIN COMPARISON *[Explanation]*

ETT versus LMA for percutaneous dilatational tracheostomy in critically ill adult patients						
Patient or population: patients with percutaneous dilatational tracheostomy in critically ill adult patients						
Settings:						
Intervention: ETT versus LMA						
Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	ETT versus LMA				
Overall mortality	Study population		RR 1.5 (0.28 to 8.04)	40 (1 study)	⊕⊕○○ low ¹	
	100 per 1000	150 per 1000 (28 to 804)				
	Moderate					
	100 per 1000	150 per 1000 (28 to 804)				
Tally of patients with one or more serious adverse events	Study population		RR 0.73 (0.35 to 1.52)	417 (7 studies)	⊕⊕○○ low	
	189 per 1000	138 per 1000 (66 to 287)				
	Moderate					
	200 per 1000	146 per 1000 (70 to 304)				

Duration of procedure	The mean duration of procedure in the intervention groups was 1.46 lower (1.92 to 1.01 lower)		324 (6 studies)	⊕⊕○○ low
Failure of procedure requiring conversion	Study population		RR 2.3 (0.56 to 9.39)	384 (7 studies) ⊕⊕○○ low
	16 per 1000	36 per 1000 (9 to 147)		
	Moderate			
	0 per 1000	0 per 1000 (0 to 0)		

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (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; RR: Risk ratio;

GRADE Working Group grades of evidence

High quality: Further research is very unlikely to change our confidence in the estimate of effect.

Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low quality: We are very uncertain about the estimate.

¹ Only one study provided explicit information on all-cause mortality

BACKGROUND

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) 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) (Ciaglia 1985) as a bedside surgical procedure. 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 performance of PDT (Mallick 2010), evidence indicates that PDT may reduce procedure-related complications compared with surgical tracheostomy (Cheng 2000; Delaney 2006; Dulguerov 1999; Freeman 2000; Higgins 2007).

Description of the condition

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 trachea is punctured with a needle usually between the second and third tracheal cartilage rings. 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 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 an 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 by using an LMA, other serious adverse events may occur instead, such as gastric insufflation, 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 relevant 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 an 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 systematic review assesses the safety and effectiveness of LMA versus ETT in performance of PDT.

OBJECTIVES

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

This review addresses the following research questions.

1. Is an LMA more effective than an ETT in terms of procedure-related or all-cause mortality?
2. Is an LMA safer than an ETT in terms of procedure-related life-threatening complications during a PDT procedure?
3. Does use of an LMA influence the conditions for performing a tracheostomy (e.g. duration of procedure)?

METHODS

Criteria for considering studies for this review

Types of studies

We included RCTs comparing the use of LMA versus ETT for securing the airway during performance of 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 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.

Long-term ventilated patients, in most cases, 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 an 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.
2. Procedure-related mortality.
3. Tally of participants with one or more serious adverse events.

Secondary outcomes

1. Duration of procedure.
2. Failure of procedure requiring conversion to any other procedure.
3. Time to extubation after tracheostomy.
4. Length of ICU stay after tracheostomy.
5. Length of hospital stay after tracheostomy.
6. Specific serious adverse events.
 - i) Fatal loss of airway.
 - ii) Non-fatal loss of airway.
 - iii) Cardiac arrest during procedure.
 - iv) Aspiration pneumonia (confirmed by bronchoscopy) within 24 hours after procedure.
 - v) Mediastinitis within 24 hours after procedure.
 - vi) Any other serious adverse event as reported by study authors.

Search methods for identification of studies

Electronic searches

We searched the Cochrane Central Register of Controlled Trials (CENTRAL) (see [Appendix 1](#) for the detailed search strategy) 2013, Issue 6 (part of *The Cochrane Library*), MEDLINE in Ovid SP (1984 to 27 June 2013) (see [Appendix 2](#)) and EMBASE in Ovid SP (1984 to 27 June 2013) (see [Appendix 3](#)) to identify relevant RCTs.

We reran the search in March 2017. We will deal with the two studies of interest when we update the review.

For this search, we used a combination of subject headings and text words related to percutaneous dilatational tracheostomy, endotracheal tube and laryngeal mask airway.

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).

We imposed no language restrictions.

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 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 reviews identified in the *Cochrane Database of Systematic Reviews* (CDSR).

Data collection and analysis

Selection of studies

Two of the following review authors (RS, JK, CP) independently screened for titles and abstracts of each reference identified by the search and applied the inclusion criteria. We independently used a predefined standardized data extraction sheet (see [Appendix 4](#)), 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 of the following review authors (RS, JK, CP) 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 4](#)).

We resolved disagreements between review authors by discussion. JK 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, JK, CP) 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 in the presence of a predetermined arbiter (CB) and reached consensus.

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 values ≤ 0.05 to be significant.

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 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.

Dealing with missing data

JK 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, CP, CB, AS, 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 replace-

ment 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 Cochran's test and computation of I^2 . We further explored heterogeneity by performing subgroup analyses.

Assessment of reporting biases

We did not assess reporting bias visually using a funnel plot because fewer than 10 studies were included 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. Significance was assumed 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 explored whether the outcome when a certain airway device was used depends on 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 vs volume controlled), physician-related factors such as experience or patient-related factors such as duration of ventilation before tracheostomy.

Two clinically experienced review authors 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 used the principles of the GRADE system (Guyatt 2008) to assess the quality of the body of evidence associated with the following specific outcomes.

1. All-cause mortality.
2. Procedure-related mortality.
3. Serious adverse events.
4. Duration of procedure.

In our review, we constructed a summary of findings (SoF) table using the GRADE software. The GRADE approach appraises the quality of a body of evidence according to the extent to which one can be confident that an estimate of effect or association reflects the item being assessed. The quality of a body of evidence is assessed by considering within-study risk of bias (methodological quality), directness of the evidence, heterogeneity of the data, precision of effect estimates and risk of publication bias.

RESULTS

Description of studies

Please see the '[Characteristics of included studies](#)', '[Characteristics of excluded studies](#)' and '[Characteristics of studies awaiting classification](#)' tables.

Results of the search

We reran the search in March 2017. After removing duplicates, we retrieved a total of 799 references, comprising references identified by our electronic searches (678), handsearching (one), assessment of the reference lists of relevant studies and reviews (115) and searches of additional trial databases (five), as shown in [Figure 1](#). Contact with experts did not result in additional studies or ongoing trials. We excluded 784 references because the title, the abstract or both did not fulfil our inclusion criteria.

Figure 1. 2 Study flow diagram.

We sought the full texts of the remaining 15 references. We excluded four because they were not RCTs (Pratt 2011; Cattano 2006) or did not compare ETT versus LMA for PDT (Carron 2010; Girgin 2007). Of the remaining 11 references, we transferred three studies found (ISRCTN27187981; Demirkan 2016; Price 2014) to the section [Studies awaiting classification](#). We had received an answer from principal investigators indicating that the study found in trial database was completed but the data were not yet analysed. Two potential new studies of interest, one of them already identified in the original review as completed but unpublished trial (Price 2014), were added to a list of 'Studies awaiting classification' and will be incorporated into the formal review findings during the review update. The remaining publications consisted of eight included studies, with 467 participants overall.

For a graphical summary, see [Figure 1](#).

Dealing with missing data

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

Included studies

Designs

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

Seven studies (Ambesh 2002; DiPietro 2006; Dosemeci 2002; Fernandez-Ortega 2005; Gründling 1998; Linstedt 2010; Turkmen 2006) compared only LMA versus ETT, and one study (Kaya 2006) compared LMA versus ETT versus cuffed oropharyngeal airway (COPA). 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 six studies enrolled 50 or more participants (Ambesh 2002; DiPietro 2006; Dosemeci 2002; Kaya 2006; Linstedt 2010; 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 (ARF) and/or chronic obstructive pulmonary disease (COPD)). The studies of Ambesh 2002; DiPietro 2006; Dosemeci 2002; Gründling 1998 and Kaya 2006 explicitly excluded patients with injuries to or diseases of the face or neck. Six studies (Ambesh 2002; Dosemeci 2002; Fernandez-Ortega 2005; Gründling 1998; Kaya 2006; Linstedt 2010) enrolled men and women, although in general they enrolled more men (n = 216, 66%) than women (n = 111, 34%). 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 (DiPietro 2006; Turkmen 2006) did not provide gender information. Participants' ages ranged from 17 (Ambesh 2002; Dosemeci 2002; Fernandez-Ortega 2005) to 90 (Gründling 1998) years, with a mean age between 42.1 (Dosemeci 2002) and 65.9 (DiPietro 2006) years. Further details are provided under [Characteristics of included studies](#).

Setting

All included studies took place in general or neurosurgical intensive care units. Five studies enrolled participants in Europe (DiPietro 2006; Fernandez-Ortega 2005; Gründling 1998; Linstedt 2010; Turkmen 2006), and three enrolled participants in Asia (Ambesh 2002; Dosemeci 2002; Kaya 2006). We found no RCTs conducted in North America, South America, Africa or Australia. Turkey conducted the largest number of studies (n = 3). All studies 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 the studies of Kaya 2006 and Fernandez-Ortega 2005, and LMA Classic and single-use LMA were used in the study of Linstedt 2010. Three studies (DiPietro 2006; Kaya 2006; Linstedt 2010) used LMA #4 for women and LMA #5 for men, and the study of Ambesh 2002 used LMA #3 for women and LMA #4 for men. The study of Fernandez-Ortega 2005 used LMA #4 or #5 for men and LMA #3 or #4 for women, adapted according to their weight. Three studies (Dosemeci 2002; Gründling 1998; Turkmen 2006) did not provide information on type or size of laryngeal masks.

PDT was performed in different ways: The study of Ambesh 2002 used Ciaglia's technique (Ciaglia 1985), the study of DiPietro 2006 used Blue Rhino technique (Byhahn 2000b) and the studies of

Fernandez-Ortega 2005 and Linstedt 2010 used Griggs method (Griggs 1990). All other studies did not provide information about the technique of PDT used.

Different handling of the nasogastric tube during the procedure was described. In the study of Dosemeci 2002, the nasogastric tube was suctioned and was left in place, but in four studies (Ambesh 2002; DiPietro 2006; Fernandez-Ortega 2005; Linstedt 2010), the nasogastric tube was removed before the procedure was begun. All other studies did not provide information about 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 (Fernandez-Ortega 2005) assessed all-cause mortality. In the intervention group, three of 20 participants (15%) died. In the control group, two of 20 participants (10%) died. According to the study author, none of these deaths was related to the procedure.

Four studies (Dosemeci 2002; Fernandez-Ortega 2005; Kaya 2006; Linstedt 2010) including 224 participants assessed procedure-related mortality. No studies reported any procedure-related mortality.

Seven studies (Ambesh 2002; DiPietro 2006; Dosemeci 2002; Fernandez-Ortega 2005; Kaya 2006; Linstedt 2010; Turkmen 2006) reported serious adverse events or absence of such events. The serious adverse event rate ranged between 0% (Linstedt 2010) and 33% (Ambesh 2002) (mean 13.7%) in the intervention group and between 0% (Kaya 2006) and 50% (Fernandez-Ortega 2005) (mean 20.2%) in the control group.

All studies but Turkmen 2006 reported on failure of the procedure requiring conversion to another procedure. The failure rate of the procedure ranged between 2.9% (Kaya 2006) and 16.7% (Ambesh 2002) in the intervention group and between 0% (Ambesh 2002; DiPietro 2006; Dosemeci 2002; Fernandez-Ortega 2005; Kaya 2006) and 10% (Kaya 2006) in the control group.

In five studies (DiPietro 2006; Dosemeci 2002; Gründling 1998; Kaya 2006; Linstedt 2010), 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 intervention group and between 5.9 minutes (Dosemeci 2002) and 13 minutes (Linstedt 2010) in the control group. The longest duration of procedure was described in the study of Fernandez-Ortega 2005, with a mean time of 30.45 minutes in the intervention group and 26.65 minutes in the con-

trol group.

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

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 studies (Cattano 2006; Pratt 2011) were excluded because they were not RCTs, and two studies (Carron 2010; Girgin 2007) because they did not compare use of LMAs versus ETT for PDT. Further details are provided in the [Characteristics of excluded studies](#) tables.

Ongoing trials

We identified no ongoing trials in our search.

Studies awaiting classification

In the mRCT, we identified one study (ISRCTN27187981) as potentially eligible. We contacted the principal investigator, who confirmed completion of the studies, but stated that trial data had not yet been analysed completely, and that no publication yet exists. We transferred this study to the section [Studies awaiting classification](#). This study will be assessed in the update of this review as soon as we receive any publication or preliminary data. We reran our search in March 2017. Two potential new studies of interest (Demirkan 2016; Price 2014) were added and will be incorporated into the formal review findings during the review update.

In total there are now three studies awaiting classification. Details of those three studies (ISRCTN27187981; Demirkan 2016; Price 2014) are given in the section [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 selective reporting and 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	+	-	+	+	?	?	-
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 (Fernandez-Ortega 2005; Linsteadt 2010) answered these questions. In the study of 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. The study of Linsteadt 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 studies. The study of 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. The study of 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 Linsteadt 2010 used a computer-generated randomization list. The study of DiPietro 2006 provided no information on concealment of allocation. Three studies (Dosemeci 2002; Kaya 2006; Turkmen 2006) did not provide information on generation of random sequence nor on concealment of allocation. 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 Linsteadt 2010, outcome assessors were not blinded. In all other studies (Ambesh 2002; DiPietro 2006; Dosemeci 2002; Gründling 1998; Kaya 2006; Turkmen 2006), it remained unclear whether assessors were blinded.

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 the studies of Ambesh 2002; DiPietro 2006; Dosemeci 2002; Fernandez-Ortega 2005; Gründling 1998; Kaya 2006 and Linsteadt 2010 was 2.54% (10/394). Dropout rates varied from 0% (Ambesh 2002; DiPietro 2006; Fernandez-Ortega 2005; Kaya 2006) to 6.9% (Gründling 1998). The study of Turkmen 2006 provided no information on dropout rates.

Five of the included studies (Ambesh 2002; DiPietro 2006; Fernandez-Ortega 2005; Kaya 2006; Linsteadt 2010) analysed data on an ITT basis. 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 participants who failed to be ventilated with LMA were dropped out in general (Dosemeci 2002; Gründling 1998), or if the total number of participants randomly assigned was unclear (Turkmen 2006).

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.

Two study authors (Fernandez-Ortega 2005; Linsteadt 2010) responded and stated that all outcomes within their studies were reported. These studies were judged to have a low risk of reporting bias. All other studies were judged 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. None of the included studies reported on sources of funding, and all were judged to have an unclear risk of bias concerning funding. The studies of [DiPietro 2006](#) and [Turkmen 2006](#) did not report gender distribution and were judged to have an unclear risk of bias concerning differences in baseline characteristics. 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 ETT versus LMA for percutaneous dilatational tracheostomy in critically ill adult patients](#)

Primary outcomes of this review

Overall mortality

In [Fernandez-Ortega 2005](#), no significant differences in the ETT versus LMA group were noted for overall mortality: RR 1.50, 95% CI 0.28 to 8.04, 40 participants, Fisher test P value 1.0.

Procedure-related mortality

Four studies ([Dosemeci 2002](#); [Fernandez-Ortega 2005](#); [Kaya 2006](#); [Linstedt 2010](#)) including 224 participants explicitly stated that no procedure-related deaths had occurred.

Tally of participants with one or more serious adverse events

In [Ambesh 2002](#), no significant differences in the ETT versus LMA group were reported for tally of participants with one or more serious adverse events: RR 1.67, 95% CI 0.69 to 4.00, 60 participants, [Analysis 1.1](#), Fisher test P value 0.382.

In [DiPietro 2006](#), no significant differences in the ETT versus LMA group were noted for tally of participants with one or more serious adverse events: RR 1.00, 95% CI 0.07 to 15.26, 60 participants, [Analysis 1.1](#), Fisher test P value 1.0.

In [Dosemeci 2002](#), no significant differences in the ETT versus LMA group were observed for tally of participants with one or more serious adverse events: RR 0.29, 95% CI 0.07 to 1.24, 56 participants, [Analysis 1.1](#), Fisher test P value 0.087.

In [Fernandez-Ortega 2005](#), a significant difference in the ETT versus LMA group was noted for tally of participants with one or more serious adverse events: RR 0.30, 95% CI 0.10 to 0.93, 40 participants, [Analysis 1.1](#), Fisher test P value 0.115.

In [Kaya 2006](#), no significant differences in the ETT versus LMA group were reported for tally of participants with one or more serious adverse events: RR 7.75, 95% CI 0.43 to 138.34, 65 participants, [Analysis 1.1](#), Fisher test P value 0.118.

In [Linstedt 2010](#), no significant differences in the ETT versus LMA group were described for tally of participants with one or more serious adverse events: RR 0.23, 95% CI 0.03 to 1.92, 63 participants, [Analysis 1.1](#), Fisher test P value 0.183.

In [Turkmen 2006](#), no significant differences in the ETT versus LMA group were noted for tally of participants with one or more serious adverse events: RR 0.99, 95% CI 0.45 to 2.16, 73 participants, [Analysis 1.1](#), Fisher test P value 1.0.

Combining all studies in a forest plot revealed no significant differences in the ETT versus LMA group for tally of participants with one or more serious adverse events: RR 0.73, 95% CI 0.35 to 1.52, 417 participants, [Analysis 1.1](#), P value ≤ 0.41 .

Subgroup analysis of all studies favouring the use of LMA (best-case scenario) also showed no significant differences in the ETT versus LMA group for serious adverse events: RR 0.54, 95% CI 0.24 to 1.01, 292 participants, P value ≤ 0.06 .

Secondary outcomes of the review

Duration of procedure

In [DiPietro 2006](#), a significant reduction in duration of procedure was reported in the LMA group compared with the ETT group: mean duration 8.45 ± 1.8 minutes (LMA) versus 9.8 ± 1.4 minutes (ETT), MD -1.35 minutes, 95% CI -2.17 to -0.53, 60 participants, [Analysis 1.2](#).

In [Dosemeci 2002](#), a significant reduction in duration of procedure was seen in the LMA group compared with the ETT group: mean duration 4.5 ± 0.8 minutes (LMA) versus 5.9 ± 1.4 minutes (ETT), MD -1.40 minutes, 95% CI -1.99 to -0.81, 56 participants, [Analysis 1.2](#).

In [Fernandez-Ortega 2005](#), no significant reduction in duration of procedure was reported when the LMA group was compared with the ETT group: mean duration 30.45 ± 13.07 minutes (LMA) versus 26.65 ± 14.45 minutes (ETT), MD 3.80 minutes, 95% CI -4.74 to 12.34, 40 participants, [Analysis 1.2](#).

In [Gründling 1998](#), a reduction in duration of procedure was observed in the LMA group compared with the ETT group: mean duration 7.7 minutes (LMA) versus 9.2 minutes (ETT). As no standard deviation was presented, we were not able to calculate significance.

In [Kaya 2006](#), a significant reduction in duration of procedure was reported in the LMA group compared with the ETT group: mean duration 4.5 ± 1.8 minutes (LMA) versus 7.1 ± 4.4 minutes (ETT), MD -2.60 minutes, 95% CI -4.28 to -0.92, 65 participants, [Analysis 1.2](#).

In [Linstedt 2010](#), no significant reduction in duration of procedure was noted when the LMA group was compared with the ETT

group: mean duration 11 ± 6 minutes (LMA) versus 13 ± 10 minutes (ETT), MD -2.00 minutes, 95% CI -6.12 to 2.12, 63 participants, [Analysis 1.2](#).

Combining all studies in a forest plot revealed a significant reduction in duration of procedure in the LMA group compared with the ETT group: MD -1.46 minutes, 95% CI -1.92 to -1.01, 324 participants, P value ≤ 0.00001 ([Figure 4](#)).

Figure 4. Forest plot of comparison: I ETT versus LMA, outcome: I.2 Duration of procedure.

Footnotes

(1) SD: N/A

Failure of procedure requiring conversion to any other procedure

In [Ambesh 2002](#), no significant differences in the ETT versus LMA group were reported for failure of procedure requiring conversion to any other procedure: RR 11.00, 95% CI 0.64 to 190.53, 60 participants, [Analysis 1.3](#), Fisher test P value 0.053.

In [DiPietro 2006](#), no significant differences in the ETT versus LMA group were noted for failure of procedure requiring conversion to any other procedure: RR 3.00, 95% CI 0.13 to 70.83, 60 participants, [Analysis 1.3](#), Fisher test P value 1.0.

In [Dosemeci 2002](#), no failure of procedure requiring conversion to any other procedure was described in any treatment group.

In [Fernandez-Ortega 2005](#), no significant differences in the ETT versus LMA group were observed for failure of procedure requiring conversion to any other procedure: RR 7.00, 95% CI 0.38 to 127.32, 40 participants, [Analysis 1.3](#), Fisher test P value 0.231.

In [Gründling 1998](#), no failure of procedure requiring conversion to any other procedure was described in any treatment group.

In [Kaya 2006](#), no significant differences in the ETT versus LMA group were reported for failure of procedure requiring conversion to any other procedure: RR 2.58, 95% CI 0.11 to 61.16, 65 participants, [Analysis 1.3](#), Fisher test P value 1.0.

In [Linstedt 2010](#), no significant differences in the ETT versus LMA group were noted for failure of procedure requiring conversion to any other procedure: RR 0.30, 95% CI 0.03 to 2.76, 63

participants, [Analysis 1.3](#), Fisher test P value 0.340.

Combining all studies in a forest plot revealed no significant differences in the ETT versus LMA group for failure of procedure requiring conversion to any other procedure: RR 2.30, 95% CI 0.56 to 9.39, 384 participants, [Analysis 1.3](#), P value ≤ 0.25.

Time to extubation after tracheostomy

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

Length of ICU stay after tracheostomy

In [Fernandez-Ortega 2005](#), no 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 value ≤ 0.52.

Length of hospital stay after tracheostomy

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

Serious adverse events

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

2.6a Fatal loss of airway

Two studies ([Fernandez-Ortega 2005](#); [Linstedt 2010](#)) explicitly stated that no fatal loss of airway occurred.

2.6b Non-fatal loss of airway

In [Ambesh 2002](#), no significant differences in the ETT versus LMA group were reported for non-fatal loss of airway: RR 3.00, 95% CI 0.33 to 27.23, 60 participants, [Analysis 1.4](#), Fisher test P value 0.612.

In [DiPietro 2006](#), no significant differences in the ETT versus LMA group were noted for non-fatal loss of airway: RR 0.33, 95% CI 0.01 to 7.87, 60 participants, [Analysis 1.4](#), Fisher test P value 1.0.

In [Dosemeci 2002](#), no significant differences in the ETT versus LMA group were observed for non-fatal loss of airway: RR 0.38, 95% CI 0.02 to 9.01, 56 participants, [Analysis 1.4](#), Fisher test P value 1.0.

In [Fernandez-Ortega 2005](#), a significant difference in the ETT versus LMA group was described for non-fatal loss of airway: RR 0.08, 95% CI 0.00 to 1.28, 40 participants, [Analysis 1.4](#), Fisher test P value 0.021, 95% CI-M 0 to 0.58.

In [Kaya 2006](#), no fatal loss of airway was described in any treatment group.

In [Linstedt 2010](#), no significant differences in the ETT versus LMA group were reported for non-fatal loss of airway: RR 0.30, 95% CI 0.01 to 7.19, 63 participants, [Analysis 1.4](#), Fisher test P value 0.477.

Combining all studies revealed no significant differences in the ETT versus LMA group for non-fatal loss of airway: RR 0.49, 95% CI 0.13 to 1.88, 344 participants, [Analysis 1.4](#), P value ≤ 0.30 .

2.6c Cardiac arrest during the procedure

Two studies ([Fernandez-Ortega 2005](#); [Linstedt 2010](#)) explicitly stated that no cardiac arrests occurred during the procedure. All other studies did not report on cardiac arrest.

2.6d 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. All other studies did not report on aspiration pneumonia

(as confirmed by bronchoscopy) within 24 hours after procedure in any treatment group.

2.6e Mediastinitis within 24 hours after procedure

Two studies ([Fernandez-Ortega 2005](#); [Linstedt 2010](#)) explicitly stated that no mediastinitis occurred within 24 hours after procedure. All other studies did not report on mediastinitis within 24 hours after procedure.

2.6f Any other serious adverse events as reported by study authors In [Ambesh 2002](#), no significant differences in the ETT versus LMA group were reported for any other serious adverse events: RR 0.40, 95% CI 0.08 to 1.90, 60 participants, [Analysis 1.4](#), Fisher test P value 0.424.

In [Dosemeci 2002](#), no significant differences in the ETT versus LMA group were noted for any other serious adverse events: RR 0.33, 95% CI 0.07 to 1.45, 56 participants, [Analysis 1.4](#), Fisher test P value 0.154.

In [Fernandez-Ortega 2005](#), no significant differences in the ETT versus LMA group were observed for any other serious adverse events: RR 0.11, 95% CI 0.01 to 1.94, 40 participants, [Analysis 1.4](#), Fisher test P value 0.107.

In [Kaya 2006](#), no significant differences in the ETT versus LMA group were reported for any other serious adverse events: RR 6.03, 95% CI 0.32 to 112.21, 65 participants, [Analysis 1.4](#), Fisher test P value 0.243.

Three studies ([DiPietro 2006](#); [Linstedt 2010](#); [Turkmen 2006](#)) did not report on any other serious adverse events.

Combining all studies revealed no significant differences in the ETT versus LMA group for any other serious adverse events: RR 0.45, 95% CI 0.14 to 1.47, 344 participants, [Analysis 1.4](#), P value ≤ 0.19 .

DISCUSSION

This review identified eight single-centre studies that met the inclusion criteria.

Summary of main results

Primary outcomes

All-cause mortality

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

Procedure-related mortality

Only four studies (Dosemeci 2002; Fernandez-Ortega 2005; Kaya 2006; Linstedt 2010) explicitly stated that no procedure-related deaths occurred. All other studies did not explicitly report on procedure-related mortality.

Tally of participants with one or more serious adverse events

In Fernandez-Ortega 2005, a significant risk reduction was reported in the intervention group. In three studies (Dosemeci 2002; Linstedt 2010; Turkmen 2006), a non-significant reduction in serious adverse events was noted in the intervention group, whereas two studies (Ambesh 2002; Kaya 2006) showed a non-significant risk increase in the intervention group. The risk ratio in the study of DiPietro 2006 was 1.

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 participants in the study of Ambesh 2002 may have had lower weight than all other participants. The study of Ambesh 2002 reported on participants' body mass index (BMI), which was 22 ± 1.6 in the intervention group and 23 ± 1.8 in the control group. However, we received no reply from any contact authors, except Fernandez-Ortega 2005, concerning participants' weight. The study of Ambesh 2002 was the first RCT undertaken to explore this topic. As both LMA devices and PDT techniques have advanced, results of the study of Ambesh 2002 may have a limited effect on daily practice. But even if the studies of Ambesh 2002 and Kaya 2006 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 value ≤ 0.06 .

Secondary outcomes

Duration of procedure

Six studies (DiPietro 2006; Dosemeci 2002; Fernandez-Ortega 2005; Gründling 1998; Kaya 2006; Linstedt 2010) provided information on duration of procedure. Three studies (DiPietro 2006; Dosemeci 2002; Kaya 2006) showed a significant reduction of duration in the intervention group. One study (Linstedt 2010) showed a non-significant reduction of duration in the LMA group. Gründling 1998 showed a mean reduction of duration only in the intervention group and provided no information on distribution of these values. Fernandez-Ortega 2005 showed a non-significant reduction of duration of procedure in the control group.

In four studies (DiPietro 2006; Dosemeci 2002; Gründling 1998; Kaya 2006), mean duration of procedure was less than 10 minutes in both treatment groups. 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 reasons for this difference, which may be related to differences in the procedure performed or in the experience of performing physicians.

Combining all studies in a meta-analysis led to a significant mean reduction of duration of 1.46 minutes (95% CI reduction 1.92 to 1.01 minutes, 324 participants, P value ≤ 0.00001) (Figure 4). 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 value ≤ 0.00001).

Failure of procedure requiring conversion to any other procedure

Seven studies (Ambesh 2002; DiPietro 2006; Dosemeci 2002; Fernandez-Ortega 2005; Gründling 1998; Kaya 2006; Linstedt 2010) assessed failure of procedure requiring conversion to any other procedure. In all of these studies, except for Dosemeci 2002, failure of procedure occurred in one or both treatment groups. Most of these outcomes occurred in the intervention group (11/193 participants (5.7%) in intervention groups vs 3/191 participants (1.6%) in control groups; RR 2.30, 95% CI 0.56 to 9.39, 384 participants, P value ≤ 0.25). Only one study (Linstedt 2010) reported on events in the control group. In all cases, tracheostomy was successfully performed by reintubating the participant or by completing faster the procedure intended to secure the participant's airway.

Most of those events ($n = 5$) occurred in the study of Ambesh 2002, which, as described above, used smaller LMAs than any other included studies. This may explain the highest event rate of unsuccessful placement of an LMA, in that achievement of pharyngeal sealment was more unlikely.

Time to extubation after tracheostomy

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

Length of ICU stay after tracheostomy

Only one study (Fernandez-Ortega 2005) provided information on length of ICU stay after tracheostomy, showing a non-significant difference between the two treatment groups. Because a small

sample size was included and little information was given, we were not able to draw further conclusions.

Length of hospital stay after tracheostomy

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

Serious adverse events

Fatal loss of airway

Only two studies (Fernandez-Ortega 2005; Linstedt 2010) explicitly stated that no fatal loss of airway occurred in any treatment group. All other studies did not give information about the occurrence of fatal loss of airway.

Non-fatal loss of airway

Six studies (Ambesh 2002; DiPietro 2006; Dosemeci 2002; Fernandez-Ortega 2005; Kaya 2006; Linstedt 2010) assessed non-fatal loss of airway. In five studies (Ambesh 2002; DiPietro 2006; Dosemeci 2002; Fernandez-Ortega 2005; Linstedt 2010), non-fatal loss of airway was reported. 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 control group (3/174 participants (1.7%) in intervention groups vs 10/170 participants (5.8%) in control groups; RR 0.49, 95% CI 0.13 to 1.88, 344 participants, Fisher test P value 0.30). The only study reporting on non-fatal loss of airway in the intervention group was Ambesh 2002. Most of all cases of non-fatal loss of airway in the control group (6/10) occurred in the study of Fernandez-Ortega 2005, which may explain the longer duration of procedure, as mentioned above.

Cardiac arrest during the procedure

Only two studies (Fernandez-Ortega 2005; Linstedt 2010) explicitly stated that no cardiac arrest occurred during the procedure in any treatment group. All other studies did not report on cardiac arrest.

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

Only one study (Linstedt 2010) stated that no aspiration pneumonia (confirmed by bronchoscopy) occurred within 24 hours after the procedure in any treatment group. All other studies did not report on this outcome.

Mediastinitis within 24 hours after procedure

Only two studies (Fernandez-Ortega 2005; Linstedt 2010) explicitly stated that no mediastinitis occurred within 24 hours after the procedure. All other studies did not report on this outcome.

Any other serious adverse events as reported by study authors

Four studies (Ambesh 2002; Dosemeci 2002; Fernandez-Ortega 2005; Kaya 2006) reported on any other serious adverse events. In the intervention group, seven 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 = 1) and skin emphysema (n = 1). In the control 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).

Overall completeness and applicability of evidence

We were able to identify only studies conducted in Europe and Asia, although percutaneous dilatational tracheostomy, as well as use of laryngeal mask airways, is not limited to these continents. We did not detect a single fatal adverse event in all 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, 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) suggests that long-term ventilation (> seven 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 an LMA for sufficient ventilation. However, replacement of an ETT with an LMA requires experience in ventilating patients with supraglottic airways. Use of LMA should be limited on ICUs to staff members who have gained previous experience in ventilating patients with LMA.

Quality of the evidence

The quality of the included studies was variable. Random sequence generation had low risk of bias in three studies (Ambesh 2002; DiPietro 2006; Linstedt 2010), 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, 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 five studies (Ambesh 2002; DiPietro 2006; Fernandez-Ortega 2005; Kaya 2006; Linstedt 2010) 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 two study authors (Fernandez-Ortega 2005; Linstedt 2010), and both 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.

Potential biases in the review process

For two studies (Fernandez-Ortega 2005; Linstedt 2010), we received additional information from the trial authors that moved some risk of bias domains from 'unclear' to 'low,' but in both studies, 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 and one retrospective study (Cattano 2006). The publication of Pratt 2011a identified all RCTs included in this review, except for two (Fernandez-Ortega 2005; Gründling 1998).

Pratt and Bromilow stated that replacing an ETT with an 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 seven 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 an LMA as the true alternative for securing airways during PDT.

AUTHORS' CONCLUSIONS

Implications for practice

Evidence on the safety of LMA for PDT is too limited to allow general conclusions on its efficacy or safety compared with ETT. Evidence indicates that use of an LMA can optimize conditions in PDT through better visualization during bronchoscopy. Also time of procedure was shortened when LMA was used instead of ETT. However, as the result of small sample sizes, few events and lack of patient-relevant outcomes, the effect on patient safety, especially concerning late complications, has not been investigated sufficiently.

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. 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 multi-factorial design and a reasonable sample size to ensure sufficient power, multi-centric approaches seem necessary for conducting significant studies.

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REFERENCES

References to studies included in this review

Ambesh 2002 {published data only (unpublished sought but not used)}

Ambesh SP, Sinha PK, Tripathi M, Matreja P. Laryngeal mask airway vs. endotracheal tube to facilitate bedside percutaneous tracheostomy in critically ill patients: a prospective comparative study. *Journal of Postgraduate Medicine* 2002;**48**(1):11–5. PUBMED: 12082319]

DiPietro 2006 {published data only (unpublished sought but not used)}

Di Pietro A, Coletta RP, Barbati G, Blasetti AG. Laryngeal mask vs. endotracheal tube in airway management during percutaneous tracheotomy using. *Acta Anaesthesiologica Italica* 2006;**57**(1):51–63.

Dosemeci 2002 {published data only (unpublished sought but not used)}

Dosemeci L, Yilmaz M, Gürpınar F, Ramazanoglu A. The use of the laryngeal mask airway as an alternative to the endotracheal tube during percutaneous dilatational tracheostomy. *Intensive Care Medicine* 2002;**28**(1):63–7. PUBMED: 11819002]

Fernandez-Ortega 2005 {published and unpublished data}

Fernandez-Ortega J, Areñas-Villatoro J, Herrera-Gutiérrez M, Besso-Centeno G, Sellar-Perez G, Curiel-Balsera E, et al. Laryngeal mask-airway vs endotracheal intubation during percutaneous tracheotomy in the ICU. *European Society of Intensive Care Medicine* 2005;**Supplement**:S116, P441 (abstract).

Gründling 1998 {published data only (unpublished sought but not used)}

Gründling M, Kuhn SO, Riedel T, Feyerherd F, Wendt M. Application of laryngeal mask airway for elective percutaneous dilatational tracheostomy [Anwendung der Larynxmaske für die elektive perkutane Dilatationstracheotomie]. *Anaesthesiologie und Reanimation* 1998;**23**(2):32–6. PUBMED: 9611360]

Kaya 2006 {published data only (unpublished sought but not used)}

Kaya FN, Girgin NK, Yavacaog lu B, Kahveci F, Korfali G. The use of the laryngeal mask airway and the cuffed

oropharyngeal airway during percutaneous tracheostomy. *Turkish Journal of Trauma & Emergency Surgery* 2006;**12**(4): 282–7. PUBMED: 17029118]

Linstedt 2010 {published and unpublished data}

Linstedt U, Zenz M, Krull K, Häger D, Prengel AW. Laryngeal mask airway or endotracheal tube for percutaneous dilatational tracheostomy: AC. *Anesthesia and Analgesia* 2010;**110**(4):1076–82. PUBMED: 20357150]

Turkmen 2006 {published data only (unpublished sought but not used)}

Turkmen A, Turgut N, Altan A, Deniz M. The use of the laryngeal mask airway during percutaneous dilatational tracheotomy. *Critical Care* 2006;**10**(Suppl 1):P53. [DOI: 10.1186/cc4400]

References to studies excluded from this review

Carron 2010 {published data only}

Carron M, Freo U, Michielan F, Ori C. Effects of tracheal intubation on ventilation with LMA classic for percutaneous dilation tracheostomy. *Minerva Anestesiologica* 2010;**76**(3): 181–7. PUBMED: 20203545]

Cattano 2006 {published data only}

Cattano D, Abramson S, Buzzigoli S, Zoppi C, Melai E, Giunta F, et al. The use of the laryngeal mask airway during guidewire dilating forceps tracheostomy. *Anesthesia and Analgesia* 2006;**103**(2):453–7. PUBMED: 16861433]

Girgin 2007 {published data only}

Girgin NK, Kahveci SF, Yavascaoglu B, Kutlay O. A comparison of the laryngeal mask airway and cuffed oropharyngeal airway during percutaneous dilatational tracheostomy. *Saudi Medical Journal* 2007;**28**(7):1139–41. PUBMED: 17603731]

Pratt 2011 {published data only}

Pratt T, Bromilow J. The Use of LMA during percutaneous tracheostomy. *The Intensive Care Society* 2011;**12**(3):238–9.

References to studies awaiting assessment

Demirkan 2016 {published data only}

Demirkan O, Bozbay S, Ayan B. The effect of Igel extraglottic airway device during percutaneous dilatational tracheostomy in ICU patients. *Anesthesia & Analgesia* 2016;**123**(3S‘Suppl):126. [DOI: 10.1213/01.ane.0000492500.26426.09]

ISRCTN27187981 {published data only}**Price 2014 {published data only}**

Price GC, McLellan S, Paterson RL, Hay A. A prospective randomised controlled trial of the LMA Supreme vscuffed tracheal tube as the airway device during percutaneoustracheostomy. *Anaesthesia* 2014;**69**:757–763. [PUBMED: 24803133]

Additional references**Ambesh 2002a**

Ambesh SP, Sinha PK, Tripathi M, Matreja P. Laryngeal mask airway vs. endotracheal tube to facilitate bedside percutaneous tracheostomy in critically ill patients: a prospective comparative study. *Journal of Postgraduate Medicine* 2002;**48**(1):11–5. [PUBMED: 12082319]

Ambesh 2002b

Ambesh SP, Pandey CK, Srivastava S, Agarwal A, Singh DK. Percutaneous tracheostomy with single dilatation technique: a prospective, randomized comparison of Ciaglia blue rhino versus Griggs’ guidewire dilating forceps. *Anesthesia and Analgesia* 2002;**95**(6):1739–45. [PUBMED: 12456450]

Arabi 2004

Arabi Y, Haddad S, Shirawa N, Al Shimemeri A. Early tracheostomy in intensive care trauma patients improves resource utilization: a cohort study and literature review. *Critical Care* 2004;**8**(5):R347–52. [PUBMED: 15469579]

Azevedo 2013

Azevedo LC, Park M, Salluh JI, Rea-Neto A, Souza-Dantas VC, Varaschin P, et al. Clinical outcomes of patients requiring ventilatory support in Brazilian intensive care units: a multicenter, prospective, cohort study. *Critical Care* 2013;**17**(2):R63. [PUBMED: 23557378]

Bishop 1985

Bishop MJ, Hibbard AJ, Fink BR, Vogel AM, Weymuller EA. Laryngeal injury in a dog model of prolonged endotracheal intubation. *Anesthesiology* 1985;**62**(6):770–3. [PUBMED: 4003797]

Brimacombe 1995

Brimacombe J. The advantages of the LMA over the tracheal tube or facemask: a meta-analysis. *Canadian Journal of Anesthesia* 1995;**42**(11):1017–23. [PUBMED: 8590490]

Brook 2000

Brook AD, Sherman G, Malen J, Kollef MH. Early versus late tracheostomy in patients who require prolonged mechanical ventilation. *American Journal of Critical Care* 2000;**9**(5):352–9. [PUBMED: 10976359]

Byhahn 2000a

Byhahn C, Wilke HJ, Halbig S, Lischke V, Westphal K. Percutaneous tracheostomy: Ciaglia blue rhino versus

the basic Ciaglia technique of percutaneous dilatational tracheostomy. *Anesthesia and Analgesia* 2000;**91**(4):882–6. [PUBMED: 11004042]

Byhahn 2000b

Byhahn C, Lischke V, Halbig S, Scheifler G, Westphal K. Ciaglia blue rhino: a modified technique for percutaneous dilatation tracheostomy. Technique and early clinical results [Ciaglia Blue Rhino: Ein weiterentwickeltes Verfahren der perkutanen DilatationstracheotomieTechnik und erste klinische Ergebnisse]. *Der Anästhesist* 2000;**49**(3):202–6. [PUBMED: 10788989]

Byhahn 2005

Byhahn C, Lischke V, Meininger D, Halbig S, Westphal K. Peri-operative complications during percutaneous tracheostomy in obese patients. *Anaesthesia* 2005;**60**(1):12–5. [PUBMED: 15601266]

Cheng 2000

Cheng E, Fee WE Jr. Dilatational versus standard tracheostomy: a meta-analysis. *The Annals of Otolaryngology, Rhinology, and Laryngology* 2000;**109**(9):803–7. [PUBMED: 11007080]

Ciaglia 1985

Ciaglia P, Firsching R, Syniec C. Elective percutaneous dilatational tracheostomy. A new simple bedside procedure; preliminary report. *Chest* 1985;**87**(6):715–9. [PUBMED: 3996056]

Confalonieri 2001

Confalonieri M, Gorini M, Ambrosino N, Mollica C, Corrado A. Respiratory intensive care units in Italy: a national census and prospective cohort study. *Thorax* 2001;**56**(5):373–8. [PUBMED: 11312406]

Delaney 2006

Delaney A, Bagshaw SM, Nalos M. Percutaneous dilatational tracheostomy versus surgical tracheostomy in critically ill patients: a systematic review and meta-analysis. *Critical Care* 2006;**10**(2):R55. [PUBMED: 16606435]

Dexter 1994

Dexter TJ. The laryngeal mask airway: a method to improve visualisation of the trachea and larynx during fiberoptic assisted percutaneous tracheostomy. *Anaesthesia and Intensive Care* 1994;**22**(1):35–9. [PUBMED: 8160947]

Dulgierov 1999

Dulgierov P, Gysin C, Perneger TV, Chevrolet JC. Percutaneous or surgical tracheostomy: a meta-analysis. *Critical Care Medicine* 1999;**27**(8):1617–25. [PUBMED: 10470774]

Egger 1997

Egger M, Smith GD, Phillips AN. Meta-analysis: principles and procedures. *BMJ* 1997;**315**(7121):1533–7. [PUBMED: 9432252]

Esteban 2000

Esteban A, Anzueto A, Alía I, Gordo F, Apezteguía C, Pálizas F, et al. How is mechanical ventilation employed in the intensive care unit? An international utilization review. *American Journal of Respiratory and Critical Care Medicine* 2000;**161**(5):1450–8. [PUBMED: 10806138]

Fantoni 1997

Fantoni A, Ripamonti D. A non-derivative, non-surgical tracheostomy: the translaryngeal method. *Intensive Care Medicine* 1997;**23**(4):386–92. [PUBMED: 9142576]

Freeman 2000

Freeman BD, Isabella K, Lin N, Buchman TG. A meta-analysis of prospective trials comparing percutaneous and surgical tracheostomy in critically ill patients. *Chest* 2000;**118**(5):1412–8. [PUBMED: 11083694]

Griffiths 2005

Griffiths J, Barber VS, Morgan L, Young JD. Systematic review and meta-analysis of studies of the timing of tracheostomy in adult patients undergoing artificial ventilation. *BMJ* 2005;**28**(330):1243. [PUBMED: 15901643]

Griggs 1990

Griggs WM, Worthley LI, Gilligan JE, Thomas PD, Myburg JA. A simple percutaneous tracheostomy technique. *Surgery, Gynecology & Obstetrics* 1990;**170**(6):543–5. [PUBMED: 2343371]

Guyatt 2008

Guyatt GH, Oxman AD, Kunz R, Vist GE, Falck-Ytter Y, Schunemann HJ. What is “quality of evidence” and why is it important to clinicians. *BMJ* 2008;**336**(7651):995–8. [PUBMED: 18456631]

Higgins 2007

Higgins KM, Punthakee X. Meta-analysis comparison of open versus percutaneous tracheostomy. *Laryngoscope* 2007;**117**(3):447–54. [PUBMED: 17334304]

Higgins 2011

Higgins JPT, Green S, editors. Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011. www.cochrane-handbook.org.

Hong 2008

Hong SB, Oh BJ, Kim YS, Kang EH, Kim CH, Park YB, et al. Characteristics of mechanical ventilation employed in intensive care units: a multicenter survey of hospitals. *Journal of Korean Medical Science* 2008;**23**(6):948–53. [DOI: 10.3346/jkms.2008.23.6.948; PUBMED: 19119434]

Kollef 1999

Kollef MH, Ahrens TS, Shannon W. Clinical predictors and outcomes for patients requiring tracheostomy in the intensive care unit. *Critical Care Medicine* 1999;**27**(9):1714–20. [PUBMED: 10507588]

Kuebler 2013

Kübler A, Maciejewski D, Adamik B, Kaczorowska M. Mechanical ventilation in ICUs in Poland: a multi-center point-prevalence study. *Medical Science Monitor* 2013;**19**:424–9. [DOI: 10.12659/MSM.883930; PUBMED: 23727991]

Lyons 1995

Lyons BJ, Flynn CG. The laryngeal mask simplifies airway management during percutaneous dilatational

tracheostomy. *Acta Anaesthesiologica Scandinavica* 1995;**39**(3):414–5. [PUBMED: 7793227]

Mallick 2010

Mallick A, Bodenham AR. Tracheostomy in critically ill patients. *European Journal of Anaesthesiology* 2010;**27**(8):676–82. [PUBMED: 20523214]

Miettinen 1985

Miettinen O, Nurminen M. Comparative analysis of two rates. *Statistics in Medicine* 1985;**4**(2):213–26. [PUBMED: 4023479]

Pratt 2011a

Pratt T, Bromilow J. Laryngeal mask airway for airway control during percutaneous dilatational tracheostomy. *Anaesthesia and Intensive Care* 2011;**39**(6):1009–13. [PUBMED: 22165351]

RevMan 5.1 [Computer program]

The Nordic Cochrane Centre, The Cochrane Collaboration. Review Manager (RevMan). Version 5.1. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2011.

Sarkar 2010

Sarkar S, Shashi P, Paswan AK, Anupam RP, Suman S, Dube SK. Use of the pro-seal laryngeal mask airway facilitates percutaneous dilatational tracheostomy in an intensive care unit. *Indian Journal of Critical Care Medicine* 2010;**4**:185–7. [PUBMED: 21572749]

Silvester 2006

Silvester W, Goldsmith D, Uchino S, Bellomo R, Knight S, Seevanayagam S, et al. Percutaneous versus surgical tracheostomy: a randomized controlled study with long-term follow-up. *Critical Care Medicine* 2006;**34**(8):2145–52. [PUBMED: 16775568]

Walz 1998

Walz MK, Peitgen K, Thürauf N, Trost HA, Wolfhard U, Sander A, et al. Percutaneous dilatational tracheostomy - early results and long-term outcome of 326 critically ill patients. *Intensive Care Medicine* 1998;**24**(7):685–90. [PUBMED: 9722038]

Westphal 1998

Westphal K, Lohrengel A, Wilke HJ, Rinne T, Wichelhaus TA, Lischke V. Percutaneous dilatational tracheostomy in a cardiac-surgery ICU [Die perkutane Dilatationstracheotomie bei Intensivpatienten in der Herzchirurgie]. *Zeitschrift für Herz-, Thorax- und Gefäßchirurgie* 1998;**12**(4):177–81. [DOI: 10.1007/s003980050037]

Westphal 2002

Westphal K, Lischke V, Byhahn C. Posterior tracheal wall perforation with the Blue Rhino tracheostomy set. *Anaesthesia* 2002;**57**(1):89–90. [PUBMED: 11843753]

References to other published versions of this review**Strametz 2012**

Strametz R, Pachler C, Byhahn C, Siebenhofer A, Weberschock T. Laryngeal mask airway versus endotracheal

tube for percutaneous dilatational tracheostomy in critically ill patients. *Cochrane Database of Systematic Reviews* 2012, Issue 6. [DOI: 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
Notes	<p>Funding body was not declared</p> <p>Abbreviations:</p> <p>ARF: acute respiratory failure</p> <p>COPD: chronic obstructive pulmonary disease</p> <p>ETT: endotracheal tube</p> <p>ITT: intention-to-treat</p> <p>LMA: laryngeal mask airway</p> <p>PDT: percutaneous dilatational tracheostomy</p> <p>PEEP: positive end-expiratory pressure</p>

Risk of bias

Risk of bias

Bias	Authors' judgement	Support for judgement
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Ambesh 2002 (Continued)

Random sequence generation (selection bias)	Low risk	Randomization was done using 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 to 5 mg), sodium thiopental (200 to 300 mg), vecuronium (4 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)
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	1. Serious adverse event: non-fatal loss of airway 2. Duration of procedure 3. Failure of procedure requiring conversion to any other procedure
Notes	Funding body was not declared Abbreviations: ETT: endotracheal tube ITT: intention-to-treat LMA: laryngeal mask airway PDT: percutaneous dilatational tracheostomy PEEP: positive end-expiratory pressure

Risk of bias**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 sex of participants
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants were sedated (propofol 1.5 to 2 mg/kg, fentanyl 2 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

Methods	This randomized, parallel-group study was conducted at a single centre in Turkey
Participants	<p>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</p> <p>Demographics of included participants</p> <ol style="list-style-type: none"> 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 <p>Exclusion criteria of the trial</p> <ol style="list-style-type: none"> 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. 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>Funding body was not declared</p> <p>Abbreviations:</p> <p>ARF: acute respiratory failure</p> <p>COPD: chronic obstructive pulmonary disease</p> <p>ETT: endotracheal tube</p> <p>LMA: laryngeal mask airway</p> <p>PDT: percutaneous dilatational tracheostomy</p> <p>PEEP: positive end-expiratory pressure</p>

*Risk of bias**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

Dosemeci 2002 (Continued)

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

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"> 1. In the intervention group, ETT was replaced with Pro-seal LMA #3-4 in women and LMA #4-5 in men 2. In ETT group, ETT was laryngoscope-assisted partially withdrawn 3. In LMA and ETT groups, nasogastric tube was not replaced. Before PDT, nasogastric tube was suctioned in both groups 4. PDT was performed using guidewire/dilating forceps technique in both groups
Outcomes	<ol style="list-style-type: none"> 1. All-cause mortality 2. 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 3. Duration of procedure 4. Failure of procedure requiring conversion to any other procedure 5. Length of ICU stay after tracheostomy
Notes	<p>Funding body was not declared</p> <p>Abbreviations:</p> <p>ETT: endotracheal tube</p> <p>ICU: Intensive care unit</p> <p>ITT: intention-to-treat</p> <p>LMA: laryngeal mask airway</p> <p>PDT: percutaneous dilatational tracheostomy</p> <p>SD: standard deviation</p>

<i>Risk of bias</i>		<i>Risk of bias</i>
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
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; polytrauma: 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
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>Funding body was not declared</p> <p>Abbreviations:</p> <p>APACHE: Acute Physiology And Chronic Health Evaluation</p> <p>ETT: endotracheal tube</p> <p>FiO₂: fraction of inspired oxygen</p> <p>ITT: intention-to-treat</p> <p>LMA: laryngeal mask airway</p> <p>PaCO₂: partial pressure of carbon dioxide in arterial blood</p> <p>PaO₂: partial pressure of oxygen in arterial blood</p> <p>PDT: percutaneous dilatational tracheostomy</p>
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<i>Risk of bias</i>		<i>Risk of bias</i>
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

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 <p>Exclusion criteria of the trial</p> <ol style="list-style-type: none"> 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
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>Funding body was not declared</p> <p>Abbreviations:</p> <p>APACHE: Acute Physiology And Chronic Health Evaluation</p> <p>ETT: endotracheal tube</p> <p>ITT: intention-to-treat</p> <p>LMA: laryngeal mask airway</p> <p>PDT: percutaneous dilatational tracheostomy</p>

*Risk of bias**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

Kaya 2006 (Continued)

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 drop-outs 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 (PaO₂/fraction of inspired oxygen (FiO₂)) < 200 mmHg (26 kPa) Positive end-expiratory pressure (PEEP) ≥ 15 mbar (15.3 cmH₂O)

Interventions	<ol style="list-style-type: none"> 1. 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 2. 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 3. PDT was performed using Griggs method (Portex Griggs-Set, Smiths Medical, Colonial Way, Watford, UK)
Outcomes	<ol style="list-style-type: none"> 1. Procedure-related mortality 2. 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 3. Duration of procedure 4. Failure of procedure requiring conversion to any other procedure
Notes	<p>Funding body was not declared</p> <p>Abbreviations:</p> <p>ETT: endotracheal tube</p> <p>FiO₂: fraction of inspired oxygen</p> <p>ITT: intention-to-treat</p> <p>LMA: laryngeal mask airway</p> <p>PaO₂: partial pressure of oxygen in arterial blood</p> <p>PDT: percutaneous dilatational tracheostomy</p> <p>PEEP: positive end-expiratory pressure</p>

<i>Risk of bias</i>		<i>Risk of bias</i>
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. 3 dropouts occurred because consent was withdrawn by relatives
Selective reporting (reporting bias)	Low risk	All outcomes were reported within studies, according to authors' responses

Linstedt 2010 (Continued)

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

Turkmen 2006

Methods	This randomized, parallel-group study was conducted at a single centre in Turkey
Participants	Investigators recruited 73 participants (42 in the ETT group; 31 in the LMA group) Demographics of included participants 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 Exclusion criteria of the trial 1. These were not reported
Interventions	
Outcomes	1. Serious adverse events: not specified
Notes	Funding body was not declared Abbreviations: ETT: endotracheal tube LMA: laryngeal mask airway

<i>Risk of bias</i>		<i>Risk of bias</i>
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

Turkmen 2006 (Continued)

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

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 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 Cuffed OroPharyngeal Airway (COPA) during PDT
Pratt 2011	This study is not a new randomized controlled trial

Abbreviations:

COPA: Cuffed OroPharyngeal Airway

ETT: endotracheal tube

LMA: laryngeal mask airway

PDT: percutaneous dilatational tracheostomy

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

Demirkan 2016

Methods	This randomized controlled 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"> 1. 5 men and 5 women in ETT group; 6 men and 4 women in LMA group 2. Mean age (range) in intervention group = 58,47±22,42 years 3. Mean age (range) in control group = 58,61±21,56 years <p>Exclusion criteria of the trial</p> <p>These were not stated in publication</p>
Interventions	ETT versus I gel for tracheostomy
Outcomes	<p>Total PDT time</p> <p>P/F before and after procedurePaO2 before and after procedureMAP before and after procedureLeakage volume</p>
Notes	DOI: 10.1213/01.ane.0000492500.26426.09

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"> 1. Intensive care unit patients <p>Exclusion criteria of the trial</p> <ol style="list-style-type: none"> 1. Not provided at time of registration
Interventions	ETT versus Pro-seal LMA for tracheostomy
Outcomes	<p>Signs of aspiration</p> <p>Duration</p> <p>Blood gas at end of procedure</p>
Notes	<p>ISRCTN27187981</p> <p>Principal investigator was contacted via email. He stated that the study is completed, but final analysis is not yet available</p> <p>Abbreviations</p> <p>ETT: endotracheal tube</p> <p>LMA: laryngeal mask airway</p>

Methods	This randomized, parallel-group study was conducted at a three sites in the United Kingdom
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"> 1. 14 men and 11 women in ETT group; 13 men and 12 women in LMA group 2. Mean age (range) in intervention group = 55 years (19 to 83 years) 3. Mean age (range) in control group = 53 years (16 to 76 years) 4. 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"> 1. Aged less than 18 years 2. Patient or relative/welfare guardian refusal 3. Treating clinician refusal
Interventions	LMA Supreme™ versus cuffed oral endotracheal tube. Duration of intervention is variable but no more than 60 minutes. There is no follow up beyond the procedure itself
Outcomes	<p>Primary outcome measure</p> <p>Change in partial pressure of carbon dioxide in arterial blood (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"> 1. Combined complications (desaturation less than 92% during procedure, repositioning of airway device during procedure, loss of airway during procedure) 2. How many people required to help with airway maintenance 3. View on bronchoscopy of procedure 4. Time to airway ready 5. Total time from incision to tracheostomy placement
Notes	ISRCTN23203142

DATA AND ANALYSES

Comparison 1. ETT versus LMA

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	7	417	Risk Ratio (M-H, Random, 95% CI)	0.73 [0.35, 1.52]
2 Duration of procedure	6	324	Mean Difference (IV, Random, 95% CI)	-1.46 [-1.92, -1.01]
3 Failure of procedure requiring conversion	7	384	Risk Ratio (M-H, Random, 95% CI)	2.30 [0.56, 9.39]
4 Specific serious adverse event	7	728	Risk Ratio (M-H, Random, 95% CI)	0.46 [0.21, 1.02]
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	7	384	Risk Ratio (M-H, Random, 95% CI)	0.45 [0.14, 1.47]

Analysis 1.1. Comparison 1 ETT versus LMA, Outcome 1 Tally of participants with 1 or more serious adverse events.

Review: Laryngeal mask airway versus endotracheal tube for percutaneous dilatational tracheostomy in critically ill adult patients

Comparison: 1 ETT versus LMA

Outcome: 1 Tally of participants with 1 or more serious adverse events

Analysis 1.2. Comparison 1 ETT versus LMA, Outcome 2 Duration of procedure.

Review: Laryngeal mask airway versus endotracheal tube for percutaneous dilatational tracheostomy in critically ill adult patients

Comparison: 1 ETT versus LMA

Outcome: 2 Duration of procedure

(1) SD: N/A

Analysis 1.3. Comparison 1 ETT versus LMA, Outcome 3 Failure of procedure requiring conversion.

Review: Laryngeal mask airway versus endotracheal tube for percutaneous dilatational tracheostomy in critically ill adult patients

Comparison: 1 ETT versus LMA

Outcome: 3 Failure of procedure requiring conversion

Analysis 1.4. Comparison 1 ETT versus LMA, Outcome 4 Specific serious adverse event.

Review: Laryngeal mask airway versus endotracheal tube for percutaneous dilatational tracheostomy in critically ill adult patients

Comparison: 1 ETT versus LMA

Outcome: 4 Specific serious adverse event

APPENDICES

Appendix 1. 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)

Appendix 2. Ovid MEDLINE search strategy

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

Appendix 3. 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 4. Study selection, quality assessment and data extraction form

Cochrane Anaesthesia Review Group

Review #236

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

Study selection, quality assessment and data extraction form

First author	Journal/Conference proceedings, etc	Year

Study eligibility

RCT	Relevant participants Critically ill participants on ICU (age 18 years and older)	Relevant interventions Elective percutaneous dilatational tracheostomy (no restriction to cer- tain technique)	Relevant outcomes · All-cause mortality · Procedure-related mortality · Any serious adverse event · Duration of procedure · 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

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		Participant characteristics
	Further details	
Age (mean, median, range, etc)		
Sex of participants (numbers/%, etc)		
Disease status/Type, etc (if applicable)		
Other		

Trial characteristics		Trial characteristics
	Further details	
Single centre/Multi-centre		
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		

(Continued)

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	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 quote concerning allocation	Low risk of bias (random)
	High risk of bias (e.g. alternate)
	Unclear

Allocation concealment	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		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		Comment on blinding
Intention-to-treat		Intention-to-treat
All participants entering trial		
15% or less excluded		
More than 15% excluded		
Not analysed as 'intention-to-treat'		
Unclear		
Withdrawals		Withdrawals
Were withdrawals described?	Yes/No/Unclear	
Discuss if appropriate		
Discuss if appropriate		Discuss if appropriate

Data extraction

Outcomes relevant to your review		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	

(Continued)

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							For Continuous data
Code of paper	Outcomes (re-name)	Unit of measurement	Intervention group		Control group		Details if outcome only described in text
			n	Mean (SD)	n	Mean (SD)	
	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				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	

(Continued)

	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?			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	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
First author	Journal / Conference	Year of publication		

WHAT'S NEW

Last assessed as up-to-date: 27 June 2013.

Date	Event	Description
16 March 2017	Amended	Search reran in March 2017; two new studies awaiting classification, which will be incorporated into the formal review findings during the review update

CONTRIBUTIONS OF AUTHORS

Conceiving of the review: Reinhard Strametz (RS)

Co-ordinating the review: RS

Undertaking manual searches: RS, Johanna Kramer (JK), Christoph Pachler (CP)

Screening search results: RS, JK, CP

Organizing retrieval of papers: RS

Screening retrieved papers against inclusion criteria: RS, JK, CP

Appraising quality of papers: RS, CP, JK, Christian Byhahn (CB), Andrea Siebenhofer (AS)

Abstracting data from papers: RS, JK, CP

Writing to authors of papers for additional information: JK

Providing additional data about papers: JK

Obtaining and screening data on unpublished studies: RS, JK, CP

Managing data for the review: RS

Entering data into Review Manager ([RevMan 5.1](#)): RS

Handling RevMan statistical data: Tobias Weberschock (TW)

Performing other statistical analyses not using RevMan: TW

Interpreting data: RS, JK, CP, CB, AS, TW

Making statistical inferences: RS, JK, CP, TW, AS, CB

Writing the review: RS, JK, CP, CB, AS, TW

Securing funding for the review: RS

Performing previous work that served as the foundation of the present study:

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.

Johanna Kramer: none known.

Christoph Pachler: none known.

Christian Byhahn: none known.

Andrea Siebenhofer: none known.

Tobias Weberschock offers standard courses in evidence-based medicine for all who are interested, with no restrictions. This means that pharmaceutical companies and other healthcare organizations are welcome to learn these principles.

SOURCES OF SUPPORT

Internal sources

- Evidence-Based Medicine Working Group, Institute of General Practice, Goethe University, Frankfurt am Main, Germany. Provision of infrastructure (e.g. PC-/Web-/Database-Access)

External sources

- No sources of support supplied

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

The following differences to the protocol ([Strametz 2012](#)) were made:

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.
2. We identified three studies ([Ambesh 2002](#); [Dosemeci 2002](#), [Fernandez-Ortega 2005](#)) with at least one participant who was 17 years old. 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, 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 did not calculate number needed to treat for an additional beneficial outcome (NNTB) or number needed to treat for an additional harmful outcome (NNTH), as no outcome except duration of procedure showed significant differences.
6. 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 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.

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