A randomised controlled trial comparing the impact of endotracheal tubes vs laryngeal mask airways on perioperative respiratory adverse events in infants

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Summary

Background

Perioperative respiratory adverse events (PRAE) are the most common critical incidents in paediatric anaesthesia, with infants particularly at risk. Laryngeal mask airways (LMA) are associated with reduced PRAE compared with endotracheal tube (ETT) in older children. We performed a randomised controlled trial to evaluate both devices in infants for their impact on the incidence of PRAE.

Methods

Following institutional research ethics committee approval and trial registration (ACTRN12610000250033), infants undergoing general ± regional/local anaesthesia for minor elective surgery were approached. We excluded patients contraindicated for LMA or ETT, with cardiac disease, airway or thoracic malformations, midazolam premedication, and anticipated intraoperative fentanyl >1mcg/kg. Participants were randomised to receive an LMA or ETT. Planned recruitment included 290 infants, with an interim analysis once 145 infants (50%) had been recruited. Demographics, risk factors for PRAE, incidence of PRAE (laryngospasm, bronchospasm, airway obstruction, desaturation <95%, severe persistent coughing, postoperative stridor) were recorded.

Findings

Following the interim analysis the study stopping rules were met and the trial halted at 181 participants. In the intention to treat analysis, overall PRAE occurred in 50 (53·2%) and 15 (18·1%) infants in ETT and LMA groups respectively (RR 2·94, 95% CI 1·79-4·83, p < 0·0001). Laryngospasm and bronchospasm (major PRAE) occurred in 18 (19·1%) and 3 (3·6%) cases for ETT and LMA, respectively (RR 5·30, 95% CI 1·62–17·35, p = 0·002).

Interpretation

In infants undergoing minor elective procedures, LMAs were associated with a clinically significantly reduction in PRAE compared to ETTs. Higher rates of severe PRAE (laryngospasm and bronchospasm) were associated with the use of ETTs in infants compared with LMAs and should be a consideration in airway device selection.

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Research in context

Evidence before this study

Perioperative respiratory adverse events (PRAE) are clinically significant events that account for around three quarters of critical incidents and a third of cardiac arrests in anaesthetised children. Infants and young children, their higher oxygen demand and low oxygen reserves, make them more vulnerable to hypoxemia and as a result the incidence of PRAE increases by up to 11% per year with decreasing age.

Whilst laryngeal mask airways (LMAs) and endotracheal tubes (ETTs) have been compared in several randomised controlled trials in paediatric populations, which found LMA to be either advantageous or equivalent to ETT, none of these included significant numbers of infants. For the infant population, there is only observational evidence from a large cohort study that overall PRAE are less frequent in infants managed with LMAs when compared to ETTs. However, the role of the LMA in the management of young infants remains controversial in the paediatric anaesthesia community with many institutions mandating the use of ETTs below a certain age (often <1 year).

Added value of this study

We examined the differences between LMA and ETT for the management of infants undergoing general ± regional/local anaesthesia.

Statistically and clinically significantly greater rates of overall PRAE were found in infants managed with ETTs compared to LMAs, with the risk of PRAE increasing three-fold with the use of an ETT. Laryngospasm and bronchospasm (major PRAE) occurred approximately five times more frequently when an ETT was used.

Implications of all the available evidence

Whilst our results are not generalisable to all infant populations, they represent a large population of infants undergoing minor elective surgery (e.g. hernia repair). When choosing the airway device for an individual patient, anaesthetists have to consider a number of factors including the occurrence of PRAE. Given that PRAE are one of the major causes of morbidity and mortality, particularly in infants, this study provides the anaesthetist with important findings which lead to a clinically significant reduction of PRAE. The results of this study should be incorporated into an evidence based anaesthetic management plan for infants.

Introduction

Perioperative respiratory adverse events (PRAE) are the most common critical incidents encountered in paediatric anaesthesia,[1–4] and account for a third of anaesthesia-related cardiac arrests.[5] While the incidence of PRAE is 15% in a general paediatric population, the rate of PRAE is doubled in infants.[6] With small airways, a low oxygen reserve and the loss of protective airway reflexes under general anaesthesia, it is of crucial importance to maintain an open and stable airway in this population.

Endotracheal tubes (ETT) have been the traditional choice of airway device in infants. Endotracheal tubes, particularly cuffed ones, reliably secure the airway and protect it from aspiration.[7,8] The use of laryngeal mask airways (LMAs) is increasing but remains less common in infants. Although the LMA is easier to insert and minimises the direct mechanical stimulation of the airway due to being positioned above the larynx,[9] it is often assumed to be less secure in infants compared to older children. Whilst smaller paediatric LMAs are more frequently associated with partial obstruction of the glottis, insertion success and quality of ventilation is not significantly different from larger sizes.[10] Conversely, a study in which airway management was performed by a single anaesthetist, higher rates of suboptimal positioning using ultrasound were observed.[11]

Observational data from our group suggests that the use of an ETT is associated with an increased risk of PRAE in infants when compared to an LMA.[6] Several randomised controlled trials comparing the use of ETT and LMA in older children have found a significantly increased incidence of perioperative airway complications with ETTs, however all but one excluded infants and none reported the number of infants included.[12–15] A 2010 systematic review reported a clinically significantly lower incidence of laryngospasm during emergence and post-operative hoarse voice and coughing when using an LMA in adults compared with an ETT.[16] Similarly, a meta-analysis including 1242 children under 12 years of age found a decreased risk of sore throat, coughing, and bronchospasm with an LMA when compared with an ETT.[17]

To date and to our knowledge no robust randomised trials in infants have compared the impact of using a laryngeal mask airway compared to an endotracheal tube on the incidence of perioperative respiratory adverse events whilst undergoing general anaesthesia. We thus designed this randomised controlled trial with the hypothesis that the incidence of PRAE will be lower in infants receiving an LMA compared with those receiving an ETT.

Methods

Study Design and participants

This single centre randomised controlled trial was carried out by the Department of Anaesthesia and Pain Management at the Princess Margaret Hospital for Children in Perth, Western Australia. Princess Margaret Hospital is the only tertiary paediatric hospital in Western Australia and approximately 15,000 procedures are performed under general anaesthesia each year, of which approximately 10% are performed on infants between zero and 12 months of age.

Ethical approval was granted by the institutional ethics committee at Princess Margaret Hospital for Children, Perth, Australia (1786/EP) and was recognised by The University of Western Australia (RA/4/1/5902). The trial was registered with the Australian New Zealand Clinical Trials Registry (ACTRN12610000250033).

Infants were evaluated for recruitment during the pre-anaesthetic assessment. Written parental/guardian consent was obtained prior to enrolment. Infants between 0 and 12 months of age, undergoing elective general anaesthesia ± regional (e.g. caudal, penile block) or local anaesthesia, who were assessed by their attending anaesthetist to be suitable for either an LMA or ETT, were eligible for recruitment into the study. The full inclusion and exclusion criteria are provided in Figure 1. Following recruitment, each infant was randomised to receive either an LMA or ETT. An interim analysis for efficacy or futility was planned for halfway through the study (n = 145). An independent data monitoring committee was established to review data and the outcomes of interim analysis. No alterations were made to the initial protocol design between the beginning and the end of this study.

Randomisation and masking

Participants were assigned to receive (1:1) either LMA or ETT by means of computer generated variable block randomisation, concealed by sequentially assigned sealed randomisation envelopes. Sequence generation and envelope preparation were performed by a person independent of the research team. Envelopes were opened immediately prior to induction of anaesthesia by the attending anaesthetist only. Study personnel were aware of the randomisation outcome only after the envelope was opened.

Procedures

Anaesthesia induction was performed at the discretion of the patient's attending anaesthetist. Induction was performed with either sevoflurane or propofol. The airway device allocated as per randomisation was inserted by the attending anaesthetist. Patients in the LMA group received a PRO-Breathe® silicone disposable laryngeal mask (Well Lead Medical Co Ltd, Panyu, China), a first generation laryngeal mask airway.[18] The technique used to insert the device was not standardised and was left to the treating anaesthetist in line with routine clinical care. The anaesthetist was free to swap the randomised device whenever deemed necessary for the benefit of the patient. Anaesthesia was subsequently maintained with sevoflurane at ≥1 MAC (Minimum Alveolar Concentration). Analgesia was given in form of regional and/or local analgesia (e.g. caudal block, penile block) as deemed necessary with intravenous fentanyl at doses up to 1 mcg/kg. Ventilation was standardised to pressure support of 10 cmH_2O with a positive end expiratory pressure of 5 cmH_2O. All patients were managed by or under the direct supervision of a specialist consultant paediatric anaesthetist with extensive experience with airway management in infants.

Data collection consisted of patient demographics, risk factors for PRAE (Table 1),[6] and incidence of PRAE intra- and post-operatively (Table 2). The occurrence and rate of each PRAE were recorded by the attending anaesthetist during induction, maintenance and emergence of anaesthesia, and by specialised nurses during recovery in the post anaesthesia care unit. The attending anaesthetist was independent of the study team. Spot checks of accuracy were performed randomly by the research team. Baseline and postoperative oxygen saturations along with the timing of the airway removal (deep or awake) were also recorded. On the day following surgery, families were contacted by telephone and the incidence of any postoperative problems, hoarse voice when crying, and any breathing problems were recorded.

Outcomes

The primary outcome was the incidence of any PRAE in relation to the type of airway device used. The impact of LMA vs. ETT on the incidence of individual PRAE and their timing (intraoperatively and postoperatively) was assessed as secondary outcomes. The incidence of events was monitored from initiation of anaesthesia until discharge from the post anaesthesia care unit. Events were considered to be postoperative if they occurred after transfer to the post anaesthesia care unit.

Statistical analysis

The sample size for this trial was based on the incidence of PRAE reported for each airway device in our previous observational cohort study.[6] Children receiving an LMA or an ETT were reported to have a PRAE

incidence of 20% and 35% respectively. Using a two group chi-square analysis, a sample size of 276 infants (138 in each group) provided an 80% power at a 0·05 two sided significance level to detect a 15% difference between groups. A 5% dropout rate was accounted for per group for unusable data due to procedure cancellations, requiring a total of 290 participants.

As a requirement by the local Ethics committee at the time of study commencement, an independent member of the anaesthesia department and a hospital biostatistician performed internal safety monitoring, Additionally, this study had an external data monitoring committee consisting of three independent anaesthesia academics with extensive expertise in conducting large randomised controlled studies who reviewed the results of the interim analysis. The interim analysis was conducted when 50% of recruitment was completed using the Haybittle-Peto boundary rule for group sequential testing (α_1 = 0·0027, α_2 = 0·04996) with a stopping condition imposed on the trial if a difference of 25% in the primary outcome was detected.

Statistical analysis was performed with SPSS version 22 (IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22·0. Armonk, NY: IBM Corp) and the R statistical environment version 3·3·0 (R Foundation for Statistical Computing, Vienna, Austria). We applied an intention to treat (ITT) principle to compensate for non-compliance and missing outcomes. Only cancelled procedures were omitted when performing an ITT analysis as we did not have PRAE outcomes in these cases. In addition to the primary outcomes, we assessed the stated secondary outcomes on the incidence of PRAE in the ETT group. The outcomes are presented as binary variables and comparison of groups was performed by means of Fisher's exact test. Demographic comparison was performed using Student's t-test for continuous variables and Fisher's exact test for categorical and binary variables. Variance of groups were compared prior to Student's t-tests. Relative risk figures and associated 95% confidence intervals are also presented and were calculated using the epitools package for R[19].

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Results

The trial commenced on the 8th of July 2010 and was halted on the 7th of May 2015 after the results of the interim analysis met the stopping criteria. One hundred and eighty one patients had been recruited when the study was stopped.

Of the 181 participants, complete datasets for 177 (119 (67·2%) males) infants aged between 0 and 12 months were available for an intention to treat analysis. Four infants were not included in the analysis: two due to cancelled procedures, one patient not meeting inclusion criteria and one missing dataset. Thus the available data sets include 83 patients assigned to LMA, and 94 assigned to ETT (Figure 2). Participant demographics and surgical speciality are detailed in Table 3 with patient management details reported in Table 4. The most common procedures were hernia repair (36, 19.9%), cystoscopy (24, 13.3%), MRI and CT (17, 9.4%), orchidopexy (12, 6.6%), hypospadias repair (11,6.1%), and circumcision (9, 5.0%).

Sixty-five (36·7%) infants experienced PRAE in this trial. Infants receiving an ETT were three times more likely to experience PRAE compared with those who received an LMA (53·2% (50) vs. 18·1% (15), RR 2·94, 95% CI 1·79 - 4·83, $p < 0·0001$). All individual PRAE occurred at lower rates over the perioperative period in the LMA group, and rates of major, minor, and overall PRAE were lower for LMA both intraoperatively and postoperatively (Table 5). Figure 3 provides an overview of the incidence of each individual PRAE for each group. In two cases (1 LMA, 1 ETT) intravenous suxamethonium was required following device removal for severe persistent laryngospasm associated with desaturation ≤ 60%.

During the routine postoperative follow-up, parents of 20 (24·7%) children in the LMA group and 22 (25.6%) in the ETT group reported general problems such as pain, irritability, feeding issues, distress, postoperative nausea and vomiting or lethargy (RR 1·03, 95% CI 0·61 - 1·75, $p = 1$), while hoarse cry was found in 17 (21.0%) vs. 28 (32.9%) of children in the LMA vs. ETT group, respectively (RR 1·57, 95% CI 0·93 - 2·64 $p = 0·012$). Parental report of postoperative breathing problems was given in 7 (8·6%) vs. 18 (22·1%) of children receiving an LMA vs. an ETT (RR 2·55, 95% CI 1·14 - 5·76, $p = 0·019$). A single ETT case required CPAP post-operatively for 2 hours and one infant who received a LMA was treated by their GP for a chest infection.

Table 6 identifies the differences seen between patients undergoing deep and awake airway device removal. Patients with respiratory symptoms displayed higher rates of PRAE with both LMA and ETT

(Figure 4: 31·4% (11) vs 68·6% (24), RR 2·18, 95% CI 1 ·27 – 3·74, p = 0.004) than those without (8·3% (4) vs 44·1% (26), RR 5·29, 95% CI 1·98 – 14·11, p < 0.0001).

Discussion

This trial is the first to examine the impact of laryngeal mask airways and endotracheal tubes on the incidence of perioperative respiratory adverse events in infants. This is a topic of significant controversy in clinical practice. PRAE, and particularly major PRAE, are clinically significant events and are major contributors to anaesthetic morbidity. Our results clearly demonstrate a clinically significant increase in the rates of PRAE, including in major PRAE, in infants whose airway was managed with an ETT rather than a LMA, and are likely to significantly influence choice of airway device in suitable infants.

Increased risk of overall PRAE with ETTs was most prominent intra-operatively (Table 5). A single major PRAE occurred in the post anaesthesia care unit (PACU) in the ETT group, with none in the LMA group. In our institution recovery nurses can manage LMAs if removed awake but ETTs are removed in theatre prior to transfer to PACU. Even though there was no direct mechanical stimulation in infants in the ETT group in PACU, the incidence of PRAE was still doubled compared to the LMA group. This is likely multifactorial: a) follow-on effect generated by mechanical stimulus by the ETT at intubation and particularly on awake extubation, b) potential intraoperative endotracheal tube movements with repositioning, c) effect of de-recruitment of the lungs following coughing and the potential administration of muscle relaxants leading to a decrease in functional residual capacity,[20] d) the tissue trauma caused by the ETT leading to a release of inflammatory mediators and a consecutive sensitisation of nerves, and e) mucosal swelling.

We found substantially higher rate of perioperative PRAE than reported for the paediatric population in general. [10] This is in line with the observed trend of increased PRAE for younger children (11% per year of age) identified in a previous large cohort study.[6] Our overall rates of major and minor PRAE were similar to those reported in a study in children (3 months to 16 years of age) with current upper respiratory tract infection. This highlights the importance of the right choice of airway management with regards to PRAE in infants.

Randomised studies comparing airway devices in older children have found that, relative to LMA, children managed using ETTs have a greater incidence of PRAE, which was also reflected in the present study.[13,21] These studies reported lower rates of PRAE in both groups than we found in infants, which

likely reflects the increase susceptibility of infants to these PRAE.[13,14,21] Whilst we found similar rates of perioperative bronchospasm to those reported in a meta-analysis comparing LMA with ETT in older children, rates of laryngospasm were greater in both groups of our study which can be explained by the younger age group in the current study.[17]

A limitation of this study is that the anaesthesia management was only partially standardised in order to provide a realistic representation of routine practice and prevent any bias generation. All infants, however, were under the management of specialist paediatric anaesthetists. A large proportion of our department staff were involved in this study, and our clinical staffing underwent only limited changes during the duration of the present study. No changes to protocols for this patient group occurred during the study. We excluded patients receiving sedating premedication, as this is not routine practice our institution, and we have previously seen an association between midazolam premedication and increased PRAE.[6]

Some might suggest that the high rates of PRAE seen with ETTs are due to our institution not mandating the use of neuromuscular blockade for intubation in this age group. While only 18 (19%) of infants in the ETT group received neuromuscular blocking agents to facilitate endotracheal intubation, the rate of PRAE was not different between the groups. Thirteen (72·2%) infants receiving neuromuscular blockade vs. 37 (48·7%) not receiving neuromuscular blockade presented with PRAE (RR 1·48, 95% CI 1·03-2·14, p = 0·113). It seems therefore unlikely that the benefit seen with LMA is due to the lack of neuromuscular blockade in the majority of infants receiving an ETT. On the contrary, we suggest that the incidence of PRAE would have, if different, been higher if all infants in the ETT group had received neuromuscular blockade. Further, timing of ETT extubation did not appear to have any significant effect on PRAE, with PRAE occurring in 50·0% (15) of deep extubations and 51·8% (29) of awake extubations (Table 6).

Our results demonstrate that the advantages seen when using the LMA in older children are also applicable in infants.[17] As seen in the general paediatric population, ETTs present a greater risk of PRAE than LMAs.[6] It is worth noting also that whilst LMAs are associated with greater incidence of PRAE compared to use of a facemask, invasive devices offer other benefits which must be considered.[6,22]

ETTs remain a useful device in the management of the infant airway and are required in cases where LMAs are contraindicated and provide the most secure airway with regards to aspiration. When choosing the airway device, the treating anaesthetist has to consider a number of factors including PRAE, which has a particular importance in infants.

A broad range of infant presentations were included in this study, including infants with and without PRAE risk factors. Our study population, however, necessarily consisted of patients who were considered suitable for management with either LMA or ETT by their attending anaesthetist and can therefore not be extrapolated onto all infants. The results of the current study will be applicable for the majority of infants undergoing minor elective surgery (e.g. hernia repair). We had a high rate of recruitment of eligible patients (75.7%) and therefore significant selection bias is unlikely.

This study was conducted at a single centre, which limits the generalisability of our results. However, the study recruited a broad sample including both infants with and without PRAE risk factors (Figure 4). A significant proportion of the anaesthetists in our department were involved in the management of study participants, which increases the generalisability. Additionally, the timing of airway removal was not standardised to reflect routine clinical care and improve generalisability. Multi-centre trials would assist with determining to what degree our results generalise across paediatric settings.

Displacement or suboptimal placement of small sized LMAs has previously been reported and may influence the incidence of PRAE.[11] This study did not use fibreoptic bronchoscopy or ultrasound to confirm positioning, with clinically good LMA positioning being confirmed by clinical auscultation and assessment of leakage of the LMA. Despite this less objective approach, only a single LMA had to be exchanged to an ETT due to excessive leakage at the induction of anaesthesia. Good ventilation was achieved in all other cases. There were no accidental displacements. The possibility of suboptimal LMA placement in this study cannot be excluded and therefore may have contributed to the rate and type of PRAE observed. Despite this limitation lower rates of PRAE in infants receiving a LMA were observed compared to those receiving an ETT. This suggests LMA placement had a negligible impact on the incidence of PRAE in this study.

While the LMA will not be suited for all infants undergoing all types of surgery, this study shows a clear benefit of the use of an LMA compared to an ETT in a large number of infants undergoing minor elective surgery. The incidence of overall PRAE, minor and major PRAE were all significantly lower when LMAs are used in infants as compared to ETTs.

Contributors

TFE D-B was involved in data collection, data analysis and data interpretation as well as manuscript preparation. AR was involved in data analysis and data interpretation as well as manuscript preparation.

GZ was involved in the study design, data analysis and data interpretation as well as manuscript preparation. GH was involved in the study design, data analysis and data interpretation as well as manuscript preparation. BS vU-St was the principal investigator, designed the study, coordinated the study team, was involved in data analysis and data interpretation as well as manuscript preparation.

Declaration of interests

We declare no competing interests.

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References

1. Murat I, Constant I, Maud'huy H. Perioperative anaesthetic morbidity in children: a database of 24,165 anaesthetics over a 30-month period. Pediatr Anesth. 2004 Feb;14(2):158–66.

2. Cravero JP, Beach ML, Blike GT, Gallagher SM, Hertzog JH, Pediatric Sedation Research Consortium. The incidence and nature of adverse events during pediatric sedation/anesthesia with propofol for procedures outside the operating room: a report from the Pediatric Sedation Research Consortium. Anesth Analg. 2009 Mar;108(3):795–804.

3. Mamie C, Habre W, Delhumeau C, Barazzone Argiroffo C, Morabia A. Incidence and risk factors of perioperative respiratory adverse events in children undergoing elective surgery. Pediatr Anesth. 2004 Mar 1;14(3):218–24.

4. Mir ghassemi A, Neira V, Ufholz L-A, Barrowman N, Mulla J, Bradbury CL, et al. A systematic review and meta-analysis of acute severe complications of pediatric anesthesia. Pediatr Anesth. 2015 Nov 1;25(11):1093–102.

5. Bhananker SM, Ramamoorthy C, Geiduschek JM, Posner KL, Domino KB, Haberkern CM, et al. Anesthesia-related cardiac arrest in children: update from the Pediatric Perioperative Cardiac Arrest Registry. Anesth Analg. 2007 Aug;105(2):344–50.

6. von Ungern-Sternberg BS, Boda K, Chambers NA, Rebmann C, Johnson C, Sly PD, et al. Risk assessment for respiratory complications in paediatric anaesthesia: a prospective cohort study. The Lancet. 2010 Sep 10;376(9743):773–83.

7. American College of Surgeons Committee on Trauma. Advanced Trauma Life Support for Doctors: Student Course Manual. 6th ed. Chicago, Illinois: American College of Surgeons; 1997.

8. Fonseca RJ, Walker RV, Betts NJ. Oral And Maxillofacial Trauma. 3rd ed. St. Louis, Missouri: Saunders; 2004. 1328 p.

9. Kaplan A, Crosby GJ, Bhattacharyya N. Airway Protection and the Laryngeal Mask Airway in Sinus and Nasal Surgery. The Laryngoscope. 2004 Apr 1;114(4):652–5.

10. von Ungern-Sternberg BS, Wallace CJ, Sticks S, Erb TO, Chambers NA. Fibreoptic assessment of paediatric sized laryngeal mask airways. Anaesth Intensive Care. 2010 Jan;38(1):50–4.

11. Kim J, Kim JY, Kim WO, Kil HK. An ultrasound evaluation of laryngeal mask airway position in pediatric patients: an observational study. Anesth Analg. 2015 Feb;120(2):427–32.

12. Tait AR, Pandit UA, Voepel-Lewis T, Munro HM, Malviya S. Use of the laryngeal mask airway in children with upper respiratory tract infections: a comparison with endotracheal intubation. Anesth Analg. 1998 Apr;86(4):706–11.

13. Jamil S, Alam M, Usmani H, Khan M. A Study of the Use of Laryngeal Mask Airway (LMA) in Children and its Comparison with Endotracheal Intubation. Indian J Anesth. 2009 Mar;53(2):174–8.

14. Lalwani J, Dubey K, Sahu B, Shah P. ProSeal laryngeal mask airway: An alternative to endotracheal intubation in paediatric patients for short duration surgical procedures. Indian J Anesth. 2010 Nov;54(6):541–5.

15. Sinha A, Sharma B, Sood J. ProSealTM as an alternative to endotracheal intubation in pediatric laparoscopy. Pediatr Anesth. 2007 Apr 1;17(4):327–32.

16. Yu SH, Beirne OR. Laryngeal Mask Airways Have a Lower Risk of Airway Complications Compared With Endotracheal Intubation: A Systematic Review. J Oral Maxillofac Surg. 2010 Oct;68(10):2359–76.

17. Patki A. Laryngeal mask airway vs the endotracheal tube in paediatric airway management: A meta-analysis of prospective randomised controlled trials. Indian J Anaesth. 2011 Sep;55(5):537–41.

18. Wallace CJ, Chambers NA, Erb TO, von Ungern-Sternberg BS. Pressure volume curves of paediatric laryngeal mask airways. Anaesthesia. 2009;64(5):527–31.

19. Developer TJA, User MPF, User DW. epitools: Epidemiology Tools [Internet]. 2012 [cited 2016 Jul 29]. Available from: https://cran.r-project.org/web/packages/epitools/index.html

20. von Ungern-Sternberg BS, Hammer J, Schibler A, Frei FJ, Erb TO. Decrease of functional residual capacity and ventilation homogeneity after neuromuscular blockade in anesthetized young infants and preschool children. Anesthesiology. 2006 Oct;105(4):670–5.

21. Patel MG, Swadia V, Bansal G. Prospective randomized comparative study of use of PLMA and ET tube for airway management in children under general anaesthesia. Indian J Anaesth. 2010 Mar;54(2):109–15.

22. Harnett M, Kinirons B, Heffernan A, Motherway C, Casey W. Airway complications in infants: comparison of laryngeal mask airway and the facemask-oral airway. Can J Anesth. 2000 Apr;47(4):315–8.

Table 1: Definitions of risk factors for PRAE

Risk Factor
Recent URTI (cold or flu in the last two weeks)
Wheeze (three or more episodes of wheezing in the last 12 months)
Wheeze on Exercise
Nocturnal Cough
Current/past Eczema
Family History of Asthma
Family History of Eczema
Family History of Hayfever
Passive smoke exposure

Table 2: Definitions of perioperative respiratory adverse events (PRAE) assessed

Major PRAE	
Laryngospasm	Complete obstruction of the airway with associated rigidity of the abdominal and chest walls.
Bronchospasm	Increased respiratory effort, particularly during expiration and wheeze on auscultation.
Minor PRAE	
Desaturation	Peripheral pulse oximetery readings below 95%. This definition aligns with institutional guidelines for PACU discharge.
Airway obstruction	Airway obstruction in combination with a snoring noise and/or increased respiratory effort.
Severe coughing	Persistent severe coughing lasting more than 10 seconds.
Postoperative stridor	High pitched breathing sounds during the postoperative period.

Table 3: Comparison of population demographics between groups.

	LMA	ETT	p
n	83	94	
Postnatal Age (months)	8·1 (1·0 – 12·8)	7·1 (1·0 – 12·7)	0·421
Corrected Age (months)	7·9 (0·3 – 12·7)	7·0 (0·0 – 12·7)	0·657
Weight (kg)	8·2 (2·9 – 12·8)	7·9 (2·3 – 12·5)	0·868
Premature	13 (15·7%)	8 (8·5%)	0·159
Male Sex	54 (65·1%)	65 (69·1%)	0·631
Risk Factors			
Respiratory Symptoms			
Recent URTI (<2 weeks)	32 (38·6%)	29 (30·9%)	0·342
Wheeze	2 (2·4%)	3 (3·2%)	1
Wheeze on exercise	0 (0·0%)	0 (0·0%)	-
Nocturnal cough	2 (2·4%)	7 (7·4%)	0·176
Any	35 (42·2%)	35 (37·2%)	0·321
Non-Respiratory Symptoms			
Current/past eczema	15 (18·1%)	13 (13·8%)	0·537
Family History of asthma	32 (38·6%)	31 (33·0%)	0·529
Family History of eczema	20 (24·1%)	22 (23·4%)	1
Family History of hay fever	41 (49·4%)	30 (31·9%)	0·021
Passive smoke exposure	28 (33·7%)	33 (35·1%)	0·875
Any	66 (80·0%)	68 (72·3%)	0·673
Number of Risk Factors			
None	11 (13·2%)	17 (18·1%)	0·415
1-2	42 (50·6%)	49 (52·1%)	0·881
≥3	30 (36·1%)	28 (29·8%)	0·423
Surgical Specialty			
General	47 (56·6%)	60 (63·8%)	0·358
Orthopaedics	11 (13·3%)	12 (12·8%)	1
Radiology	8 (9·6%)	7 (7·4%)	0·788
Plastics	7 (8·4%)	10 (10·6%)	0·295

Other	10 (11·5%)	5 (5·3%)	0·045

Data are presented as median (range) or frequency (proportion)

Table 4: Anaesthetic management in both groups

	LMA	ETT
Number of infants	83	94
Induction Technique		
Inhalational	81 (97·6%)	90 (95·7%)
Intravenous	2 (2·4%)	4 (4·3%)
Maintenance Agent		
Sevoflurane	78 (94·0%)	91 (96·8%)
Isoflurane	5 (6·0%)	3 (3·2%)
Opioids		
Fentanyl	40 (48·2%)	55 (58·5%)
Morphine	0 (0·0%)	1 (1·1%)
Neuromuscular Blockade	-	18 (19·1%)
Regional Anaesthesia	36 (43·4%)	41 (43·6%)
Device Removal Timing		
Data Available	78	86
Deep[1]	61 (78·2%)	30 (34·9%)
Awake	17 (21·8%)	56 (65·1%)
Anaesthesia Duration	60 (12 – 175)	65 (17 – 182)
Recovery Duration	31 (4 – 95)	36 (12 – 89)

Data are presented as median (range) or frequency (proportion). [1]Defined as removal of airway device whilst MAC ≥ 1.

Table 5: Comparison of incidence of PRAE between groups overall, intraoperatively, and postoperatively.

	Total	LMA	ETT	Risk Ratio (95% CI)	p
			Perioperative		
Major PRAE[2]	21 (11·9%)	3 (3·6%)	18 (19·1%)	5·30 (1·62 – 17·35)	0.002
Minor PRAE[3]	64 (36·2%)	15 (18·1%)	49 (52·1%)	2·88 (1·75 – 4·74)	< 0·0001
Overall	65 (36·7%)	15 (18·1%)	50 (53·2%)	2·94 (1·79 – 4·83)	< 0·0001
			Intraoperative[1]		
Major PRAE[2]	20 (11·3%)	3 (3·6%)	17 (18·1%)	5·00 (1·52 – 16·47)	0.003
Minor PRAE[3]	51 (28·8%)	9 (10·8%)	42 (44·7%)	4·12 (2·14 – 7·95)	< 0·0001
Overall	53 (29·9%)	10 (12·0%)	43 (45·7%)	3·80 (2·04 – 7·07)	< 0·0001
			Postoperative		
Major PRAE[1]	1 (0·6%)	0 (0·0%)	1 (1·1%)	-	-
Minor PRAE[2]	30 (16·9%)	8 (9·6%)	22 (23·4%)	2·43 (1·14 – 5·16)	0·016
Overall	30 (16·9%)	8 (9·6%)	22 (23·4%)	2·43 (1·14 – 5·16)	0·016

Data are presented as frequency (proportion). [1]Between induction and emergence. [2]Defined as laryngospasm or bronchospasm. [3]Defined as airway obstruction, coughing, desaturation < 95%, or postoperative stridor.

Table 6: Rates of PRAE in children undergoing deep and awake airway device removal for LMA and ETT groups.

	Deep	**Awake**	**Risk Ratio (95% CI)**	**p**
LMA	9 (14.8%)	4 (23.5%)	0.63 (0.22 - 1.79)	0.464
ETT	15 (50.0%)	29 (51.8%)	0.97 (0.62 - 1.50)	1

Figure 1: Diagrammatic representation of inclusion and exclusion criteria

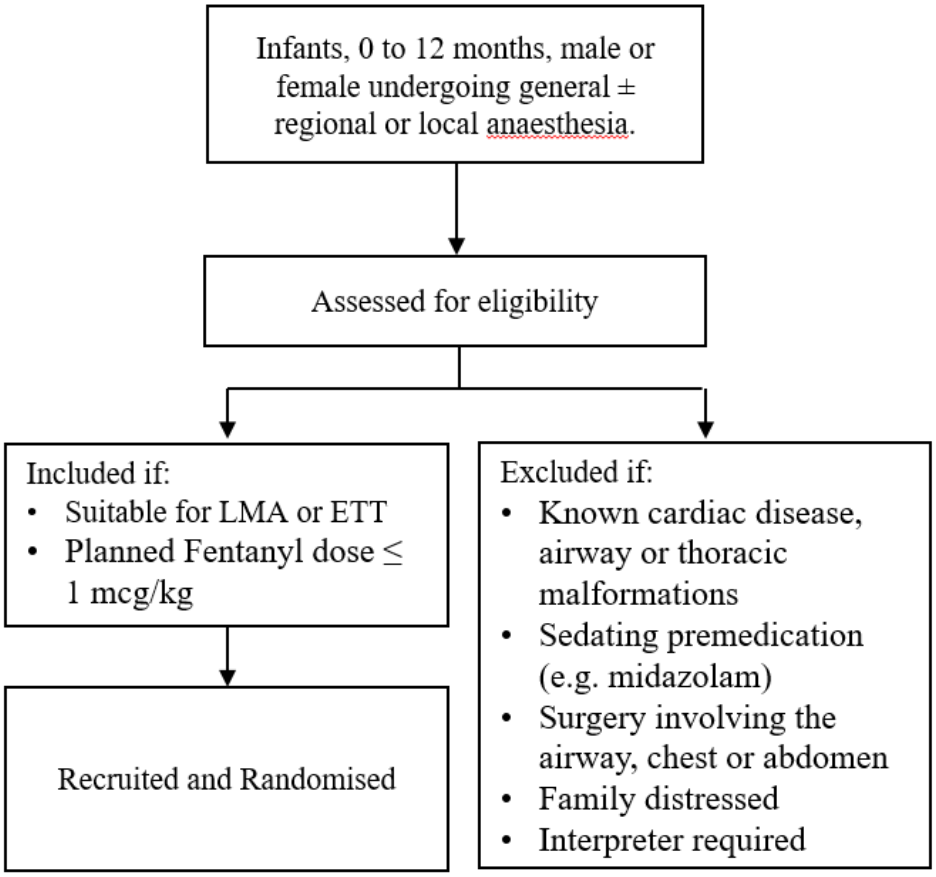

Figure 2: Diagrammatic representation of study recruitment, randomisation, and allocation of analysis

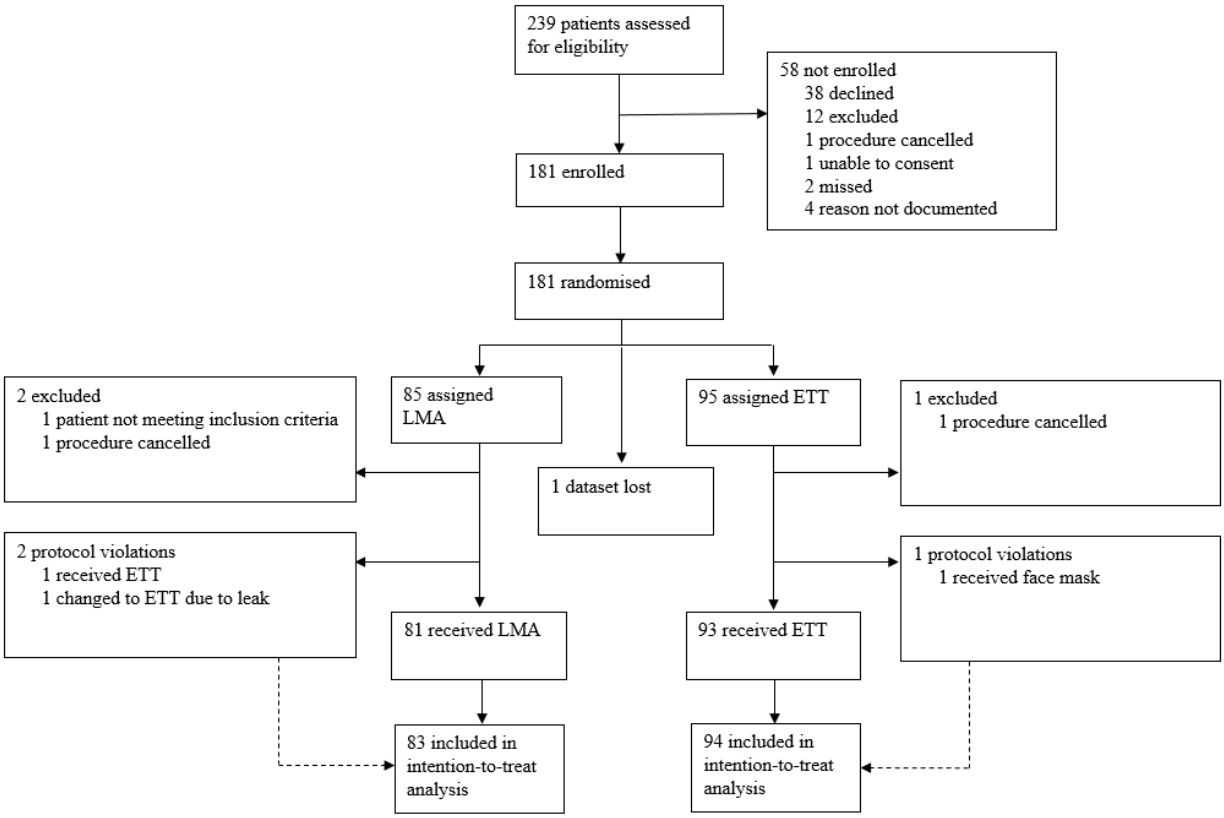

Figure 3: Rates of individual PRAE over the perioperative period for LMA and ETT groups. Values are risk ratio (95% CI) and p values.

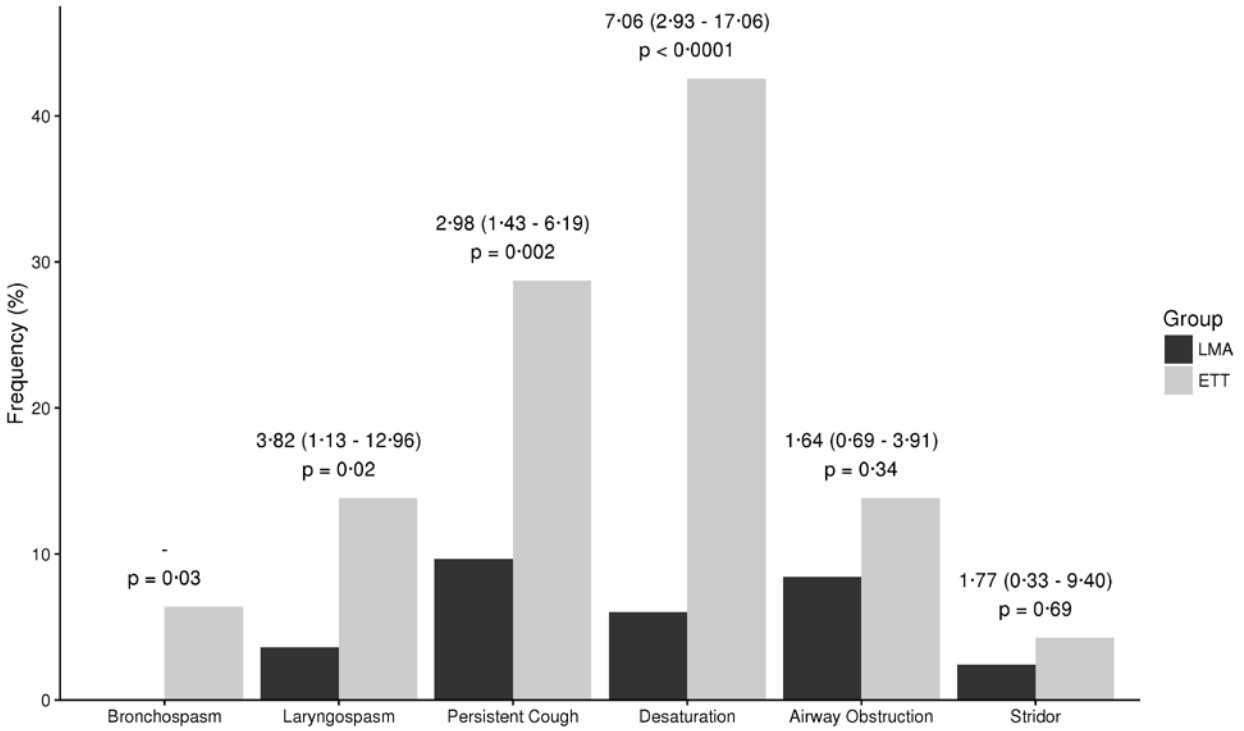

Figure 4: Rates of PRAE in children with and without respiratory symptoms for LMA and ETT groups. Values are risk ratio (95% CI).