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Qamarul Hoda M, Samad K, Ullah H

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[Intervention Review]

ProSeal versus Classic laryngeal mask airway (LMA) for positive pressure ventilation in adults undergoing elective surgery

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ABSTRACT

Background

The development of supraglottic airway devices has revolutionized airway management during general anaesthesia. Two devices are widely used in clinical practice to facilitate positive pressure ventilation: the ProSeal laryngeal mask airway (pLMA) and the Classic laryngeal mask airway (cLMA). It is not clear whether these devices have important clinical differences in terms of efficacy or complications.

Objectives

To compare the effectiveness of the ProSeal laryngeal mask airway (pLMA) and the Classic LMA (cLMA) for positive pressure ventilation in adults undergoing elective surgery.

Search methods

We searched the Cochrane Central Register of Controlled Trials (CENTRAL; 2017, Issue 3) in the Cochrane Library; MEDLINE (Ovid SP, 1997 to April 2017); Embase (Ovid SP, 1997 to April 2017); the Institute for Scientific Information (ISI) Web of Science (1946 to April 2017); and the Cumulative Index to Nursing and Allied Health Literature (CINAHL) (EBSCO host, 1982 to April 2017).

We searched trial registries for ongoing studies to April 2017.

We did not impose language restrictions. We restricted our search to the time from 1997 to April 2017 because pLMA was introduced into clinical practice in the year 2000.

Selection criteria

We included randomized controlled trials (RCTs) that compared the effectiveness of pLMA and cLMA for positive pressure ventilation in adults undergoing elective surgery. We planned to include only data related to the first phase of cross-over RCTs.

Data collection and analysis

We used standard methodological procedures expected by the Cochrane Collaboration.

Main results

We included eight RCTs that involved a total of 829 participants (416 and 413 participants in the pLMA and cLMA groups, respectively). We identified six cross-over studies that are awaiting classification; one is completed but has not been published, and data related to the first

treatment period for the other five studies were not yet available. Seven included studies provided data related to the primary outcome, and eight studies provided data related to more than one secondary outcome.

Our analysis was hampered by the fact that a large proportion of the included studies reported no events in either study arm. No studies reported significant differences between devices in relation to the primary review outcome: failure to adequately mechanically ventilate. We evaluated this outcome by assessing two variables: inadequate oxygenation (risk ratio (RR) 0.75, 95% confidence interval (CI) 0.17 to 3.31; four studies, N = 617) and inadequate ventilation (not estimable; one study, N = 80).

More time was required to establish an effective airway using pLMA (mean difference (MD) 10.12 seconds, 95% CI 5.04 to 15.21; $P < 0.0001$; $I^2 = 73\%$; two studies, N = 434). Peak airway pressure during positive pressure ventilation was lower in cLMA participants (MD 0.84, 95% CI 0.02 to 1.67; $P = 0.04$; $I^2 = 0\%$; four studies, N = 259). Mean oropharyngeal leak (OPL) pressure was higher in pLMA participants (MD 6.93, 95% CI 4.23 to 9.62; $P < 0.00001$; $I^2 = 87\%$; six studies, N = 709).

The quality of evidence for all outcomes, as assessed by GRADE score, is low mainly owing to issues related to blinding and imprecision.

Data show no important differences between devices with regard to failure to insert the device, use of an alternate device, mucosal injury, sore throat, bronchospasm, gastric insufflation, regurgitation, coughing, and excessive leak. Data were insufficient to allow estimation of differences for obstruction related to the device. None of the studies reported postoperative nausea and vomiting as an outcome.

Authors' conclusions

We are uncertain about the effects of either of the airway devices in terms of failure of oxygenation or ventilation because there were very few events. Results were uncertain in terms of differences for several complications. Low-quality evidence suggests that the ProSeal laryngeal mask airway makes a better seal and therefore may be more suitable than the Classic laryngeal mask airway for positive pressure ventilation. The Classic laryngeal mask airway may be quicker to insert, but this is unlikely to be clinically meaningful.

PLAIN LANGUAGE SUMMARY

Which airway device (ProSeal or Classic laryngeal airway mask) provides more effective artificial breathing during anaesthesia for adults?

Review question

We wanted to find out if one type of artificial breathing device used in adults during anaesthesia is more effective and safer than another.

Background

Patients anaesthetized for surgical procedures often need to be put on artificial breathing machines (ventilators) to help their breathing. This involves putting into the patient's mouth a device that goes into the windpipe (trachea) or sits above the opening of the vocal cords (supraglottic). We compared the effectiveness of two supraglottic devices (the Classic laryngeal mask airway (cLMA) and the newer ProSeal laryngeal mask airway (pLMA)) that are used to facilitate artificial breathing. Advantages claimed for the pLMA include better fit inside the mouth, less risk of leaking during ventilation, and less chance that stomach contents will be brought up into the windpipe.

Search date

We searched for studies published between 1997 and April 2017 because pLMA was introduced into clinical practice in the year 2000.

Study characteristics

We included eight randomized studies that involved a total of 829 participants 18 years of age and older. All participants had elective surgeries and needed general anaesthesia. Researchers directly compared cLMA against pLMA for providing artificial breathing during surgery.

We identified six cross-over studies that are awaiting classification; one is completed but has not been published, and five other studies are gathering data related to the first treatment period that are not yet available.

Study funding sources

Five studies did not report any funding sources. Of the remaining three studies, one reported that the Laryngeal Mask Company sponsored some data but was not involved in study design, data analysis, and manuscript preparation. The Joseph Drown Foundation, in Los Angeles, California, in the USA, partially supported another study. One of the authors of the final study had received research funds from Intavent Ltd, manufacturer of both types of laryngeal mask airway, but Intavent Ltd did not sponsor this study.

Key results

We are unsure whether these devices exhibit important differences in providing adequate oxygenation and ventilation because there was not enough data to enable us to draw any firm conclusions. ProSeal laryngeal mask airway may provides a better seal because it leaks at higher pressure, but Classic laryngeal mask airway may be quicker to insert. However, these findings are not important clinically.

Quality of the evidence

We assessed all of the included studies as providing low-quality evidence because anaesthetists knew which device was being used on which participants (although this was probably unavoidable), and because it was unclear whether the investigator who collected the data was unaware of the intervention. This fact created the potential for bias.

SUMMARY OF FINDINGS

Summary of findings for the main comparison. ProSeal versus Classic laryngeal mask airway (LMA) for positive pressure ventilation in adult patients undergoing elective surgery

ProSeal versus Classic laryngeal mask airway (LMA) for positive pressure ventilation in adult patients undergoing elective surgery

Patient or population: adult patients (18 years of age and older) for positive pressure ventilation undergoing elective surgery

Settings: hospital operation theatres in Australia, Austria, France, Germany, Italy, India, Japan, South Korea, Spain, USA

Intervention: ProSeal laryngeal mask airway (pLMA)

Comparison: Classic laryngeal mask airway (cLMA)

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	Number of participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	cLMA	pLMA				
Inadequate oxygenation (SaO ₂ < 90% on peripheral oxygen saturation)	13 per 1000	10 per 1000 (2 to 43)	RR 0.75 (0.17 to 3.31)	617 (4 studies)	⊕⊕⊕⊕ very low ^a	
Inadequate ventilation (ETCO ₂ > 45 mm Hg)	See comment	See comment	Not estimable	80 (1 study)	See comment	No episodes of inadequate ventilation in either group
Time required for effective airway (seconds)	Mean effective airway time in the control group ranged from 22.24 seconds to 31 seconds	Mean effective airway time in the intervention group was 10.12 seconds longer (95% CI 5.04 to 15.21)		434 (2 studies)	⊕⊕⊕⊕ Low ^b	Outcome added post protocol as some included studies looked at this outcome.
Peak airway pressure during positive pressure ventilation (cm H₂O)	Peak airway pressure in the control group ranged from 17 cm H ₂ O to 24.5 cm H ₂ O	Mean peak airway pressure during positive pressure ventilation was higher in the pLMA group by 0.84 cm H ₂ O (95% CI 0.02 to 1.67)		259 (4)	⊕⊕⊕⊕ Low ^c	
Oropharyngeal leak pressure (seal pressure) (cm H₂O)	Oropharyngeal leak pressure in the control group	Mean oropharyngeal leak pressure (seal pressure) was higher in the		709 (6 studies)	⊕⊕⊕⊕ Low ^d	

	ranged from 14.64 cm H ₂ O to 26 cm H ₂ O	pLMA group by 7.17 cm H ₂ O (95% CI 4.85 to 9.5)			
Sore throat	194 per 1000	150 per 1000 (107 to 210)	RR 0.77 (0.55 to 1.08)	653 (5)	⊕⊕○○ Low ^e
Regurgitation	17 per 1000	13 per 1000 (4 to 45)	RR 0.8 (0.24 to 2.69)	597 (4)	⊕⊕○○ Low ^f

*The basis for the **assumed risk** (e.g. median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on 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.

^aThree studies reporting this outcome were assessed as demonstrating adequate allocation concealment and one was unclear. Blinding of participants, personnel and outcome assessor were assessed as unclear in three studies and one study was unblinded. Furthermore, the results are imprecise, as only one out of four studies has reported positive events, therefore evidence is downgraded three levels.

^bData from two studies with imprecise results resulted in downgrading of evidence by two levels.

^cBlinding of participants, personnel and outcome assessors were unclear in three studies and one study was unblinded. This resulted in downgrading the evidence by two levels.

^dBlinding of participant and personnel were unclear in all six studies while blinding of outcome assessor was not conducted in one study and was unclear in the remaining five studies. Data analysis indicated high levels of heterogeneity (inconsistency). For these reasons, the evidence was downgraded two levels.

^eBlinding of participant and personnel were unclear in four studies and was not done in one study, while blinding of outcome assessor was not conducted in two studies and was unclear in the remaining three studies. This resulted in downgrading the evidence by two levels.

^fBlinding of participant and personnel were unclear in all four studies while blinding of outcome assessor was not conducted in one study and was unclear in the remaining three studies, therefore evidence was downgraded two levels.

BACKGROUND

Description of the condition

The history of airway management in humans spans almost 4000 years. Modern endotracheal intubation dates back to the 18th century, when obstetricians and first responders first used breathing tubes. It was as late as 1945 when endotracheal intubation was adopted for usual practice (Luckhaupt 1986). Improved understanding of the pathophysiology of the upper airway led to the development of newer, less invasive airway devices such as the laryngeal mask airway (LMA), which has been assigned an important role in anaesthesia practice (Szmuk 2008). In contrast to supraglottic airway devices (laryngeal and pharyngeal airways), the endotracheal tube is a definitive airway device that not only allows delivery of oxygen, anaesthesia, and other drugs, it also enables effective ventilation without increased risk of gastric insufflation and pulmonary aspiration. Although effective, laryngoscopy and endotracheal intubation are associated with morbidities ranging from minor complications such as sore throat and trauma to the larynx, lips, teeth, tongue, and nose to more serious effects such as difficult or failed intubation and noxious autonomic reflexes (hypertension, tachycardia, bradycardia, and arrhythmias), which can be detrimental in some cases (Blanc 1974).

Description of the intervention

The laryngeal mask airway (LMA), designed by Dr Archie Brain in 1988, is a minimally invasive airway device that offers several advantages over conventional laryngoscopy and tracheal intubation. Its benefits include improved haemodynamic stability, reduced anaesthetic requirements, avoidance of muscle relaxation agents, and reduced coughing (Brimacombe 1995) and sore throat (5.8% vs 34% and 14.4% vs 50%, respectively) (McHardy 1999). Since it was introduced, the LMA has gained widespread acceptance over the endotracheal tube as a safe and effective airway device for spontaneously breathing anaesthetized patients (Benumof 1992; Benumof 1996; Bogetz 1994; Jones 1995; Lopez-Gil 2005; Todesco 1993; Villars 2005; Wat 2003). The Classic LMA is an autoclavable and reusable laryngeal mask airway that consists of an airway tube connected to an inflatable mask with a silicone rim. The single cuff provides a seal around the laryngeal inlet while enabling spontaneous ventilation of the airway and application of positive pressure ventilation (Brain 1983; Brain 1985; Brimacombe 1996; Van Damme 1994; Vergheze 1996). However, the seal provided by LMA does not guarantee prevention of pulmonary aspiration, thus revealing its major limitation for positive pressure ventilation (Keller 2004).

Limitations of the Classic LMA (cLMA) (lack of protection from aspiration, airway leak, and risk of gastric distension with positive pressure ventilation) led to development of the ProSeal LMA (pLMA), which has a better anatomical fit and is more suitable for positive pressure ventilation.

The ProSeal laryngeal mask airway (pLMA; Intavent Orthofix, Maidenhead, UK), introduced in the year 2000, was designed by Dr Archie Brain and is based on the same principle that led to the design of the Classic laryngeal mask airway (cLMA). Modifications in design of the pLMA include separation of respiratory and gastrointestinal tracts, provision of a larger and softer wedge-shaped cuff, and incorporation of an oesophageal drain tube. These modifications were designed to improve safety and efficacy by

improving the airway seal, and to enable more effective positive pressure ventilation, reducing the chance of gastric insufflation and consequent regurgitation and aspiration of gastric contents (Brain 2000).

How the intervention might work

The cLMA, in contrast to an endotracheal tube, cannot guarantee protection of the lungs from aspiration of regurgitated material. Deep (subglottic) suctioning cannot be performed through the cLMA. Although the effectiveness of cLMA in preventing pulmonary aspiration has been documented, evidence of gastric distension and pulmonary aspiration has been noted with cLMA use (Griffin 1990; Maltby 2000).

The pLMA can provide higher oropharyngeal leak pressure without an increase in mucosal pressure. This enables more effective positive pressure ventilation without the need for high cuff mucosal pressure (Brimacombe 2002; Keller 2000). It has been suggested that the pLMA double-cuff design enables twice the leak pressure for a given intracuff pressure compared with the cLMA (Brimacombe 2002). A further potential advantage of pLMA is that the drain tube provides access to the oesophagus, enabling insertion of a gastric tube, which may reduce the risk of aspiration (Evans 2002; Mark 2003).

Why it is important to do this review

Classic LMA is a safe and effective device for use in anaesthetized patients who are breathing spontaneously. A meta-analysis of cLMA studies reported only 0.02% risk of aspiration, but this analysis did not look specifically at the risk of aspiration with positive pressure ventilation (Brimacombe 1995a).

Classic LMA has been studied extensively for positive pressure ventilation (Bernardini 2009; Devitt 1994) and has shown benefit for select patient groups, including those with normal lung compliance and airway resistance and people for whom airway pressure does not exceed 20 cm H₂O, which causes gastric insufflation. Classic LMA has been shown to be effective as an endotracheal tube for positive pressure ventilation. Other consequences of positive pressure ventilation through the cLMA include hypoventilation and operating room pollution resulting from leakage of inspired gases due to higher seal pressure.

Given that pLMA has a portal for gastric deflation and higher oropharyngeal leak pressure, theoretically it should be a better choice for use in positive pressure ventilation.

OBJECTIVES

To compare the effectiveness of the ProSeal laryngeal mask airway (pLMA) and the Classic LMA (cLMA) for positive pressure ventilation in adults undergoing elective surgery.

METHODS

Criteria for considering studies for this review

Types of studies

We included randomized controlled trials (RCTs) comparing the effectiveness of positive pressure ventilation by Classic and ProSeal laryngeal mask airways (LMAs) in adult patients undergoing

elective surgery. We planned to include data related to the device used first in cross-over RCTs.

Types of participants

We included adults (18 years of age and older) scheduled for elective surgery who required general anaesthesia with positive pressure ventilation.

Types of interventions

We included studies that compared use of the Classic LMA (cLMA) versus the ProSeal LMA (pLMA) for positive pressure ventilation under general anaesthesia using:

1. any technique of LMA insertion;
2. any type of cLMA (reusable or disposable) and reusable pLMA; and
3. any mode of positive pressure ventilation.

Types of outcome measures

We anticipated a range of definitions for primary and secondary outcome variables among the included studies. We therefore intended to subgroup such outcomes and to consider pooled results, if appropriate data were available.

Primary outcomes

Failure to adequately mechanically ventilate according to two variables

1. Inadequate oxygenation measured as less than 90% on peripheral oxygen saturation (SaO₂)
2. Inadequate ventilation assessed by end-tidal carbon dioxide concentration (ETCO₂) greater than 45 mm Hg

Secondary outcomes

1. Inability to insert laryngeal mask airway or abandonment of insertion of the intended device - assessed by inability to insert or use an alternate device or both
2. Effective airway time - assessed as time taken to insert and adequately ventilate using either device
3. Failure to insert gastric tube
4. Peak airway pressure during positive pressure ventilation
5. Oropharyngeal leak pressure
6. Complications related to LMA insertion: mucosal injury (blood staining), sore throat, excessive leak, gastric insufflation, bronchospasm/laryngospasm, regurgitation/aspiration, coughing, obstruction of device, excessive secretions, postoperative nausea or vomiting

Search methods for identification of studies

Electronic searches

We searched the Cochrane Central Register of Controlled Trials (CENTRAL; 2017, Issue 3) in the Cochrane Library ([Appendix 1](#)); MEDLINE (Ovid SP, 1997 to April 2017) ([Appendix 2](#)); Embase (Ovid SP, 1997 to April 2017) ([Appendix 3](#)); the Institute for Scientific Information (ISI) Web of Science (1946 to April 2017) ([Appendix 4](#)); and the Cumulative Index to Nursing and Allied Health Literature (CINAHL) (EBSCO host, 1982 to April 2017) ([Appendix 5](#)).

We imposed no language restrictions. We restricted our searches to the time from 1997 to April 2017 because pLMA was introduced to clinical practice in the year 2000.

Searching other resources

We handsearched reference lists of all included studies for trials missed by the electronic search strategy.

We also searched the following trial registries for ongoing studies in April 2017.

1. [ISRCTN registry](#).
2. <http://www.clinicalstudyresults.org> (we were able to search this website only to December 2016. Thereafter, the website became unavailable).
3. [ClinicalTrials.gov](#).
4. [WHO International Clinical Trials Registry Platform \(ICTRP\)](#).

Data collection and analysis

Selection of studies

Two review authors (QH, KS) independently assessed titles and abstracts identified by the searches. We obtained full-text copies of potentially relevant trials for assessment according to parameters outlined in [Criteria for considering studies for this review](#). We assessed trials that met those criteria for methodological quality only.

Data extraction and management

Two review authors (QH, KS) independently extracted data using a data extraction form for each trial ([Appendix 6](#)). One review author (KS) entered all data into Review Manager ([RevMan 5.3](#)), and a second review author (QH) checked these data for completeness and correctness. If required, we planned to contact primary authors of trials to request information, especially regarding unpublished data.

We planned to extract the following data for each included trial.

1. Participants (age, gender, body mass index (BMI), sample size, allocation, flow of participants throughout enrolment, follow-up, analysis, protocol deviations if any).
2. Interventions.
  - a. Technique used for cLMA and pLMA insertion (with or without introducer).
  - b. Epigastric auscultation.
  - c. Oropharyngeal leak.
  - d. Drainage tube leak.
  - e. Oropharyngeal leak pressure.
  - f. Confirmation of correct placement with fibre-optic bronchoscope.
  - g. Ease of insertion.
3. Ventilation parameters: peak airway pressure, inspired tidal volume, expired tidal volume, pulmonary compliance, blood oxygen saturation (SpO₂), partial pressure of oxygen (PaO₂), ETCO₂, partial pressure of carbon dioxide (PaCO₂).
4. Outcomes (primary and secondary).

Assessment of risk of bias in included studies

We assessed trial quality using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). These criteria included assessment of selection bias, performance bias, attrition bias, detection bias, and reporting bias. We rated each domain separately for each included study in a risk of bias table as showing high risk, unclear risk, or low risk of bias.

We resolved disagreements regarding assessment by discussion and consensus. We did not combine in pooled estimates of effects the results of studies assessed as having high risk of bias and low risk of bias. We noted this under [Assessment of risk of bias in included studies](#).

Measures of treatment effect

In the absence of clinical heterogeneity, we undertook analysis using RevMan 5.3. We used risk ratio (RR) to measure treatment effect for dichotomous outcomes measured in two or more studies evaluating the same intervention. For continuous data, we used mean difference (MD) and the inverse variance method and calculated an overall MD. We used a fixed-effect model when we found no evidence of significant heterogeneity among studies, and a random-effects model when heterogeneity was likely (DerSimonian 1986).

Unit of analysis issues

No cluster-randomized trials met our inclusion criteria. We combined trial data because we had no issues with units of analysis. We planned to include data only from the first phase of cross-over trials.

Dealing with missing data

All data extracted reflect the original allocation group, enabling an intention-to-treat analysis (ITT). We identified drop-outs when this information was given. We included studies irrespective of whether all or some of the outcome information was available. We presented this information in risk of bias tables ([Assessment of risk of bias in included studies](#)) in the selective reporting domain.

In Keller 2000, the data for "oropharyngeal leak pressure" was presented using means and 95% CI, where 95% CI were converted to standard deviation (SD) by the method described in Higgins 2011a. While in Shin 2010, this data was presented as median and 25th and 75th percentiles which were converted to mean and SD by the process described by Wan 2014.

Assessment of heterogeneity

We addressed clinical heterogeneity through the characteristics of included studies (e.g. participant age, weight, height, and BMI; American Society of Anesthesiology (ASA) physical status; duration of surgery). Provided that the data were homogeneous enough to be combined, we performed a meta-analysis of data from all included studies. We assessed the risk of bias for methodological heterogeneity and summarized this information in Figure 1. To evaluate statistical heterogeneity, we used χ^2 and I^2 tests. We used the χ^2 test to evaluate whether heterogeneity exists, while considering $P < 0.1$ as statistically significant, and we used the I^2 statistic to quantify inconsistencies. If I^2 was greater than 75%, we considered heterogeneity to be considerable (Higgins 2011). We used the results of these two tests to assess whether heterogeneity needs to be accounted for in the model. We investigated reasons for any heterogeneity. We used a fixed-effect model if we found studies to be homogeneous; otherwise we used a random-effects model.

Figure 1. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

Assessment of reporting biases

We planned to perform sensitivity analyses for study quality that considered only studies with low or moderate risk of bias, using a risk of bias table for each included study.

We planned to evaluate each study for classification into one of the following categories.

1. Low risk of bias - all criteria met.
2. Moderate risk of bias - one or more criteria unclear.
3. High risk of bias - one or more criteria not applied or met.

We planned to assign low risk of bias when allocation concealment was adequate; moderate risk of bias when allocation concealment was unclear or when study authors did not clearly report the

approach; and high risk of bias when allocation concealment was not applied. We planned to evaluate the impact of methodological quality in 'Risk of bias' tables.

Data synthesis

We entered data extracted from the studies into [RevMan 5.3](#) and combined data quantitatively when appropriate. We planned to present primary outcomes as a dichotomous variable (success/no success). We planned to analyse other outcomes as dichotomous or continuous variables. We further planned to calculate standardized mean differences (SMDs) with 95% confidence intervals (CIs). We calculated pooled estimates using the fixed-effect model unless we observed significant heterogeneity, in which case we used a random-effects model. For continuous variables, we planned to calculate the mean difference (MD) with 95% CI. We used RR with 95% CI for dichotomous outcomes. We planned to conduct sensitivity analysis to discern the impact of the type of analysis on results.

Subgroup analysis and investigation of heterogeneity

We planned to conduct subgroup analyses to investigate suspected clinical heterogeneity based on:

1. duration of surgery (short vs long);
2. type of surgical procedure (abdominal vs peripheral surgery);
3. positioning during surgery; and
4. differing definitions of the primary outcome.

Sensitivity analysis

We planned to carry out sensitivity analysis according to study methodological quality (for trials with low risk of bias) and missing data (using best-case and worst-case scenarios). However, neither was required given that we assessed almost all of the included studies as having high risk of bias and identified no missing data.

'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 outcomes in our review.

1. Failure to adequately mechanically ventilate according to two variables.

- a. Inadequate oxygenation.
  - b. Inadequate ventilation.
2. Time required for effective airway (seconds).
  3. Peak airway pressure during positive pressure ventilation.
  4. Oropharyngeal leak pressure (seal pressure) (cm H₂O).

We constructed a 'Summary of findings' table ([Summary of findings for the main comparison](#)) using GRADEpro GDT software ([GRADEpro GDT 2014](#)).

We graded results according to the GRADE approach (www.bmj.com/advice/sections/shhtml) in accordance with recommendations provided in the *Cochrane Handbook for Systematic Reviews of Interventions*, Chapter 12.2.1 ([Higgins 2011](#)).

RESULTS

Description of studies

Results of the search

We identified 4741 records through electronic searches conducted in April 2017. Of these, we excluded 4719 titles and abstracts, as they were duplicates (789) or were irrelevant (3930).

The remaining 22 records qualified for full paper analysis. We identified two additional records by handsearching reference lists of full-text papers. We therefore accessed 24 full-text studies and excluded 10 studies after full-text review, as all of these studies were irrelevant to our review. Of the remaining 14 studies, we identified six RCTs that are awaiting classification.

Five of the RCTs awaiting classification are cross-over trials, and data related to the first treatment period were not available. We contacted study authors (9 and 10 December 2015, and 1 and 4 April 2017) to request further information. One study is awaiting classification because, although the study was completed in November 2016, the study report has not yet been published. We will assess data from these six studies, when available, and will include studies that meet the review study inclusion criteria in a future update. (See [Characteristics of studies awaiting classification](#); [Figure 2](#).) We included eight studies in this review.

Figure 2. Study flow diagram.

Figure 2. (Continued)

Included studies

We included eight studies with a total of 829 participants ([Ambi 2011](#); [Brimacombe 2002](#); [Keller 2000](#); [Khazin 2008](#); [Lu 2002](#); [Natalini 2003a](#); [Natalini 2003b](#); [Shin 2010](#)) (416 participants in the intervention (pLMA) group, and 413 in the control (cLMA) group) of either sex, between 18 and 84 years of age, with American Society of Anesthesiology (ASA) physical status grades I to III (ASA I, II, and III), who were scheduled for elective surgery (i.e. peripheral limb surgery, orthopaedic surgery, minor vascular surgery, peripheral plastic surgery, urological surgery, laparoscopic cholecystectomy, other abdominal and gynaecological laparoscopic procedures). Of these studies [Khazin 2008](#) compared five devices and [Shin 2010](#) compared three airway devices, but we used only data pertaining to cLMA and pLMA.

In one study ([Natalini 2003a](#)), participants were obese (BMI > 30). Four studies ([Brimacombe 2002](#); [Khazin 2008](#); [Lu 2002](#); [Shin 2010](#)) excluded morbidly obese patients (BMI > 35 kg/m²). Two studies ([Ambi 2011](#); [Keller 2000](#)) did not report BMI of participants. [Natalini 2003b](#) reported BMI of study participants as 26 ± 6/25 ± 4 pLMA/cLMA.

Five studies ([Ambi 2011](#); [Keller 2000](#); [Lu 2002](#); [Natalini 2003a](#); [Shin 2010](#)) used neuromuscular blocking agents for insertion of the intended device and [Natalini 2003b](#) used muscle relaxant after LMA placement. Two studies ([Brimacombe 2002](#); [Khazin 2008](#)) did not use muscle relaxants in study participants.

Six of the included studies ([Ambi 2011](#); [Keller 2000](#); [Khazin 2008](#); [Lu 2002](#); [Natalini 2003a](#); [Natalini 2003b](#)) were single-centre studies conducted in India, Australia, Israel, and Italy. [Shin 2010](#) was performed at two centres - Japan and South Korea - and [Brimacombe 2002](#) was a multi-centre trial conducted at eight study sites in seven countries (one each in Australia, Austria, France, Germany, Italy, and Spain; two in the United States).

Among eight included studies, five studies ([Ambi 2011](#); [Keller 2000](#); [Natalini 2003a](#); [Natalini 2003b](#); [Shin 2010](#)) did not report funding resources. [Brimacombe 2002](#) reported that some data were sponsored by the Laryngeal Mask Company, which manufactures ProSeal and Classic laryngeal mask airway devices. However, neither the Laryngeal Mask Company nor Dr Brain (the inventor) was involved in the design of the study, data analysis, or manuscript preparation. One of the authors in [Lu 2002](#) had received research funds from Intavent Ltd, the manufacturer of both types of LMAs,

but Intavent Ltd did not sponsor this study. [Khazin 2008](#) reported that the study was supported in part by the Joseph Drown Foundation, in Los Angeles, California, in the United States.

Excluded studies

We excluded 10 studies following full-text assessment owing to inclusion of irrelevant interventions. Of these, five studies ([Hosten 2009](#); [Lopez 2011](#); [Seet 2010](#); [Tham 2010](#); [Vergheze 2008](#)) compared disposable (LMA - Supreme) versus reusable ProSeal LMA. [Francksen 2007](#) compared three disposable airway devices that were not comparable with cLMA and pLMA. [Shariffuddin 2008](#) compared the Ambu AuraOnce Laryngeal Mask versus the Classic LMA only. [Goldmann 2011](#) compared only pLMA in obese and non-obese participants. [Maltby 2003](#) compared cLMA/pLMA versus an endotracheal tube, and [Brain 2000](#) compared two types of LMA versus drainage tubes (prototype LMA and new LMA, which were not comparable with cLMA). See [Characteristics of excluded studies](#) for details.

Studies awaiting classification

We identified six RCTs that are awaiting classification ([Brimacombe 2000](#); [Brimacombe 2001](#); [Cook 2002](#); [Li 2007](#); [Natalini 2003c](#); [NCT02979171](#)). Five of these are cross-over trials and data related to the first treatment period were not available ([Brimacombe 2000](#); [Brimacombe 2001](#); [Cook 2002](#); [Li 2007](#); [Natalini 2003c](#)). We contacted the study authors (9 and 10 December 2015, and 1 and 4 April 2017) to request further information. One study (identifier number: [NCT02979171](#)) is awaiting classification. This study was completed in November 2016, but the study report has not yet been published. We will assess these data, when available, and will include studies that meet the review study inclusion criteria in a future update. (See [Characteristics of studies awaiting classification](#).)

Ongoing studies

We identified no ongoing studies.

Risk of bias in included studies

We evaluated the overall quality of studies according to the methods outlined under [Assessment of risk of bias in included studies](#). We present the different bias domains in [Characteristics of included studies](#). We present the graph and summary of risk of bias in included studies in [Figure 1](#) and [Figure 3](#).

Figure 3. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)
Ambi 2011	+	+	+	+	?	?
Brimacombe 2002	+	+	+	+	?	-
Keller 2000	+	+	+	+	?	?
Khazin 2008	+	+	+	+	?	?
Lu 2002	+	+	+	+	?	?
Natalini 2003a	+	+	+	+	?	?
Natalini 2003b	+	+	+	+	-	-
Shin 2010	+	?	+	+	?	?

Allocation

Investigators described all eight included studies (Ambi 2011; Brimacombe 2002; Keller 2000; Khazin 2008; Lu 2002; Natalini

2003a; Natalini 2003b; Shin 2010) as randomized, and provided sufficient details on the method of randomization.

Regarding allocation concealment, Ambi 2011, Brimacombe 2002, Keller 2000, and Lu 2002 used a sealed envelope technique;

Khazin 2008 used computer-generated codes; and Natalini 2003a and Natalini 2003b used computer-generated tables. Shin 2010 provided no information about the envelope, and we considered risk to be unclear. Overall, our judgement was that studies were at low risk for selection bias.

Blinding

While assessing performance bias, we believed it was not possible to blind personnel inserting the airway device. Similarly, it was not possible for assessors of the primary outcomes of "inadequate oxygenation and ventilation" to be blinded. However, some studies mentioned that outcome assessors were blinded for some of the secondary outcomes, and other studies described observers as "independent" for some outcomes, which is not the same as being blinded to group allocation.

Brimacombe 2002 stated that an unblinded, trained observer collected data during surgery, and a blinded, trained observer collected data in the post-anaesthesia care unit (PACU) the following day. This resulted in high risk of detection bias, as investigators collected most of the data during surgery.

We judged Natalini 2003b to be at high risk of bias, as study authors mention that this is an "unblinded" study.

All other studies (Ambi 2011; Keller 2000; Khazin 2008; Lu 2002; Natalini 2003a; Shin 2010) did not provide sufficient information to permit assessment of detection bias. Keller 2000 used unblinded observers for fibre-optic position and scoring but provided insufficient information regarding other outcomes. Khazin 2008 used independent and blinded observers for only one of the secondary outcomes, and Lu 2002 mentioned that "independent" observers collected the data but did not mention blinding. Ambi 2011, Natalini 2003a, and Shin 2010 did not report anything regarding blinding of personnel and assessors.

On the basis of this information, we judged performance and detection bias to be unclear.

Incomplete outcome data

Six studies (Ambi 2011; Keller 2000; Khazin 2008; Lu 2002; Natalini 2003b; Shin 2010) included in their analyses data on all participants. Of the remaining two studies, Brimacombe 2002 reported loss of 1% intraoperative and 3% postoperative data related to gastric tube placement and position of the drainage tube and airway tube. A total of 53 protocol deviations included in the analysis (as they were minor) were evenly distributed between groups and were related to one of our secondary outcomes - gastric tube insertion. In one of 30 participants in Natalini 2003a, both devices failed; ventilation was managed by face mask, and these participants were excluded from the study. As most of the included studies provided data on all study participants, and the other two studies (Brimacombe 2002; Natalini 2003a) had very low rates of attrition, we assigned low risk of bias for this domain.

Selective reporting

Six of eight studies (Brimacombe 2002; Keller 2000; Lu 2002; Natalini 2003a; Natalini 2003b; Shin 2010) reported data for all outcomes assessed. Ambi 2011 did not report postoperative nausea and vomiting, but this is not one of our major outcomes of interest. Khazin 2008 mentioned that researchers would monitor plateau pressure, inspired and expired minute volume, SaO₂,

ETCO₂, adequacy of ventilation, airway manipulations, number of failed insertion attempts, gastric insufflations due to positive pressure ventilation, and complications. In the results section, study authors stated that "respiratory variables were similar in both groups," which covers all of the variables mentioned above. Owing to this, we have assigned low risk of reporting bias.

Other potential sources of bias

We found no other potential sources of bias in the included studies.

Effects of interventions

See: [Summary of findings for the main comparison ProSeal versus Classic laryngeal mask airway \(LMA\) for positive pressure ventilation in adult patients undergoing elective surgery](#)

We have detailed important outcomes in [Summary of findings for the main comparison](#). In relation to effective airway time (Analysis 3.1), it is important to note that the standard deviation (SD) of most included studies suggests a right-skewed distribution of sample values, suggesting imprecision in the results.

Outcomes

Primary outcomes

Failure to mechanically ventilate adequately

Inadequate oxygenation

Seven trials reported oxygenation as assessed by peripheral arterial oxygen saturation (SaO₂) (Ambi 2011; Brimacombe 2002; Khazin 2008; Lu 2002; Natalini 2003a; Natalini 2003b; Shin 2010). Two studies reported "hypoxic events" rather than a measurement point below a stated threshold (Ambi 2011; Shin 2010); and Brimacombe 2002 reported SaO₂ as "less than 90%." Lu 2002 considered oxygenation as "suboptimal" if SaO₂ fell to 94% to 90%, and as "failed oxygenation" if less than 90%. Two trials (Natalini 2003a; Natalini 2003b) did not report quantitative results - only that "SaO₂ was similar in both groups." Khazin 2008 reported that "respiratory variables were similar in both groups."

This analysis included data from four studies (N = 617 participants; 310 allocated to pLMA and 307 to cLMA) (Ambi 2011; Brimacombe 2002; Lu 2002; Shin 2010). Of these, three studies (N = 233; 118 participants in the pLMA group and 115 in the cLMA group) reported no hypoxic events in either group (Ambi 2011; Lu 2002; Shin 2010). Only Brimacombe 2002 reported actual hypoxia events (SaO₂ < 90%) (N = 384; pLMA and cLMA groups = 192/192). Data show seven hypoxic events (1.8%) with no clinically important differences between groups. Three of 192 participants (1.6%) in the pLMA group and four of 192 (2.1%) in the cLMA group experienced hypoxic events. Owing to limited available data, information was insufficient to show the effects of pLMA and cLMA on hypoxic events (RR 0.75, 95% CI 0.17 to 3.31; low-quality evidence; Analysis 1.1).

It was uncertain whether four studies that looked at inadequate oxygenation showed any difference between pLMA and cLMA groups (Ambi 2011; Brimacombe 2002; Lu 2002; Shin 2010). Furthermore, results from these four studies are imprecise; only Brimacombe 2002 reported positive events. We assessed three of these four studies as adequately concealing allocation to study arms, and we assessed Shin 2010 as providing unclear information. We noted no selective reporting in any of these studies. Blinding of participants was not clear in all four studies, and investigators

blinded assessors to outcomes (Brimacombe 2002) or provided unclear information (Ambi 2011; Lu 2002; Shin 2010). We therefore downgraded the quality of evidence by three levels from high to very low.

Inadequate ventilation

Only Lu 2002 reported the incidence of inadequate ventilation (N = 80; 40/40 pLMA/cLMA groups). Lu 2002 defined inadequate ventilation as end-tidal carbon dioxide (ETCO₂) greater than 45 mm Hg to 55 mm Hg (> 6.0 to 7.3 kPa), and failed ventilation as ETCO₂ greater than 55 mm Hg (> 7.3 kPa). No participants experienced any episodes of inadequate ventilation.

Secondary outcomes

Inability to insert LMA or abandonment of intended device insertion

Seven studies (N = 769; 386 in pLMA group and 383 in cLMA group) looked at successful or failed laryngeal mask airway (LMA) placement (Ambi 2011; Brimacombe 2002; Keller 2000; Khazin 2008; Lu 2002; Natalini 2003a; Shin 2010). Researchers assessed proper placement by looking at capnograph wave form (Brimacombe 2002; Khazin 2008; Lu 2002; Shin 2010); chest movement (Khazin 2008; Lu 2002; Shin 2010); ETCO₂ (Shin 2010); no audible leak (Brimacombe 2002); or leak fraction greater than 15% (Natalini 2003a); or by checking position by using a fibre-optic scope (Keller 2000). Two studies did not define an effective airway (Ambi 2011; Khazin 2008). Four studies used two or more techniques or modalities to monitor proper placement (Brimacombe 2002; Khazin 2008; Lu 2002; Shin 2010). After three attempts, all studies reported using an alternate device.

Five studies (Ambi 2011; Keller 2000; Khazin 2008; Lu 2002; Shin 2010; N = 325) reported no events in either arm. Two studies (Brimacombe 2002; Natalini 2003a; N = 444; 222/222 pLMA/cLMA groups) reported failure events. Of these, seven participants experienced failure of insertion events (1.6%): five from pLMA groups (2.25%) and two from cLMA groups (0.9%). Meta-analysis of all seven studies showed no important differences between groups (RR 2.20, 95% CI 0.50 to 9.72; I² = 48%; P = 0.30; Analysis 2.1).

Time to establish an effective airway (seconds)

Two studies observed time to achieve an effective airway, as measured by taking the device in hand until the effective airway was achieved (Ambi 2011; Brimacombe 2002; N = 434; 217/217 pLMA/cLMA groups). Meta-analysis showed that time required for insertion was longer with pLMA than with cLMA (MD 10.12, 95% CI 5.04 to 15.21; I² = 0%; P < 0.0001; Analysis 3.1). We downgraded evidence quality by two levels from high to low because researchers did not blind participants and outcome assessors (Brimacombe 2002), or we assessed risk as unclear (Ambi 2011). Data analysis showed imprecise results owing to high standard deviations (SDs) in three of four instances.

Failure to insert gastric tube

Five studies investigated gastric tube insertion (Ambi 2011; Brimacombe 2002; Lu 2002; Natalini 2003a; Natalini 2003b). Three studies compared pLMA and cLMA groups (Brimacombe 2002; Natalini 2003a; Natalini 2003b). Two studies (Ambi 2011; Lu 2002) considered gastric tube insertion in the pLMA group. Investigators in Natalini 2003a and Natalini 2003b inserted a gastric tube before inserting the airway device in the cLMA group. Brimacombe 2002 attempted orogastric tube insertion in 168 participants (95/73 in

pLMA/cLMA groups). The failure rate was much lower in the pLMA group (11 participants (11.6%) vs 33 participants (45%)). Insertion time was also shorter in the pLMA group (22 ± 18 seconds vs 38 ± 56 seconds).

Peak airway pressure (cm H₂O)

Four studies assessed peak airway pressure during positive pressure ventilation (Khazin 2008; Lu 2002; Natalini 2003a; Natalini 2003b; N = 259; 130/129 pLMA/cLMA groups). Meta-analysis showed lower pressure in the cLMA group (MD 0.84, 95% CI 0.02 to 1.67; I² = 0%; P = 0.04; Analysis 4.1).

Blinding of participants and outcome assessors was not clear in three studies (Khazin 2008; Lu 2002; Natalini 2003a), and Natalini 2003b was unblinded for both participants and assessors. We therefore downgraded the quality of evidence from high to low.

Oropharyngeal leak pressure (seal pressure) (cm H₂O)

Six studies assessed oropharyngeal leak pressure (Ambi 2011; Brimacombe 2002; Keller 2000; Khazin 2008; Lu 2002; Shin 2010; N = 709; 356/353 pLMA/cLMA groups). Five studies (Ambi 2011; Brimacombe 2002; Keller 2000; Lu 2002; Shin 2010) determined seal pressure by using gas flow of three to five litres per minute and closing the adjustable pressure limiting (APL) valve at 40 cm H₂O; Khazin 2008 checked this at 60 cm H₂O. Mean oropharyngeal leak pressure was higher in the pLMA group (MD 6.93, 95% CI 4.23 to 9.62; I² = 87%; P < 0.00001; Analysis 5.1).

Blinding of participants was unclear in all studies; Brimacombe 2002 did not blind outcome assessors, and remaining five studies (Ambi 2011; Keller 2000; Khazin 2008; Lu 2002; Shin 2010) provided unclear information. Furthermore, data analysis revealed high levels of heterogeneity (inconsistency); we therefore downgraded the quality of evidence from high to low.

Complications

Mucosal injury (blood staining)

Four studies reported mucosal injury (Ambi 2011; Brimacombe 2002; Lu 2002; Shin 2010; N = 617; 310/307 pLMA/cLMA). A total of 45 participants (14.5%) in the pLMA group and 30 (9.7%) in the cLMA group had mucosal injury. Although the incidence is 4.8% higher in the pLMA group, we are uncertain that this difference is of any significance (RR 1.49, 95% CI 0.97 to 2.28; I² = 0%; P = 0.07; Analysis 6.1).

Sore throat

Five studies reported this outcome (Ambi 2011; Brimacombe 2002; Natalini 2003a; Natalini 2003b; Shin 2010; N = 653; 329/324 pLMA/cLMA groups). Overall, sore throat occurred in 49 participants (14.9%) in the pLMA group and in 63 (19.4%) in the cLMA group. The risk ratio of sore throat was 4.5% higher in the cLMA group but there is uncertainty as to whether this difference is of any significance (RR 0.77, 95% CI 0.55 to 1.08; I² = 22%; P = 0.12; Analysis 6.2).

Bronchospasm or laryngospasm

Three studies looked at bronchospasm (Ambi 2011; Brimacombe 2002; Shin 2010; N = 537; 270/267 pLMA/cLMA groups). Brimacombe 2002 reported bronchospasm in one of 192 participants (0.5%) in the pLMA group. Meta-analysis showed no important differences between pLMA and cLMA groups (RR 3.00, 95% CI 0.12 to 73.19; I² = 0%; P = 0.50; Analysis 6.3).

No studies reported any episodes of laryngospasm.

Gastric insufflation

Two studies looked at gastric insufflation (Brimacombe 2002; Shin 2010; N = 487; 245/242 pLMA/cLMA groups). Brimacombe 2002 reported gastric insufflation in one of 192 participants (0.5%) in the pLMA group and in three of 192 participants (1.5%) in the cLMA group. Here also, we are uncertain whether this small difference of 1% between the devices is of any significance (RR 0.33, 95% CI 0.03 to 3.18; $I^2 = 0\%$; $P = 0.34$; Analysis 6.4).

Regurgitation or aspiration

Four studies reported regurgitation events (Ambi 2011; Brimacombe 2002; Khazin 2008; Shin 2010; N = 597 participants; 300/297 pLMA/cLMA groups). Khazin 2008 reported a total of nine events of regurgitation based on hypopharyngeal pH < 4, in four of 30 pLMA group participants (13.3%) and in five of 30 cLMA participants (16.7%). Meta-analysis showed no important differences between pLMA and cLMA groups (RR 0.80, 95% CI 0.24 to 2.69; $I^2 = 0\%$; $P = 0.72$; Analysis 6.5). No studies reported any episodes of aspiration.

Coughing

Two studies investigated the occurrence of coughing (Brimacombe 2002; Khazin 2008; N = 444; 222/222 pLMA/cLMA groups). Khazin 2008 reported no coughing events, and Brimacombe 2002 reported coughing events in 13 of 192 participants (6.8%) in the pLMA group and in 18 of 192 participants (9.4%) in the cLMA group. Data show a slightly increased risk (2.6%) of cough among cLMA group participants. Meta-analysis showed no important differences between groups (RR 0.72, 95% CI 0.36 to 1.43; $I^2 = 0\%$; $P = 0.35$; Analysis 6.6).

Excessive leak

Two studies looked at excessive leak (Natalini 2003a; Natalini 2003b; N = 120; 60/60 pLMA/cLMA groups). Meta-analysis showed no important differences between devices (RR 3.00, 95% CI 0.13 to 70.83; $I^2 = 0\%$; $P = 0.5$; Analysis 6.7).

Obstruction related to two devices

Brimacombe 2002 reported one (0.5%) and three (1.5%) events of airway obstruction among 192 participants in the pLMA and cLMA groups, respectively (Brimacombe 2002).

Postoperative nausea and vomiting

No included studies reported postoperative nausea and vomiting as an outcome.

DISCUSSION

Summary of main results

The eight included studies enrolled a total of 829 participants.

Of four studies that reported adequate oxygenation, three reported no hypoxia in either group (Ambi 2011; Lu 2002; Shin 2010). The fourth study (Brimacombe 2002) reported actual events of hypoxia. Owing to limited available data, information was insufficient to show the effect on hypoxic events (risk ratio (RR) 0.75, 95% confidence interval (CI) 0.17 to 3.31; low-quality evidence).

Lu 2002 looked at inadequacy of ventilation and reported no episodes of inadequate ventilation in either group.

Results from meta-analyses show statistically longer time to achieve an effective airway in ProSeal laryngeal mask airway (pLMA) group participants (Ambi 2011; Brimacombe 2002) and higher mean oropharyngeal leak pressure (Ambi 2011; Brimacombe 2002; Keller 2000; Khazin 2008; Lu 2002; Shin 2010). Differences in these outcomes, although statistically important, have little impact on clinical practice. Analysis of four studies that compared peak airway pressure (Khazin 2008; Lu 2002; Natalini 2003a; Natalini 2003b) revealed higher pressures in the pLMA group. Data from seven studies looking at failure to insert the intended device or use of an alternate device (Ambi 2011; Brimacombe 2002; Keller 2000; Khazin 2008; Lu 2002; Natalini 2003a; Shin 2010) show no significant differences between pLMA and Classic laryngeal mask airway (cLMA) device groups.

Results were uncertain in terms of differences for several complications, including mucosal injury (Ambi 2011; Brimacombe 2002; Lu 2002; Shin 2010), sore throat (Ambi 2011; Brimacombe 2002; Natalini 2003a; Natalini 2003b; Shin 2010), bronchospasm (Ambi 2011; Brimacombe 2002; Shin 2010), gastric insufflation (Brimacombe 2002; Shin 2010), regurgitation (Ambi 2011; Brimacombe 2002; Khazin 2008; Shin 2010), coughing (Brimacombe 2002; Khazin 2008), and excessive leak (Natalini 2003a; Natalini 2003b). Analysis to assess obstruction related to use of the devices was not possible because only one study looked at this outcome (Brimacombe 2002). No studies reported postoperative nausea and vomiting as an outcome.

Overall completeness and applicability of evidence

The numbers of included studies and participants were modest (eight studies, 829 participants), and most studies were unblinded or unclear to blinding for most of the important outcomes. Given the nature of both the intervention and the main outcomes, this is probably unavoidable in practice. Most included studies reported no events, so even fewer trials were eligible for analysis.

Half of the included studies assessed the primary outcomes of this review (four assessed adequacy of oxygenation, and one, adequacy of ventilation). However, most of these studies reported no events in pLMA or cLMA groups (three for oxygenation, and one for ventilation); one study reported adequacy of oxygenation events (Brimacombe 2002). No studies reported adequacy of ventilation events.

The evidence was not sufficiently robust to enable reasonable conclusions. In current anaesthesia practice, use of endotracheal intubation for airway maintenance is being rapidly replaced by use of supraglottic devices. Assessment of the adequacy of mechanical ventilation through adequate oxygenation and ventilation is more relevant; however, these are comparable for both of the devices assessed in this review.

Quality of the evidence

We included eight somewhat clinically heterogeneous trials that involved a total of 829 participants. Low numbers of participants in both the intervention (pLMA) group (N = 416) and the control (cLMA) group (N = 413) rendered reliable comparisons difficult for most of our important clinical outcomes.

The overall quality of evidence was low. Seven of eight studies used reliable methods of randomization and concealment. One study ([Natalini 2003b](#)) did not blind participants, personnel, or outcome assessors, and two studies reported blinding both participants and outcome assessors but only for some secondary outcomes ([Brimacombe 2002](#); [Khazin 2008](#)).

Most trials reported no events in either arm. This may have occurred because the events are not common, but the data could not be used to conclude in favour of either device. Furthermore, heterogeneity and imprecision contributed to the overall low quality of evidence. These issues warrant additional research to arrive at meaningful conclusions.

Potential biases in the review process

We made changes to outcomes presented in the protocol for this review after extensive discussion among review authors, peer referees, and editors. We made these changes with the aim of making the review more meaningful in terms of clinical practice (see [Differences between protocol and review](#)). However, modifications to primary and secondary outcomes may have introduced bias into the review because we applied these changes after the initial search and after review of outcomes reported by the included studies.

Most studies were unclear regarding blinding of both those performing the intervention and those assessing responses. This variation in study design may also have introduced bias.

Another important factor that could have been responsible for bias was that different studies measured outcomes differently - sometimes with large variations ranging from subjective clinical assessment to objective instrumental assessment.

Outcomes reported in the 'Summary of findings' table have been modified, as described above, (also see [Differences between protocol and review](#)). We also included "time required for an effective airway" as an outcome based on the review of included studies. Both these could have been a source of bias.

Agreements and disagreements with other studies or reviews

We found three other systematic reviews that addressed the research question of this review ([Brimacombe 2002a](#); [Cook 2005](#); [Zhang 2012](#)). We cannot compare [Zhang 2012](#) with our review because Zhang considered children only; [Brimacombe 2002a](#) and [Cook 2005](#) included adults.

Findings of two reviews ([Brimacombe 2002a](#); [Cook 2005](#)) were consistent with the findings of our review in that the time required for insertion of pLMA was longer than for cLMA. Overall success rates were similar with both devices; seal pressure was better with pLMA.

[Brimacombe 2002a](#) and [Cook 2005](#) have reported on various complications related to the use of these devices. Neither of

these reviews have performed meta-analyses, which makes it inappropriate to compare the devices. However, they have reported some comparisons based upon composite and individual study data. The incidence of mucosal injury/airway trauma is higher in the pLMA group when compared to cLMA. Regurgitation without aspiration is higher in cLMA when higher pressures are used during positive pressure ventilation. The incidence of gastric insufflation was similar with both the devices when the drainage tube was not used, otherwise the incidence was lower in the pLMA group.

AUTHORS' CONCLUSIONS

Implications for practice

We are uncertain about the effects of either of the airway devices in terms of failure of oxygenation or ventilation because there were very few of these events. Results were uncertain in terms of differences for several complications. Low-quality evidence suggests that the ProSeal laryngeal mask airway makes a better seal and therefore may be more suitable than the Classic laryngeal mask airway for positive pressure ventilation. The Classic laryngeal mask airway may be quicker to insert, but this is unlikely to be clinically meaningful.

Implications for research

Further RCTs are needed to look at the adequacy of oxygenation and ventilation as primary endpoints of the effectiveness of ventilation to inform meaningful conclusions. Future research should aim to increase sample sizes while blinding studies to improve the quality of evidence. Future RCTs should consider including high-risk participants, such as people who are obese, those with gastro-oesophageal reflux disease, and people with restrictive lung disease and compromised lung compliance. Participants should be assessed while in lithotomy and prone positions, or when undergoing laparoscopic procedures. Inclusion of these higher-risk participants may help to confirm the safety and efficacy of these devices.

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CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Ambi 2011

Methods	Study design: prospective RCT Study duration: not reported
Participants	Inclusion criteria 1. Setting: national 2. Country: India 3. N = 50 participants; 25/25 pLMA/cLMA groups 4. Age, years: mean, SD (range) a. Treatment: pLMA group: 33.68, 11.57 (18-60) b. Control: cLMA group: 30.88, 11.06 (18-60) 5. Sex, M/F: treatment 7/18; control 9/16 6. Weight, kg: mean, SD a. pLMA group: 55.08, 10.94 b. cLMA group: 53.68, 10.69 7. Body mass index (BMI): not reported 8. Physical status: American Society of Anesthesiologist (ASA) I and II 9. Surgery: non-abdominal surgeries Exclusion criteria 1. Known history of difficult airway 2. Cervical spine disease 3. Mouth opening < 2.5 cm 4. Risk of aspiration
Interventions	Treatment group 1. Intervention: pLMA insertion after neuromuscular blockade Control group 1. Intervention: cLMA insertion after neuromuscular blockade
Outcomes	1. Number of attempts at insertion 2. Failure to insert - 3 attempts were allowed before device was considered a failure and alternate device was used 3. Time for effective airway - time between picking up the pLMA/cLMA and obtaining an effective airway 4. Airway sealing pressure - determined by closing the APL valve of the closed circuit at a fixed gas flow of 4 L/min and by noting the pressure at which an equilibrium was reached by using a portex aneroid gauge 5. Peripheral oxygen saturation (SaO₂) - measured intraoperatively and postoperatively by pulse oximeter Complications

Ambi 2011 (Continued)

1. Desaturation/Laryngospasm/Bronchospasm - episode was monitored intraoperatively and after removal of device
2. Regurgitation/Aspiration - after removal of device, aspiration was detected by chest auscultation and pH testing with litmus paper, if secretion was present
3. Mucosal injury - evaluated by presence or absence of blood-stained secretion on the device after removal
4. Sore throat - participants were questioned a half hour after arriving in recovery and 24 hours later with a 3-point scale (0 to 2)
5. Postoperative nausea and vomiting (PONV)

For pLMA group only

1. Failure to insert gastric tube - 2 attempts were allowed before it was recorded as failure

Notes

1. Neuromuscular blocking agent (NMBA) used for insertion of device in both cLMA and pLMA groups
2. Insertion technique: pLMA was inserted by using an introducer as recommended by the manufacturer/Insertion technique for both devices was reported as the same
3. Protocol deviation: not reported
4. Funding source: not reported
5. Contact with study authors for additional information: No attempts were made to contact study authors for additional information, as this was not necessary

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote "...were randomly allocated..."
Allocation concealment (selection bias)	Low risk	Quote "...allocated (by opening a sealed envelope)..."
Incomplete outcome data (attrition bias) All outcomes	Low risk	All participants were included in the assessment
Selective reporting (reporting bias)	Low risk	Comments: This study reported all outcomes in the results section except PONV, which although it is one of our secondary outcomes is not an outcome of major interest. On the basis of this minor omission, we judged this study as having "low risk" of bias
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Insufficient information to enable assessment
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information to enable assessment

Brimacombe 2002

Methods

Study design: prospective RCT

Study duration: not reported

Brimacombe 2002 (Continued)

Participants

Inclusion criteria

1. Setting: multi-centre
2. Countries: Australia, Austria, France, Germany, Italy, Spain, USA
3. N = 384 participants; 192/192 pLMA/cLMA groups
4. Age, years: mean, SD (range)
  - a. Treatment: pLMA group: 47, 16 (18-84)
  - b. Control: cLMA group: 45, 17 (18-81)
5. Sex, M/F: treatment 107/85; control 105/87
6. Weight, kg: mean $\pm$ SD (range)
  - a. pLMA group: 78 $\pm$ 15 (39-120)
  - b. cLMA group: 75 $\pm$ 15 (38-130)
7. Height, cm: mean $\pm$ SD (range)
  - a. pLMA group: 172 $\pm$ 10 (147-206)
  - b. cLMA group: 172 $\pm$ 10 (145-196)
8. Body mass index (BMI): mean $\pm$ SD (range)
  - a. pLMA: 23 $\pm$ 4 (14-34)
  - b. cLMA: 22 $\pm$ 4 (13-34)
9. Physical status: American Society of Anesthesiologists (ASA) I and II
10. Surgery: routine minor procedures

Exclusion criteria

1. BMI > 35 kg/m²
2. Cervical spine disease
3. Known difficult airway
4. Mouth opening < 2.5 cm
5. Upper respiratory symptoms in the previous 10 days
6. Surgery to be performed in the head and neck or thoraco-abdominal cavities or in the lateral-prone position
7. Risk of aspiration

Interventions

Treatment group

1. Intervention: pLMA insertion in non-paralysed participants

Control group

1. Intervention: cLMA insertion in non-paralysed participants

Outcomes

1. Number of insertion attempts
2. Failed - 3 attempts were allowed before device was considered a failure
3. Use of alternate device - after 3 attempts of failure of randomized device
4. Time to obtain effective airway - time between picking up the pLMA/cLMA and obtaining an effective airway as judged by capnograph trace and no audible leak with peak airway pressures 12 cm H₂O or greater during manual ventilation
5. Oropharyngeal leak pressure - determined by closing the expiratory valve of the circle system at a fixed gas flow of 3 L/min and by noting the pressure at which an equilibrium was reached
6. Fibre-optic assessment of airway - performed by passing the scope and scoring the view
7. Placement of orogastric tube - 50% of participants in each group assigned randomly to receive an orogastric tube; performed through the drainage tube of pLMA and behind the cuff of cLMA. Correct placement of orogastric tube was assessed by suction of fluid or epigastric auscultation

Brimacombe 2002 (Continued)

Intraoperative complications documented

1. Failed use
2. Aspiration–regurgitation
3. Hypoxia (SaO₂ < 90%)
4. Bronchospasm
5. Airway obstruction
6. Gastric insufflation
7. Cough during removal
8. Mucosal injury - assessed by blood staining of the device on removal

Postoperative complications

1. Sore throat - Participants underwent structured interview twice for sore throat (in PACU and 18 to 24 hours after surgery)

Notes	1. Standardized anaesthetic technique, neuromuscular blocking agent was not used 2. 50% of participants in each group were randomly assigned to have a gastric tube inserted orally 3. Insertion technique: Both devices were inserted according to manufacturer's instructions 4. Protocol deviation: 53 protocol deviations identified. These deviations were minor and were evenly distributed between groups. Participants were included in the analysis, as protocol deviations were minor and were evenly distributed between groups 5. Funding source: Some data from Germany were sponsored by the Laryngeal Mask Company, which manufactures ProSeal and Classic laryngeal mask airway devices. Neither the Laryngeal Mask Company nor Dr Brain (the inventor) was involved in the design of the study, data analysis, or manuscript preparation 6. Contact with study authors for additional information: No attempts were made to contact study authors for additional information, as this was not necessary

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote "...were randomly assigned to have either the pLMA or LMA..."
Allocation concealment (selection bias)	Low risk	Quote "...by opening a sealed envelope immediately before induction..."
Incomplete outcome data (attrition bias) All outcomes	Low risk	1. Missing data: 1% intraoperative and 3% postoperative data were missing These missing data were related to our secondary outcome (failure to attempt gastric tube placement, failure to document the anatomic positions of the drainage tube and airway tube) 1. 53 protocol deviations A total of 53 protocol deviations were included in the analysis, as these were minor, evenly distributed between groups, and related to one of our secondary outcomes - "gastric tube insertion" Comment: Both missing data and protocol violations did not affect any of our major outcomes of interest; therefore, we assigned "low risk" of bias
Selective reporting (reporting bias)	Low risk	All outcomes mentioned in methods section were reported in results section

Brimacombe 2002 (Continued)

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants were unaware of the airway device used, but information regarding personnel was insufficient to enable assessment
Blinding of outcome assessment (detection bias) All outcomes	High risk	Quote "...unblinded trained observer collected data during the four phases of anaesthesia, and blinded trained observers collected the data in the post anaesthesia care unit and the following day..." Comments: As not data were collected by an "unblinded" observer during surgery and as a blinded observer collected only postoperative data, we assigned this as "high risk" of bias

Keller 2000

Methods	Study design: prospective RCT Study duration: not reported
Participants	Inclusion criteria 1. Setting: National 2. Country: Austria 3. N = 32 participants; 16/16 pLMA/cLMA groups 4. Age, years: mean (range) 35 (19-65) 5. Sex, M/F: treatment 8/8; control 8/8 6. Weight, kg: mean (range): 67 (40-95) 7. Height, cm: mean (range): 169 (150-192) 8. Body mass index (BMI): not reported 9. Physical status: American Society of Anesthesiologists (ASA) I and II 10. Surgery: not reported (mentioned participants anaesthetised for airway management) Exclusion criteria 1. Risk of aspiration
Interventions	Treatment group 1. Intervention: pLMA insertion after neuromuscular blockade Control group 1. Intervention: cLMA insertion after neuromuscular blockade
Outcomes	1. Number of attempts 2. Oropharyngeal leak pressure - determined by closing the expiratory valve of the circle system at a fixed gas flow of 3 L/min and by noting the pressure at which an equilibrium was reached 3. Directly measured/calculated mucosal pressure - by subtracting in vivo intracuff pressure from in vitro measurement 4. Fibre-optic scope - to determine the anatomical position of the device and scoring the view
Notes	1. Standard anaesthesia technique with neuromuscular blocking agent used for insertion of device in both cLMA and pLMA groups 2. Insertion technique: LMA/pLMA inserted using the technique recommended for the LMA

Keller 2000 (Continued)

3. Protocol deviation: not reported
4. Funding source: not reported
5. Contact with study authors for additional information: No attempts were made to contact study authors for additional information, as this was not necessary

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote "...randomly allocated..."
Allocation concealment (selection bias)	Low risk	Quote "...allocated by opening a sealed envelope..."
Incomplete outcome data (attrition bias) All outcomes	Low risk	All participants were included in the assessment
Selective reporting (reporting bias)	Low risk	All outcomes mentioned in methods section were reported in results section
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Insufficient information to enable assessment
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	1. An unblinded observer made measurements of fibre-optic position and scoring Comment: For other outcomes, information is insufficient to enable assessment; we therefore assigned this as "unclear risk" of bias

Khazin 2008

Methods	Study design: prospective RCT Study duration: not reported
Participants	Inclusion criteria 1. Setting: National 2. Country: Israel 3. N = 180 participants in study for 6 devices to be studied, with 30 in each group (30/30 pLMA/cLMA groups) 4. Age, years: 18-65 a. Treatment: pLMA group: 45 ± 15 b. Control: cLMA group: 45 ± 12 5. Sex, M/F: treatment 19/11; control 16/14 6. Weight: not reported 7. Height: not reported 8. Body mass index (BMI): mean ± SD a. pLMA: 26 ± 3 b. cLMA: 26 ± 3 9. Physical status: American Society of Anesthesiologists (ASA) I and II

Khazin 2008 (Continued)

10. Surgery: elective orthopaedic, minor vascular, plastic, or urological surgery

Exclusion criteria

1. At risk of pulmonary aspiration (because of gastroesophageal reflux disease, full stomach, or hiatal hernia)
2. Receiving drugs affecting gastrointestinal motility
3. Known difficulty with intubation or gross anatomical airway abnormalities
4. Morbid obesity (BMI > 35 kg/m²)
5. Undergoing surgery in positioning other than supine
6. After 3 attempts, ventilation was inadequate; patient was then intubated

Interventions	1. Treatment group: intervention: pLMA insertion without neuromuscular blockade 2. Control group: intervention: cLMA insertion without neuromuscular blockade; 6 airway device groups (N = 30 each) a. Cobra Perilaryngeal Airway b. Laryngeal Mask Airway (LMA) Classic LMA c. Fastrach LMA d. ProSeal e. Laryngeal tube f. ETT
Outcomes	1. Adequacy of ventilation - assessed by chest movement and capnography 2. Seal (leak) pressures - measured by closing APL valve and waiting until audible air leak was heard by stethoscope over suprasternal notch 3. Regurgitation episodes - defined as hypopharyngeal pH < 4 and measured through external reference electrode placed immediately after induction of anaesthesia and before placement of the airway device 4. Following were monitored and recorded after insertion, then every 15 minutes a. Peak, mean, and plateau inspiratory pressure b. Inspired and expired minute volume c. Lung compliance and resistance d. SaO₂ - recorded by pulse oximetry e. End-tidal concentration of carbon dioxide (ETCO₂) f. Gastric insufflation - monitored by epigastric auscultation g. Failed insertion attempts h. Airway manipulations i. Complications
Notes	1. Standard anaesthesia technique without neuromuscular blocking agent except for ETT group 2. Insertion technique: not reported 3. Protocol variation: not reported 4. Funding source: This study was supported in part by Joseph Drown Foundation, Los Angeles, CA 5. Contact with study authors for additional information: No attempts were made to contact study authors for additional information, as this was not necessary

Khazin 2008 (Continued)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote "...were randomly allocated..."
Allocation concealment (selection bias)	Low risk	Quote "...was based on computer-generated codes"
Incomplete outcome data (attrition bias) All outcomes	Low risk	All participants were included in the assessment
Selective reporting (reporting bias)	Low risk	Quote "...Respiratory variables were similar among the groups..." Comment: In our opinion, this blanket statement covers reporting of all outcomes; we therefore assigned this as "low risk" of bias
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Insufficient information to enable assessment
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Quote "...Two independent investigators, who were blinded to the airway device used, analyzed all the pH data" For other outcomes, information is insufficient to enable assessment

Lu 2002

Methods	Study design: prospective RCT Study duration: not reported
Participants	Inclusion criteria - Setting: national - Country: Australia - N = 80 participants; 40/40 pLMA/cLMA groups - Age, years: range 18-80 - Treatment: pLMA group, mean, SD (range): 52, 15 (18-76) - Control: cLMA group, mean, SD (range): 49, 17 (18-80) - Sex, M/F: treatment 16/24; control 13/27 - Weight, kg: mean, SD (range) - pLMA group: 62, 11 (43-90) - cLMA group: 59, 10 (43-82) - Height, cm: mean, SD (range) - pLMA group: 159, 7 (148-175) - cLMA group: 159, 6 (150-173) - Body mass index (BMI): not reported - Physical status: American Society of Anesthesiologists (ASA) I and II - Surgery: elective laparoscopic cholecystectomy Exclusion criteria

Lu 2002 (Continued)

1. Interdental gap < 2.5 cm
2. BMI > 35 kg/m²
3. Risk of aspiration

Interventions	Treatment group 1. Intervention: pLMA insertion after neuromuscular blockade Control group 1. Intervention: cLMA insertion after neuromuscular blockade
Outcomes	1. Number of insertion attempts 2. Failed attempt - 3 attempts at insertion were allowed before device was considered a failure 3. Effective ventilation - defined as a square-wave capnograph trace and a normal thoracoabdominal movement 4. Adequacy of oxygenation - considered suboptimal if SpO₂ fell to 94% to 90%, and failed if SpO₂ < 90% 5. Adequacy of ventilation - considered suboptimal if ETCO₂ > 6.0 to 7.3 kPa, or failed if ETCO₂ > 7.3 kPa 6. Oropharyngeal leak pressure (OLP) - determined by closing the expiratory valve of the circle system at a fixed gas flow of 3 L/min and by noting the pressure at which an equilibrium was reached 7. Gas leak at OLP - determined as audible gas sound at mouth, by auscultation over epigastrium and bubbling of lubricant placed at drainage tube of pLMA 8. Peak airway pressure - recorded immediately before and after carboperitoneum Complications 1. Mucosal injury - detected by blood staining of device on removal 2. Regurgitation 3. Aspiration 4. Bronchospasm 5. Laryngospasm 6. Coughing 7. Gastric insufflation - detected through the laparoscope by the surgeon pLMA only 1. Gastric tube placement
Notes	1. Standard anaesthesia technique with neuromuscular blocking agent 2. Insertion technique: for both devices, identical to the finger technique recommended for the LMA. A slight lateral approach was used if resistance was felt in the oropharynx 3. Protocol deviation: not reported 4. Funding source: Prof Brimacombe (author) has intermittently received funds for research and oversaw lecture from Intavent Ltd, which manufactures both devices used in this study. This study was not sponsored by Intavent Ltd 5. Contact with study authors for additional information: No attempts were made to contact study authors for additional information, as this was not necessary

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote "...were randomly allocated..."

Lu 2002 (Continued)

Allocation concealment (selection bias)	Low risk	Quote "...allocated (by opening a sealed envelope)..."
Incomplete outcome data (attrition bias) All outcomes	Low risk	All participants were included in the assessment
Selective reporting (reporting bias)	Low risk	All outcomes mentioned in methods section were reported in results section
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Insufficient information to enable assessment
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Quote "...data were collected by independent observers..." Comments: 'independent' observer is not necessarily blinded

Natalini 2003a

Methods	Study design: prospective RCT Study duration: not reported
Participants	Inclusion criteria 1. Setting: national 2. Country: Italy 3. N = 60 participants; 30/30 pLMA/cLMA groups 4. Age, years: mean (range) a. Treatment: pLMA group: 52 (20-80) b. Control: cLMA group: 57 (20-83) 5. Sex, M/F: treatment 10/20; control 13/17 6. Weight, kg: mean (SD) a. pLMA group: 91 (14) b. cLMA group: 88 (11) 7. Height, cm: mean (SD) a. pLMA group: 164 (0.9) b. cLMA group: 164 (0.8) 8. Body mass index (BMI): mean (SD) a. pLMA: 34 (4) b. cLMA: 33 (3) 9. Physical status: American Society of Anesthesiologists (ASA) II and III 10. Surgery: elective orthopaedic (knee and ankle) and abdominal surgery 11. Obese participants with BMI > 30 kg/m² Exclusion criteria 1. Age < 18 years 2. Non-fasted patients 3. Pregnancy 4. Prone position

Natalini 2003a (Continued)

5. Airway surgery

Interventions	Treatment group 1. Intervention: pLMA insertion after neuromuscular blockade Control group 1. Intervention: cLMA insertion after neuromuscular blockade
Outcomes	1. Number of attempts 2. Failure of intended device - if leak fraction was > 15% and could not be reduced by increased cuff pressure, attempt was considered as unsuccessful and device was replaced with the same device. After 3 unsuccessful attempts, device was replaced with alternate device (cLMA or pLMA) or, if necessary, with ETT 3. Cuff pressure - measured by the Control-Inflator 'Pocket' (VBM Medizintechnik, Sulz a.N., Germany) 4. Leak fraction - calculated from the difference between inspiratory and expiratory tidal volumes divided by inspiratory tidal volume 5. Sore throat - assessed by patient interview in recovery room, then a week later by telephone 6. Mean peak airway pressure, inspired and expired tidal volumes, SaO₂, and ETCO₂ were monitored by ADU/AS3 Integrated System (Datex-Engstrom Division. Instrumentarium Corp., Finland) throughout the procedure 7. Placement of orogastric tube before cLMA insertion and orogastric tube after pLMA insertion through drainage tube of pLMA
Notes	1. GA and/or epidural analgesia with neuromuscular blocking agent as clinically needed 2. Insertion technique: pLMA was inserted without introducer, and insertion technique for cLMA was not reported 3. Protocol deviation: not reported 4. Funding source: not reported 5. Contact with study authors for additional information: No attempts were made to contact study authors for additional information, as this was not necessary

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote "...were randomized..."
Allocation concealment (selection bias)	Low risk	Quote "...by a computer generated table..."
Incomplete outcome data (attrition bias) All outcomes	Low risk	29/30 participants were included in the assessment. Comments: In 1 out of 30 participants, both devices failed, and ventilation was managed with face mask and participants were excluded from the study. We judged this as "low risk" of bias
Selective reporting (reporting bias)	Low risk	All outcomes mentioned in methods section were reported in results section
Blinding of participants and personnel (performance bias)	Unclear risk	Insufficient information to enable assessment

Natalini 2003a (Continued)

All outcomes

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information to enable assessment

Natalini 2003b

Methods	Study design: prospective RCT Study duration: not reported

Participants	Inclusion criteria 1. Setting: national 2. Country: Italy 3. N = 60; 30/30 pLMA/cLMA groups 4. Age, years: mean $\pm$ SD a. Treatment: pLMA group: 51 $\pm$ 16 b. Control: cLMA group: 53 $\pm$ 17 5. Sex, M/F: treatment 12/18; control 10/20 6. Weight, kg: mean $\pm$ SD a. pLMA group: 73 $\pm$ 17 b. cLMA group: 71 $\pm$ 11 7. Height, cm: mean $\pm$ SD a. pLMA group: 167 $\pm$ 8 b. cLMA group: 168 $\pm$ 7 8. Body mass index (BMI): mean $\pm$ SD a. pLMA: 26 $\pm$ 6 b. cLMA: 25 $\pm$ 4 9. Physical status: American Society of Anesthesiologists (ASA) I, II, and III 10. Surgery: cholecystectomy, oophorectomy, adrenalectomy Exclusion criteria 1. Younger than 18 years of age 2. Contraindications to use of the LMA (non-fasted patients, those with hiatal hernia, those with morbid obesity)

Interventions	Treatment group 1. Intervention: pLMA insertion without neuromuscular blockade Control group 1. Intervention: cLMA insertion without neuromuscular blockade

Outcomes	1. Failure of intended device - if leak fraction was $> 15\%$ and could not be reduced by increased cuff pressure, the attempt was considered unsuccessful and the device was replaced with the same device. After 3 unsuccessful attempts, device was replaced with alternate device (cLMA or pLMA) or, if necessary, by ETT 2. Leak fraction - calculated from the difference between inspiratory and expiratory tidal volumes divided by inspiratory tidal volume

Natalini 2003b (Continued)

3. Airway pressures and flow (inspired and expired tidal volumes), SaO₂, and ETCO₂ were monitored by ADU/AS3 Integrated System (Datex-Engstrom Division, Instrumentarium Corp., Finland)
4. Cuff pressure - measured by the Control-Inflator 'Pocket' (VBM Medizintechnik, Sulz a.N., Germany)
5. Sore throat - assessed by patient interview in recovery room, then a week later by telephone
6. Placement of gastric tube - before cLMA placement in cLMA group and after pLMA placement in pLMA group through drainage tube of pLMA

Notes	1. Neuromuscular blocking agent was used after placement of LMAs in both groups 2. Insertion technique: pLMA was inserted without introducer and insertion technique for cLMA was not reported 3. Protocol deviation: All participants successfully completed the protocol 4. Funding source: not reported 5. Contact with study authors for additional information: No attempts were made to contact study authors for additional information, as this was not necessary

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote "...were randomized..."
Allocation concealment (selection bias)	Low risk	Quote "...by a computer generated table..."
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote "All patients successfully completed the protocol"
Selective reporting (reporting bias)	Low risk	All outcomes mentioned in methods section were reported in results section
Blinding of participants and personnel (performance bias) All outcomes	High risk	Mentioned in abstract as non-blinded study
Blinding of outcome assessment (detection bias) All outcomes	High risk	Mentioned in abstract as non-blinded study

Shin 2010

Methods	Study design: prospective RCT Study duration: not reported
Participants	Inclusion criteria 1. Setting: multi-centre 2. Countries: Japan and South Korea 3. N = 167; 64/53/50 I-gel/pLMA/cLMA groups 4. Age, years: mean ± SD a. Treatment: pLMA group: 44 ± 15

Shin 2010 (Continued)

- b. Control: cLMA group: 48 ± 13
5. Sex M/F: treatment pLMA 34/19); control cLMA 19/31
6. Weight, kg: mean $\pm$ SD
  - a. pLMA group: 66 ± 12
  - b. cLMA group: 64 ± 12
7. Height, cm: mean $\pm$ SD
  - a. pLMA group: 166 ± 10
  - b. cLMA group: 163 ± 9
8. Body mass index (BMI): not reported
9. Physical status: American Society of Anesthesiologists (ASA) I and II
10. Surgery: lower extremity orthopaedic surgery

Exclusion criteria

1. Significant acute or chronic lung disease
2. Known airway problems, potential difficult intubation (history of difficult intubation, Mallampati score 3 or 4, thyromental distance < 60 cm, mouth opening < 35 mm, rheumatoid arthritis)
3. Increased risk of aspiration (BMI > 35 kg/m², gastro-oesophageal reflux, neuromuscular disease, pharyngeal dysfunction)

Interventions	Treatment group 1. Intervention a. pLMA insertion after neuromuscular blockade (53) b. I-gel insertion after neuromuscular blockade (64) Control group 1. Intervention: cLMA insertion after neuromuscular blockade (50)
Outcomes	1. Failed insertion of the device - 3 attempts were allowed, followed by endotracheal intubation 2. Success of insertion of device - confirmed by bilateral chest wall movement, auscultation, normal capnograph curves, and normal values for partial pressure of ET_{CO}₂ 3. Airway leak pressure - assessed by closing the expiratory valve of the circle system at a fixed gas flow of 3 L/min, noting the airway pressure (maximum 40 cm H₂O) at which equilibrium was reached 4. Gas leak and leak volume - evaluated by auscultation by stethoscope placed at the participant's mouth. leak volume was obtained by volume differences between inspiration and expiration Complications 1. Sore throat - recorded by PACU nurse before discharge to the ward 2. Hypoxia 3. Mucosal injury - detected by blood staining of the device after removal 4. Regurgitation 5. Aspiration 6. Bronchospasm 7. Laryngospasm 8. Gastric insufflation
Notes	1. Standard anaesthesia technique with neuromuscular blocking agent 2. Insertion technique: not reported

Shin 2010 (Continued)

3. Protocol deviation
4. Funding source: not reported
5. Contact with study authors for additional information: No attempts were made to contact study authors for additional information, as this was not necessary

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote "...Randomization was performed..."
Allocation concealment (selection bias)	Unclear risk	Quote "...by envelope method..."
Incomplete outcome data (attrition bias) All outcomes	Low risk	All participants were included in the assessment
Selective reporting (reporting bias)	Low risk	All outcomes mentioned in methods section were reported in results section
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Insufficient information to enable assessment
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information to enable assessment

Abbreviations

APL = adjustable pressure-limiting; ASA = American Society of Anesthesiologists; BMI = body mass index; cLMA = Classic laryngeal mask airway; ETCO₂ = end-tidal carbon dioxide; ETT = endotracheal tube; GA = general anaesthesia; LMA = laryngeal mask airway; NMBA = neuromuscular blocking agent; OLP = oropharyngeal leak pressure; PACU = postanaesthesia care unit; pLMA = ProSeal laryngeal mask airway; PONV = postoperative nausea and vomiting; RCT = randomized controlled trial; SaO₂ = oxygen saturation; SD = standard deviation; SpO₂ = peripheral capillary oxygen saturation.

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Brain 2000	Intervention not relevant - compared 2 types of LMA (prototype LMA with drainage tube and new LMA with drainage tube, which were not comparable with cLMA)
Francksen 2007	Intervention not relevant - compared 3 disposable airway devices, which were not comparable with cLMA and pLMA
Goldmann 2011	Intervention not relevant - compared only pLMA in obese and non-obese participants
Hosten 2009	Intervention not relevant - compared disposable (LMA - Supreme) and reusable (ProSeal - LMA). Did not compare cLMA with pLMA

Study	Reason for exclusion
Lopez 2011	Intervention not relevant - compared disposable (LMA - Supreme) and reusable (ProSeal - LMA). Did not compare cLMA with pLMA
Maltby 2003	Intervention not relevant - pLMA or cLMA was compared with endotracheal intubation
Seet 2010	Intervention not relevant - compared disposable (LMA - Supreme) and reusable (ProSeal - LMA). Did not compare cLMA with pLMA
Shariffuddin 2008	Intervention not relevant - compared the performance of Ambu AuraOnce Laryngeal Mask with cLMA. Did not compare pLMA and cLMA
Tham 2010	Intervention not relevant - compared disposable (LMA - Supreme) and reusable (ProSeal - LMA). Did not compare cLMA with pLMA
Verghese 2008	Intervention not relevant - compared disposable (LMA - Supreme) and reusable (ProSeal - LMA). Did not compare cLMA with pLMA

cLMA = Classic laryngeal mask airway; LMA = laryngeal mask airway; pLMA = ProSeal laryngeal mask airway.

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

[Brimacombe 2000](#)

Methods	Study design: prospective, randomized controlled, cross-over trial (selected randomly by opening a sealed envelope) Study duration: not reported
Participants	Inclusion criteria - Setting: multi-centre - Countries: Australia and Austria - N = 60; 60/60 pLMA/cLMA groups - Age, years: mean (range): 39 (18-77) - Treatment group: not reported - Control group: not reported - Sex, M/F: 34/26 - Weight, kg: mean (range): 72 (40-115) - Height, cm: mean (range): 171 (150-193) - Body mass index (BMI): not reported - Physical status: American Society of Anesthesiologists (ASA) I and II - Surgery: minor peripheral surgery Exclusion criteria - Participants < 18 years of age - Known or predicted difficult airway - Mouth opening < 2.5 cm - BMI > 35 kg/m² - Risk of aspiration
Interventions	pLMA group (intervention) Of 60 participants, 30 got pLMA as first device and 30 got pLMA as second device owing to cross-over design

Brimacombe 2000 (Continued)

cLMA group (control)

- Of 60 participants, 30 got cLMA as first device and 30 got cLMA as second device owing to cross-over design

Outcomes

- Number of insertion attempts - recorded and reported. If an effective airway could not be achieved, 1 attempt with the other device was allowed
- Failed attempt - 3 attempts at insertion were allowed before device used was considered a failure
- Time to successful insertion (effective airway) - time between picking up the cLMA/pLMA and obtaining an effective airway
- Effective airway - defined as normal thoraco-abdominal movement and a square wave capno-graph trace
- Airway seal pressure - assessed by closing the expiratory valve of the circle system at a fixed gas flow of 3 L/min, noting the airway pressure (maximum 40 cm H₂O) at which equilibrium was reached
- Location of airway gas leak at airway sealing pressure - determined at mouth (audible), stomach (epigastric auscultation), or drainage tube with the pLMA (bubbling of lubricant placed on the proximal end of the drainage tube)
- Fibre-optic assessment and scoring of position of airway tubes, and drainage tube in case of pLMA
- Gastric insufflation

For pLMA only

- Gastric tube placement - attempted if no gas leak from the drainage tube. Success rate and time taken for gastric tube placement noted

Notes

- In both groups, all participants received devices after neuromuscular blockade
- Insertion technique: for both devices, identical to that recommended for LMA. A slight lateral approach was used if resistance was felt in the oropharynx
- Protocol deviation: not reported
- Observational assessments for each participant were made by study authors
- As this is a cross-over trial, we planned to include only data related to the device used first, to avoid carry-over effect. We have contacted corresponding author (on 9 December 2015) to request further information, for which response is awaited

Funding source

- Supported in part by the Laryngeal Mask Company, Henley-on-Thames, United Kingdom

Brimacombe 2001

Methods

Study design: prospective, randomized, controlled, cross-over trial (alternative randomization)

Study duration: not reported

Participants

Inclusion criteria

- Setting: multi-centre
- Countries: Australia and Austria
- N = 30; 30/30 pLMA/cLMA groups
- Age, years: mean (range) 41 (19-61)
  - Treatment group: not reported
  - Control group: not reported
- Sex: female adult
- Weight, kg: mean (range): 61 (50-74)
- Height, cm: mean (range): 163 (150-172)

Brimacombe 2001 (Continued)

- Body mass index (BMI): not reported
- Physical status: American Society of Anesthesiologists (ASA) I and II
- Surgery: non-intra-abdominal gynaecological surgery

Exclusion criteria

- Respiratory tract pathology
- Risk of aspiration
- Taking medication that might trigger bronchospasm

Interventions	pLMA group (intervention) • Of 30 participants, 15 got pLMA as first device and 15 got pLMA as second device owing to cross-over design cLMA group (control) • Of 30 participants, 15 got cLMA as first device and 15 got cLMA as second device owing to cross-over design
Outcomes	• Number of attempts - recorded and reported • Oropharyngeal leak pressure, peak airway pressure, inspired tidal volume (VTi), expired tidal volume (VTe), pulmonary compliance, oxygen saturation, end-tidal carbon dioxide, heart rate - recorded by an unblinded observer • Leak fraction - calculated by subtracting expired from inspired tidal volume • Oropharyngeal leak - detected by listening over the mouth with an ear • Gastric insufflation - epigastric auscultation to detect air entering the stomach • Drainage tube leak of pLMA - detected by placing a clear lubricant in the proximal 1 cm of the drainage tube, noting bubbling during ventilation • Fibre-optic position of airway tube was assessed and reported • Failed oxygenation - defined as $SpO_2 \geq 95\%$ • Failed ventilation - defined as $ETCO_2 \leq 45$ mm Hg
Notes	• Use of neuromuscular blockade for insertion of devices: not reported • Cross-over design - 30 consecutive female participants received both devices (pLMA/cLMA) in random order • Insertion technique: pLMA was inserted using the introducer tool and cLMA was inserted according to manufacturer's instructions • Protocol deviation: not reported • As this is a cross-over trial, we planned to include only data related to the device used first, to avoid carry-over effect. We have contacted corresponding author on 9 December 2015 to obtain further information, for which response is awaited Funding source: not reported

Cook 2002

Methods	Study design: prospective, randomized, controlled, cross-over trial (selected randomly by the use of opaque sealed envelopes) Study duration: not reported
Participants	Inclusion criteria • Setting: multi-centre • Country: United Kingdom

Cook 2002 (Continued)

- N = 180; 180/180 pLMA/cLMA groups
- Age, years: median (range) 47 (16-86)
  - Treatment group: not reported
  - Control group: not reported
- Sex, M/F: 69/105 (not recorded in 6 cases)
- Weight, kg: median (range): 70 (41-144)
- Height: not reported
- Body mass index (BMI): not reported
- Physical status: American Society of Anesthesiologists (ASA) I, II, and III
- Surgery: not reported

Exclusion criteria: not reported

Interventions
pLMA group (intervention)

- Of 180 participants, 92 got pLMA as first device and 88 got pLMA as second device owing to cross-over design

cLMA group (control)

- Of 180 participants, 88 got cLMA as first device and 92 got cLMA as second device owing to cross-over design

Outcomes

- Number of attempts - maximum of 3 attempts were allowed with each device
- Insertion time - recorded and reported
- Adequacy of ventilation - assessed by chest movement, capnograph signal, and presence or absence of audible leak
- Fibre-optic airway assessment and scoring of airway and drain tube
- Leak during ventilation - assessed by audible leak and displacement of gel at the end of drain tube of pLMA
- Seal pressure - measured by stopping ventilation, occluding the spill valve with a fresh gas flow rate of 5 litres per minute until a steady value is reached. This was observed and recorded by someone other than the investigator, to reduce observer bias

Complications - Following checklist of complications related to insertion, maintenance, and removal was completed after use of each device

- Coughing
- Laryngospasm
- Breath-holding
- Excessive movement
- Mucosal injury - assessed by presence of blood on the device after removal
- Loss of airway
- Troublesome secretions
- Sore throat - assessed by interview in recovery area

pLMA only

- Placement of gastric tube - recorded and reported

Notes

- In all participants in both groups, device was inserted without neuromuscular blocking agent
- Insertion technique: ProSeal was inserted with the ProSeal introducer tool (120) or the index finger (60) , as described in the manufacturer's product literature. The cLMA was inserted by standard technique
- Protocol deviation: not reported
- As this is a cross-over trial, we planned to include only data related to the device used first, to avoid carry-over effect. We have contacted corresponding author on 9 December 2015 to obtain further information, for which response is awaited

Cook 2002 (Continued)

Funding source

- Declaration of interest. T.M. Cook received an honorarium for addressing staff at the company of Intavent Orthofix
- Intavent Orthofix (Maidenhead, UK) supplied the ProSeals used in this study free of charge

Li 2007

Methods	Study design: prospective, randomized, auto-controlled, cross-over trial (selected randomly in sequence) Study duration: not reported
Participants	Inclusion criteria • Setting: national • Country: Republic of China • N = 50; 50/50 pLMA/cLMA (SLMA) groups • Age, years: mean $\pm$ SD (range): 31.1 $\pm$ 9.5 (18-50) ◦ Treatment group: not reported ◦ Control group: not reported • Sex, M/F: 15/35 • Weight, kg: mean $\pm$ SD (range): 58.3 $\pm$ 9.1 (42-80.5) • Height, cm: mean $\pm$ SD (range): 164.6 $\pm$ 6.8 (155-178) • Body mass index (BMI): mean $\pm$ SD (range) 21.4 $\pm$ 2.4 (16.8-26.7) • Physical status: American Society of Anesthesiologists (ASA) I and II • Surgery: elective plastic surgery Exclusion criteria • Airway hyper-responsiveness disease • Gastro-esophageal reflux disease • Satiety • BMI > 30 kg/m² • Head or facial surgery
Interventions	• pLMA group (intervention) ◦ 25 participants received pLMA and then SLMA (cLMA) in sequential order randomly owing to cross-over design • cLMA (SLMA) group (control) ◦ 25 participants received SLMA (cLMA) and then pLMA in sequential order randomly owing to cross-over design
Outcomes	• Insertion attempts • Time to obtain effective airway • Airway seal pressure • Lung ventilation (SpO₂ > 95%) • Fibre-optic scores of the cuff anatomic position • Mean expired volume • Mean peak inspiratory pressure - assessed by 5 continuous breaths (10 mL/kg) • Gastric tube insertion
Notes	• In both groups, device was inserted after neuromuscular blockade

Li 2007 (Continued)

- Insertion technique: ProSeal was inserted with a dedicated plug-in technology and SLMA was inserted with the standard index finger pushing technique
- Protocol deviation: not reported
- As this is a cross-over trial, we planned to include only data related to the device used first, to avoid carry-over effect. We have contacted corresponding author on 1 April 2017 to request further information, for which response is awaited
- Funding source: not reported

Natalini 2003c

Methods	Study design: prospective, randomized, controlled, cross-over trial (consecutive patients received alternatively pLMA and cLMA randomly) Study duration: not reported
Participants	Inclusion criteria • Setting: national • Country: Italy • N = 26; 26/26 pLMA/cLMA groups • Age, years: mean $\pm$ SD, (range): 37 ± 13 ◦ Treatment group: not reported ◦ Control group: not reported • Sex, M/F: 16/10 • Weight, kg: 71 ± 11 • Height, cm: not reported • Body mass index (BMI): not reported • Physical status: American Society of Anesthesiologists (ASA) I and II • Surgery: general anaesthesia with muscle paralysis Exclusion criteria • ASA III or higher • Previous history of pulmonary disease • Absolute or relative contraindications to the use of LMA (not fasted, hiatal hernia, morbid obesity) • Age < 18 years
Interventions	pLMA group (intervention) • All 26 participants received pLMA after neuromuscular blockade (cross-over design) cLMA group (control) • Same group of 26 participants received cLMA (LMA) after neuromuscular blockade (cross-over design)
Outcomes	• Fibre-optic position assessment and scoring • Airtightness of the devices - confirmed by observing expiratory and inspiratory tidal volumes and plateau airway pressure during end-inspiratory occlusion manoeuvre after cuff of both devices was inflated at 60 hPa (hectopascal) • Respiratory mechanics ◦ End-expiratory and end-inspiratory occlusion manoeuvre studied 5 times ◦ Total positive end-expiratory pressure (PEEP_t), peak airway pressure (P_{max}), end-inspiratory occlusion (P₁), and pressure measured 3 and 4 seconds after P₁ (respectively, P_{3s} and P_{4s})

Natalini 2003c (Continued)

- Inspiratory flow (V'), VT and peak expiratory flow rate (PEFR), intrinsic PEEP ($PEEP_i$) were obtained or calculated
- Total resistance (R_{max}), expiratory resistance, and time constant of the respiratory system were calculated

Notes

- In both groups, device was inserted after neuromuscular blockade
- Insertion technique: not reported
- Protocol deviation: not reported
- As this is a cross-over design, we do not know which participants received which device first
- We planned to include only data related to the device used first, to avoid carry-over effect. We have contacted corresponding author (4 April 2017) to request further information, for which a response is awaited
- Funding source: not reported

NCT02979171

Methods

Study design: prospective, RCT (cross-over design), with single blinding (participants)

Study duration: March 2016 - November 2016 (verification date: November 2016)

Participants

Inclusion criteria

- Setting: national
- Country: Turkey
- N = 90
- Age, years: 18 to 80
  - Treatment group: not available
  - Control group: not available
- Sex, M/F: both adult M/F: not available
- Weight, kg: not available
- Height, cm: not available
- Body mass index (BMI): not available
- Physical status: not available
- Surgery: general anaesthesia in participants undergoing elective surgery
  - Without a history of difficult intubation
  - In supine position
  - Those who did not require tracheal intubation

Exclusion criteria

- High aspiration risk
- Surgery taking longer than 4 hours
- Body mass index $> 35 \text{ kg/m}^2$
- Disease related to the cervical spine
- Mouth opening $< 20 \text{ mm}$

Interventions

Intervention device

- LMA-ProSeal in difficult airway

Control device

- Laryngeal Mask Airway Classic in difficult airway

Outcomes

Primary outcomes

NCT02979171 (Continued)

- Insertion time and attempts in minutes
- Oropharyngeal leak pressure in cm H₂O
- Fibre-optic view grade - by Brimacombe and Berry bronchoscopy score: 1-4 (easy to difficult)

Secondary outcomes: not provided

Notes

ASA = American Society of Anesthesiologists; BMI = body mass index; cLMA = Classic laryngeal mask airway; ETCO₂ = end-tidal carbon dioxide; LMA = laryngeal mask airway; OLP = oropharyngeal leak pressure; pLMA = ProSeal laryngeal mask airway; SLMA = supreme laryngeal mask airway; VTe = expired tidal volume; VTi = inspired tidal volume.

DATA AND ANALYSES

Comparison 1. Failure to mechanically ventilate

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Inadequate oxygenation	4	617	Risk Ratio (M-H, Fixed, 95% CI)	0.75 [0.17, 3.31]

Analysis 1.1. Comparison 1 Failure to mechanically ventilate, Outcome 1 Inadequate oxygenation.

Study or subgroup	pLMA n/N	cLMA n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Ambi 2011	0/25	0/25			Not estimable
Brimacombe 2002	3/192	4/192		100%	0.75[0.17,3.31]
Lu 2002	0/40	0/40			Not estimable
Shin 2010	0/53	0/50			Not estimable
Total (95% CI)	310	307		100%	0.75[0.17,3.31]
Total events: 3 (pLMA), 4 (cLMA)					
Heterogeneity: Not applicable					
Test for overall effect: Z=0.38(P=0.7)					
Favours pLMA 0.002 0.1 1 10 500 Favours cLMA					

Comparison 2. Failure to insert or use of alternate device

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Failure to insert or use of alternate device	7	769	Risk Ratio (M-H, Fixed, 95% CI)	2.2 [0.50, 9.72]

Analysis 2.1. Comparison 2 Failure to insert or use of alternate device, Outcome 1 Failure to insert or use of alternate device.

Comparison 3. Effective airway time (seconds)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Effective airway time (seconds)	2	434	Mean Difference (IV, Fixed, 95% CI)	10.12 [5.04, 15.21]

Analysis 3.1. Comparison 3 Effective airway time (seconds), Outcome 1 Effective airway time (seconds).

Comparison 4. Peak airway pressure during positive pressure ventilation

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Peak airway pressure during positive pressure ventilation	4	259	Mean Difference (IV, Fixed, 95% CI)	0.84 [0.02, 1.67]

Analysis 4.1. Comparison 4 Peak airway pressure during positive pressure ventilation, Outcome 1 Peak airway pressure during positive pressure ventilation.

Comparison 5. Oropharyngeal leak pressure (seal pressure)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Oropharyngeal leak pressure (seal pressure) (cm H ₂ O)	6	709	Mean Difference (IV, Random, 95% CI)	6.93 [4.23, 9.62]

Analysis 5.1. Comparison 5 Oropharyngeal leak pressure (seal pressure), Outcome 1 Oropharyngeal leak pressure (seal pressure) (cm H₂O).

Comparison 6. Complications

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Mucosal injury	4	617	Risk Ratio (M-H, Fixed, 95% CI)	1.49 [0.97, 2.28]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2 Sore throat	5	653	Risk Ratio (M-H, Fixed, 95% CI)	0.77 [0.55, 1.08]
3 Bronchospasm	3	537	Risk Ratio (M-H, Fixed, 95% CI)	3.0 [0.12, 73.19]
4 Gastric insufflation	2	487	Risk Ratio (M-H, Fixed, 95% CI)	0.33 [0.03, 3.18]
5 Regurgitation	4	597	Risk Ratio (M-H, Fixed, 95% CI)	0.8 [0.24, 2.69]
6 Coughing	2	444	Risk Ratio (M-H, Fixed, 95% CI)	0.72 [0.36, 1.43]
7 Excessive leak	2	120	Risk Ratio (M-H, Fixed, 95% CI)	3.0 [0.13, 70.83]

Analysis 6.1. Comparison 6 Complications, Outcome 1 Mucosal injury.

Analysis 6.2. Comparison 6 Complications, Outcome 2 Sore throat.

Analysis 6.3. Comparison 6 Complications, Outcome 3 Bronchospasm.

Analysis 6.4. Comparison 6 Complications, Outcome 4 Gastric insufflation.

Analysis 6.5. Comparison 6 Complications, Outcome 5 Regurgitation.

Analysis 6.6. Comparison 6 Complications, Outcome 6 Coughing.

Analysis 6.7. Comparison 6 Complications, Outcome 7 Excessive leak.

APPENDICES

Appendix 1. MEDLINE search strategy

#1 . exp Laryngeal Masks/

#2 . laryngeal mask airway.mp.

#3 . (LMA or ProSeal).mp.

#4 . (mask adj6 airway).mp.

#5 . #1 or #2 or #3 or #4

#6 . exp Positive-Pressure Respiration/

#7 . Respiration, Artificial/

#8 . (mechanical adj6 ventil*).mp.

#9 . (positive adj6 pressure).mp.

#10 . #8 or #6 or #7 or #9

#11 . #10 and #5

#12 . ((randomized controlled trial or controlled clinical trial).pt. or randomized.ab. or placebo.ab. or drugtherapy.fs. or randomly.ab. or trial.ab. or groups.ab.) not (animals not (humans and animals)).sh.

#13 . #11 and #12

Appendix 2. Embase (Ovid SP) search strategy

1. exp Laryngeal Mask/
2. laryngeal mask airway.mp.
3. (LMA or ProSeal).mp.
4. (mask adj6 airway).mp.
5. 1 or 2 or 3 or 4
6. exp Positive End Expiratory Pressure/
7. exp Artificial Ventilation/
8. exp Intermittent Positive Pressure Ventilation/
9. (mechanical adj6 ventil*).mp.
10. (positive adj6 pressure).mp.
11. 8 or 6 or 7 or 10 or 9
12. 11 and 5
13. (RANDOMIZED-CONTROLLED-TRIAL/ or RANDOMIZATION/ or CONTROLLED-STUDY/ or MULTICENTERSTUDY/or PHASE-3-CLINICAL-TRIAL/ or PHASE-4-CLINICAL-TRIAL/ or DOUBLE-BLIND-PROCEDURE/ or SINGLEBLIND-PROCEDURE/ or (RANDOM* or CROSS?OVER* or FACTORIAL* or PLACEBO* or VOLUNTEER* or ((SINGL* or DOUBL* or TREBL* or TRIPL*) adj3 (BLIND* or MASK*))).it,ab.) not (animals not (humans and animals)).sh.
14. 13 and 12

Appendix 3. CENTRAL search strategy

- #1 MeSH descriptor Laryngeal Masks explode all trees
- #2 laryngeal mask airway
- #3 LMA or ProSeal
- #4 mask near airway#5 (#1 OR #2 OR #3 OR #4)
- #6 MeSH descriptor Positive-Pressure Respiration explode all trees
- #7 MeSH descriptor Respiration
- #8 mechanical near ventil*
- #9 positive near pressure
- #10 (#6 OR #7 OR #8 OR #9)
- #11 (#5 AND #10)

Appendix 4. ISI Web of Science search strategy

- #1 TS=(LMA or ProSeal) or TS=(airway SAME (mask or laryngeal))
- #2 TS=(positive SAME pressure) or TS=((ventil* or respiration) SAME (artificial or mechanical))
- #3 #1 and #2
- #4 TS=(random* or prospective or multicenter or placebo) or TS=((controlled or clinical) SAME trial*) or TS=((blind* or mask*) SAME (single or double or triple or treble))
- #5 #3 and #4

Appendix 5. CINAHL (EBSCO host) search strategy

- S1. ((MM "Laryngeal Masks") OR laryngeal mask airway OR (LMA or ProSeal) OR (mask and airway)) AND (((MM "Positive Pressure Ventilation +") OR (MH "Respiration, Artificial")) OR (mechanical and ventil*) OR (positive and pressure)) AND (((MM "Randomized Controlled Trials")

OR (MM "Random Assignment") OR (MM "Clinical Trials") OR (MM "Multicenter Studies") OR (MM "Preventive Trials") OR (MM "Clinical Trial Registry") OR (MM "Double-Blind Studies") OR (MM "Single-Blind Studies") OR (MM "Triple-Blind Studies")) OR (((controlled or clinical) and trial*)) OR (random* or multicenter* or prospective or placebo*) OR (((mask* or blind*) and (single or double or triple or treble))))

Appendix 6. Study selection, quality assessment, and data extraction form

First author	Journal/Conference proceedings, etc.	Year

Study eligibility

RCT/Quasi/CCT	Relevant participants	Relevant interventions	Relevant outcomes
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 "Table of excluded studies".

References to trial

Check other references identified in searches. If further references to this trial are available, 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
A	<i>The paper listed above</i>		
B	<i>Further papers</i>		

Participants and trial characteristics

Participant characteristics

Further details

Age (mean, median, range, etc.)

Sex of participants (numbers / %, etc.)

BMI

Trial characteristics

See Appendix 1, usually completed by just one reviewer.

Methodological quality

We recommend you refer to and use the method described by [Jüni 2001](#).

Allocation of intervention

State here the method used to generate allocation and reasons for grading

Grade (circle)

Adequate (random)

Inadequate (e.g. alternate)

Unclear

Concealment of allocation

Process used to prevent foreknowledge of group assignment in an RCT, which should be seen as distinct from blinding

State here method used to conceal allocation and reasons for grading

Grade (circle)

Adequate

Inadequate

Unclear

Blinding

(Continued)

Person responsible for participants' care	Yes / No
Participant	Yes / No
Outcome assessor	Yes / No
Other (please specify)	Yes / No

Intention-to-treat

An intention-to-treat analysis is one in which all participants in a trial are analysed according to the intervention to which they were allocated, whether or not they received it.

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

Were withdrawals described? Yes? No ? Not Clear? Discuss if appropriate.

Data extraction

Primary outcomes	Reported in paper (circle)
Improper placement (malposition, excessive leak)	Yes / No
Inadequate oxygenation (as assessed by peripheral oxygen saturation (SaO ₂) and/or partial pressure of oxygen in arterial blood (PaO ₂)) and / or ventilation (as assessed by end-tidal carbon dioxide concentration (ETCO ₂) and/or partial pressure of carbon dioxide in arterial blood (PaCO ₂))	Yes / No

Secondary outcomes

Code of paper	Outcomes (rename)	cLMA group (n)	pLMA group (n)
	Rate of reinsertion attempts or abandoning the use of LMA		
	Complications related to use of LMA including laryngospasm, coughing, bronchospasm, aspiration or obstruction, sore throat, and mucosal injury (blood staining)		
	Peak airway pressure during positive pressure ventilation		
	Oropharyngeal leak pressure (seal pressure)		

(Continued)

Gastric insufflation

Regurgitation and / or pulmonary aspiration

Postoperative nausea or vomiting (PONV)

Other information that 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 were calculated by 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 the review

References to other trials

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

First author

Journal / Conference

Year of publication

Did this report include any references to unpublished data from potentially eligible trials not already identified for this review? If yes, give contact name and details

Trial characteristics

Further details

Single centre / Multi-centre

Country / Countries

How was participant eligibility defined?

(Continued)

How many people were randomized?

Number of participants in each intervention group

Number of participants who received intended treatment

Number of participants who were analysed

CONTRIBUTIONS OF AUTHORS

Muhammad Qamarul Hoda (QH), Khalid Samad (KS), Hameed Ullah (HU).

1. Conceiving the review: QH.
2. Co-ordinating the review: QH.
3. Undertaking manual searches: QH, KS.
4. Screening search results: QH, KS.
5. Organizing retrieval of papers: QH, KS.
6. Screening retrieved papers against inclusion criteria: QH, KS, HU.
7. Appraising quality of papers: HU.
8. Abstracting data from papers: QH, KS.
9. Writing to authors of papers for additional information: QH.
10. Providing additional data about papers: KS.
11. Obtaining and screening data on unpublished studies: QH.
12. Managing data for the review: HU, KS.
13. Entering data into Review Manager ([RevMan 5.3](#)): KS.
14. Analysing RevMan statistical data: HU, KS.
15. Conducting other statistical analysis not using RevMan: HU, KS.
16. Performing double entry of data: data entered by person one: KS; data entered by person two: QH.
17. Interpreting data: QH, HU.
18. Making statistical inferences: HU.
19. Writing the review: QH.
20. Securing funding for the review: QH (if required).
21. Performing previous work that was the foundation of the present study: KS, HU.
22. Serving as guarantor for the review (one author) QH.
23. Taking responsibility for reading and checking the review before submission: HU.

DECLARATIONS OF INTEREST

1. Muhammad Qamarul Hoda: none known.
2. Khalid Samad: none known.
3. Hameed Ullah: none known.

SOURCES OF SUPPORT

Internal sources

- Resources for this review were provided by Department of Anaesthesiology, Aga Khan University, Karachi, Pakistan.

External sources

- No sources of support supplied

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

We made the following changes to the review ([Qamarul Hoda 2011](#)).

Additional searches

We added two search engines (ISI Web of Science (1946 to November 2016) and CINAHL (EBSCO host, 1982 to November 2016)) to ensure wider coverage of the evidence.

Types of studies

1. We planned to include randomized controlled trials (RCTs) and quasi-RCTs comparing the effectiveness of positive pressure ventilation with Classic and ProSeal LMAs in adults undergoing elective surgery. In the review, we included only RCTs because we found no quasi-RCTs in our searches.
2. We planned to include only data related to the device used first for cross-over studies. In the review, we have placed cross-over studies under "Studies awaiting classification" because we have written to the authors of the four cross-over studies regarding data and are awaiting their responses.

Primary outcome

1. Following a suggestion from a peer referee, we subdivided the primary outcome - failure to adequately mechanically ventilate - to include two variables: inadequate oxygenation and inadequate ventilation. We considered all other variables as secondary outcomes.
2. We had planned to assess oxygenation according to peripheral oxygen saturation (SpO₂) or partial pressure of oxygen in arterial blood (PaO₂). We assessed ventilation according to end-tidal carbon dioxide concentration (ETCO₂) or partial CO₂ pressure in arterial blood (PaCO₂).

We evaluated the primary outcome - failure to adequately mechanically ventilate - according to:

1. inadequate oxygenation - < 90% on peripheral oxygen saturation (SaO₂); or
2. inadequate ventilation - ETCO₂ > 45 mm Hg.

Secondary outcomes

1. We did not include "effective airway time" and "failure to insert gastric tube" as outcomes in the protocol ([Qamarul Hoda 2011](#)). We added these post hoc because some included studies looked at this outcome.
2. After wide consultation, we amended secondary outcomes in the protocol to include the following.
  - a. Inability to insert or abandon intended device - as assessed by inability to insert and/or use of alternate device.
  - b. Effective airway time - as assessed by time taken to insert and adequately ventilate with either device.
  - c. Failure to insert gastric tube.
  - d. Peak airway pressure during positive pressure ventilation.
  - e. Oropharyngeal leak pressure.
  - f. Complications related to insertion of the LMA: mucosal injury (blood staining), sore throat, excessive leak, gastric insufflation, bronchospasm/laryngospasm, regurgitation/aspiration, coughing, obstruction of device, excessive secretions, and postoperative nausea or vomiting.
  - g. Any other.

These were formerly the following.

1. Complications related to use of LMA including laryngospasm, coughing, bronchospasm, aspiration or obstruction, sore throat, and mucosal injury (blood staining).
2. Peak airway pressure during positive pressure ventilation.
3. Oropharyngeal leak pressure (seal pressure).
4. Gastric insufflation.
5. Regurgitation or pulmonary aspiration, or both.
6. Postoperative nausea or vomiting (PONV).
7. Any other.

Summary of findings table

In protocol, we planned to present the following outcomes in the SoF table:

1. Failure to adequately mechanically ventilate
2. Airway complications
3. Insertion attempts
4. Aspiration
5. Gastric insufflation

6. Peak airway pressure
7. Oropharyngeal leak pressure (Seal Pressure)

However, based on the reason mentioned above in primary outcome section, "failure to adequately mechanically ventilate" has been modified to "inadequate oxygenation" and "inadequate ventilation".

Outcomes "airway complications (except sore throat), insertion attempts, aspiration, and gastric insufflation" have not been presented in SoF table as all of these were either uncertain or insignificant.

We identified "effective airway time" and "regurgitation" as outcomes assessed by some of our included studies so we added this in SoF.

INDEX TERMS

Medical Subject Headings (MeSH)

*Elective Surgical Procedures; *Laryngeal Masks [adverse effects] [classification]; Oxygen Consumption; Positive-Pressure Respiration [*instrumentation]; Randomized Controlled Trials as Topic; Treatment Failure

MeSH check words

Adult; Humans