Original Article

Emergence characteristics comparing endotracheal tube to reinforced laryngeal mask airway during endoscopic sinus surgery – A randomised controlled study

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ABSTRACT

Background and Aims: During endoscopic sinus surgery, anaesthetic conditions significantly impact the intraoperative surgical field and bleeding during emergence. While the endotracheal tube (ETT) has been traditionally used in sinus surgery, a reinforced laryngeal mask airway (RLMA) that produces less upper airway stimulation may result in smoother emergence. **Methods:** A randomised controlled trial of 72 patients undergoing elective sinus surgery was conducted, with the allocation of airway technique to either ETT with a throat pack or RLMA. The primary outcome measure was emergence time, measured by time to opening eyes on commands at the cessation of anaesthesia, and the secondary outcomes were time to removal of airway device, remifentanil use, procedure times, mean arterial pressure (MAP) and the RLMA grade of blood contamination. The continuous variables were analysed using Student's *t*-tests and discrete variables, count tables were analysed using Fisher's exact tests. **Results:** There was no significant difference in the emergence time between the ETT and RLMA groups ($P = 0.83$). Remifentanil use was significantly higher in the ETT group than in the RLMA group ($P = 0.022$). The ETT group showed a significantly increased total anaesthetic time ($P = 0.01$). MAP was not significant during preinduction, maintenance or post-RMLA removal. The highest grade of contamination was grade 2 in RLMA. RLMA had lower rates of postoperative adverse events. **Conclusions:** RLMA comparable to ETT in terms of emergence time. The RMLA group had lower remifentanil use, anaesthesia duration and fewer postoperative adverse events such as cough and throat pain.

Keywords: Anaesthesia, emergence time, endoscopic sinus surgery, endotracheal tube, laryngeal masks, paranasal sinuses, reinforced

INTRODUCTION

Endoscopic sinus surgery can pose specific challenges for delivering a smooth general anaesthetic. There is a shared airway with the surgeon, where bleeding, surgical debris or irrigation confers a risk of soiling and aspiration. There is also a well-established link between the intraoperative mean arterial blood pressure (MAP) and intraoperative bleeding affecting the surgical field.[1]

During endoscopic sinus surgery, tracheal intubation with an endotracheal tube (ETT) is commonly used to secure the airway. A supraglottic airway in the form of a reinforced laryngeal mask airway (RLMA) provides a potentially advantageous alternative due to the

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decreased level of airway stimulation.[2-5] This would result in a smoother emergence from anaesthetic, a period where haemodynamic perturbations and coughing can potentially increase bleeding risks. In addition, reduced intraoperative laryngeal stimulation from RLMA may facilitate better titration of general anaesthetic and haemodynamic control, thereby reducing surgical site bleeding. A commonly held concern regarding using RLMA, particularly in the context of a shared airway in endoscopic sinus surgery, is the potential for difficulties with insertion, inadequate airway seal or displacement of the device mid-surgery.[3]

The second generation supraglottic devices can better mitigate regurgitation and aspiration events; most commercially available second generation devices are not kink-resistant. Furthermore, when attached to the catheter mount and anaesthetic circuit, this assembly projects vertically over the space where the surgeons need to manoeuvre their instruments. This will impact the surgeon's accessibility to the surgical field. Conversely, the precurved RLMA is easy to insert, can be bent and secured close to the chest wall, and does not interfere with surgical instrumentation. Although supraglottic devices have been well explored in other settings to promote smoother extubation, the literature is scarce on their application for sinus surgery and emergence time.[6-8] We hypothesised that the noxious stimuli of RLMA would be minimal compared to ETT, with an expectation of early emergence on termination of anaesthesia. We conducted a randomised trial with the primary objective of assessing the time to open eyes on commands and emergence time for patients undergoing sinus surgery. Secondary outcome measures included time to remove the airway device, total dose of anaesthetic required, total anaesthetic and procedure time, the grade of blood contamination over the airway device and adverse events.

METHODS

The study was approved by our Local Health Network Human Research Ethics Committee (vide approval number HREC NO:/18/CALHN 680, dated 21 December 2018). It was registered in the Australian and New Zealand Clinical Trials Registry (vide registration number ACTRN12619000495123, accessible at https://www.anzca.edu.au). Informed consent was obtained for participating in the study and using the patient data for research and educational purposes. Ethical standards were maintained according to guidelines outlined in the World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects.[9]

This randomised controlled trial was conducted between April 2019 and June 2022, with a pause due to the coronavirus disease 2019 (COVID-19) pandemic. Patients scheduled for elective endoscopic sinus surgery were recruited from a single institution. The inclusion criteria were age between 18 and 80 years and American Society of Anesthesiologists physical status I-III. Exclusion criteria were patients with a body mass index above 40 kg/cm^2, those with gastro-oesophageal reflux disease, hiatus hernia, previous oesophageal surgery or complex skull base pathology requiring extended surgery with the possibility of significant blood loss. Success was defined as delivering the whole anaesthetic from induction to emergence without converting from RMLA to an ETT tube. Patients who required conversion from RLMA to ETT were excluded.

Patients were randomly allocated to either the ETT or the RLMA group. The randomisation schedule was generated by the clinical trials division of the institution using computerised sequence generation. The clinical trials division also concealed the allocation in a sealed opaque envelope, which the nursing staff opened in the theatre. The group allocation was blinded beforehand; however, at the time of surgery, the anaesthetist could not be blinded due to the nature of the procedure.

General anaesthesia was administered in both groups using total intravenous anaesthesia with propofol and remifentanil, utilising a target-controlled infusion (TCI) based on the Schneider model (Clear Fusion Alaris Health Rolle, Switzerland). In patients randomised to ETT, Ring, Adair and Elwyn (Shiley™ Covidien Ireland Ltd Tullamore, Ireland**)** tubes of size 7 and 8 mm internal diameter were used in females and males, respectively. In patients randomised to RLMA, a size 3 or 4 Flexible PreCurved™ RLMA (Teleflex Medical, Mascot, Australia) was inserted based on the manufacturer's recommendations, with sizing at the discretion of the anaesthetist. Correct insertion was confirmed in both groups by the adequacy of manual bag-mask ventilation with chest rise and capnography waveform within the range of 35–45 mmHg. For RLMA patients, an adequate airway seal was demonstrated by the absence of an audible gas leak using an adjustable pressure-limiting valve at a setting of 15–20 cm H_2O with cuff pressures limited to 60 cm

H_2O. A neuromuscular blocking drug and a throat pack were used in all patients in the ETT group but not in the RLMA group.

Hypotensive anaesthesia was administered to minimise intraoperative bleeding. MAP was reduced to 20% from the baseline through titration of intravenous remifentanil TCI. Intermittent positive pressure ventilation was achieved in both groups using a pressure-controlled mode to maintain the end-tidal carbon dioxide within normal limits.

After surgery, with anaesthesia maintained, fibreoptic laryngoscopy was performed to inspect the hypopharynx and larynx above the laryngeal mask in the RLMA group and up to the glottic opening in the ETT group. The oropharyngeal secretions and debris were suctioned out in both groups before removing the device. In patients randomised to the RLMA group, the device was examined after removal and an assessment of the grade of contamination was made as follows[7]: Grade 1- clean, Grade 2- lightly soiled on the outer surface posteriorly, Grade 3- fully soiled on the outer surface posteriorly and Grade 4- blood within the inner aspect of the laryngeal mask airway cuff and aperture bars.

In both groups, termination of anaesthesia was measured from the cessation of intravenous anaesthetic agents on completion of the surgery, accompanied by administration of reversal of residual neuromuscular blockade in the ETT group. The primary outcome measure, emergence time, was calculated from the time (in min) of termination of propofol and remifentanil to eye opening in response to verbal commands. Secondary outcome measures included haemodynamics like MAP, time to remove the airway device, total dose of anaesthetic required, total anaesthetic, procedure time, the grade of blood contamination over the airway device and adverse events. Remifentanil was the primary analgesic–hypotensive agent used, with other adjuvants such as beta-blockers, magnesium sulphate and clonidine used as required. The usage of these adjuvants, along with rescue fentanyl for analgesia, was recorded. MAP was measured preinduction, during maintenance, immediately postintubation and every 5 min after the removal of airway devices. Recorded adverse events included excessive bleeding, coughing, laryngospasm and postoperative sore throat, including aspiration of gastric contents. Coughing was defined as any evidence of irritation in the airway from blood or secretions. The nurse noted the presence of a sore throat in the post-anaesthesia care unit on inquiry or if the patient complained of a sore throat.

We could not identify any previous trials assessing emergence time in this context. A 2-min reduction in emergence time was deemed as a clinically meaningful difference. Applying this, with a type I error of 5% and a power of 0.8, the resulting sample size was 36 patients in each intervention group. Statistical analysis was performed with R v 4.1.2 (R Core Team, Vienna, Austria). Differences between continuous variables (time to eye opening, time to removal of airway device, duration of anaesthesia, duration of the procedure, intraoperative remifentanil use, post-general anaesthetic fentanyl use, rescue fentanyl boluses, MAP preinduction, MAP postinduction, MAP maintenance, MAP postextubation) were analysed using Student's *t*-tests. Differences between discrete variables (total adverse events, throat or cough adverse events) and count tables were analysed using Fisher's exact tests. A P value of <0.05 was considered to denote significance.

RESULTS

Of the 77 patients screened for inclusion, 72 met the eligibility criteria for enrolment. In total, 36 patients were allocated to the ETT group and 35 to the RMLA group [Figure 1]. One patient was excluded from the RLMA group due to poor fit, and tracheal intubation was required. After excluding this patient in the RLMA group, 70 patients were included in the final analysis. Table 1 details the demographics and operative procedures.

There was a 97.14% success rate of use of RLMA, defined by insertion success and completion of surgery with the device *in situ*. There was no significant difference in eye opening time between the ETT and RLMA groups [mean (standard deviation (SD) 6.05 (3.45) min vs. 5.89 (2.55) min, $P = 0.834$] [mean difference (95% confidence interval (CI)) 0.16 (−1.31–1.62)].

The time for removal of the airway device also showed no significant difference between the groups [ETT vs. RLMA: mean (SD) 7.61 (3.47) min vs. 7.14 (2.93) min, $P = 0.542$] [mean difference (95% CI) 0.48 (−1.08–2.03)]. MAP was not significantly different in the ETT group versus RLMA at all time points (see Figure 2): preinduction [ETT vs. RLMA: mean (SD) 112.81 (48.13) mmHg vs. 100.09 (29.51) mmHg, $P = 0.185$] [mean difference (95% CI)

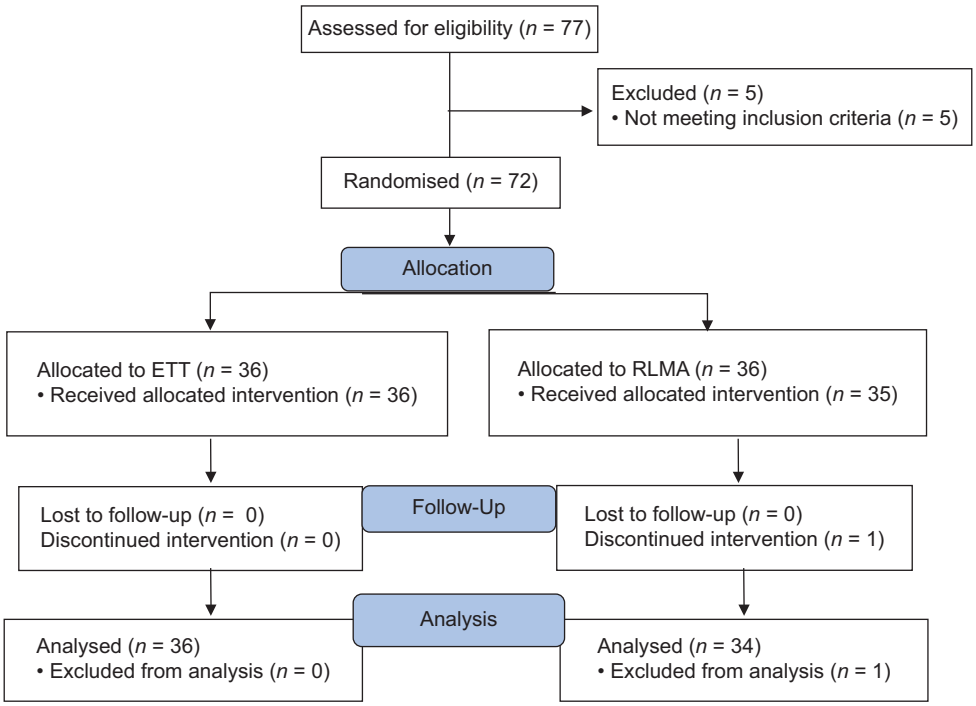

Figure 1: Consolidated Standards of Reporting Trials (CONSORT) flow diagram. ETT = endotracheal tube, RLMA = reinforced laryngeal mask airway

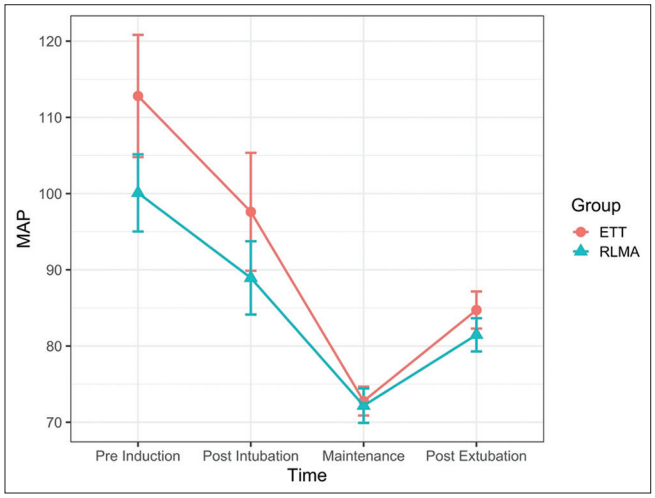

Figure 2: MAP trends during pre-induction, postintubation, maintenance and post-extubation or airway removal time points. MAP was not significantly different in the ETT group versus RLMA at all time points ($P > 0.05$). ETT = endotracheal tube, MAP = mean arterial pressure, RLMA = reinforced laryngeal mask airway

12.72 (–6.27–31.701)], postinduction [ETT vs. RLMA: mean (SD) 97.61 (46.44) mmHg vs. 88.94 (28.02) mmHg, $P = 0.345$] [mean difference (95% CI) 8.67 (–9.57–26.91)], maintenance [ETT vs. RLMA: mean (SD) 72.78 (11.33) mmHg vs. 72.84 (13.18) mmHg, $P = 0.849$] [mean difference (95% CI) 0.60 (–5.28–6.48)] and postextubation or airway removal phase [ETT vs. RLMA: mean (SD) 84.72 (14.60) mmHg vs. 81.47 (12.72) mmHg, $P = 0.323$] [mean difference (95% CI) 3.25 (–3.27–9.77)] [Table 2].

Table 1: Demographic data

	Group ETT (*n*=36)	Group RLMA (*n*=34)
Age (years)	48.72 (16.88)	41.00 (14.96)
Weight (kg)	82.08 (17.35)	80.03 (18.00)
Height (cm)	163.69 (19.34)	168.06 (7.67)
Gender (female:male)	25:11	19:15
Type of surgery		
Septoplasty	11	10
Sinus surgery	16	12
Turbinoplasty	6	7
Maxillary mass excision/concha reduction	1	1
Nasal lesions	2	4

Data expressed as mean (standard deviation) or numbers. *n*=number of patients, ETT=endotracheal tube, RLMA=reinforced laryngeal mask airway

There was a significantly longer total duration of anaesthesia and procedure time for the ETT group compared to the RLMA group: [mean (SD) 127.95 (67.00) min vs. 95.68 (38.75) min, $P = 0.011$] [mean difference (95% CI) 34.08 (8.05–60.10)] and [mean (SD) 123.31 (63.94) min vs. 93.35 (39.65) min, $P = 0.014$] [mean difference (95% CI) 29.96 (6.24–53.67)].

Remifentanil usage was significantly higher in the ETT group versus the RLMA group [mean (SD) 1439.06 (953.14) µg vs. 988.53 (597.46) µg, $P = 0.022$] [mean difference (95% CI) 450.53 (68.24–832.81)]. Eight patients in the ETT group, compared

Table 2: Outcome measures

Variable measures	Group ETT (*n*=36)	Group RLMA (*n*=34)	Mean difference (95% confidence interval)	*P*
Time to eye opening (min)	6.05 (3.45) (4.86–7.23)	5.89 (2.55) (4.99–6.80)	0.16 (-1.31–1.62)	0.834
Time to removal of airway device (min)	7.61 (3.47) (6.42–8.81)	7.14 (2.93) (6.10–8.18)	0.48 (-1.08–2.03)	0.542
Duration of anaesthesia (min)	127.95 (67.00) (107.08–152.42)	95.68 (38.75) (82.15–109.20)	34.08 (8.05–60.10)	0.011
Duration of procedure (min)	123.31 (63.94) (101.67–144.94)	93.35 (39.65) (83.01–103.70)	29.96 (6.24–53.67)	0.014
Total adverse events	14	4	NA	0.013
Throat or cough adverse events	10	2	NA	0.024
Intraoperative remifentanil use (μg)	1439.06 (953.14) (1111.64–1766.47)	988.53 (597.46) (780.06–1196.99)	450.53 (68.24–832.81)	0.022
Post-general anaesthetic fentanyl use (μg)	90.50 (64.56) (68.65–112.35)	80.79 (70.39) (56.23–105.36)	9.71 (-22.58–41.99)	0.550
Rescue fentanyl boluses (μg)	8	0	NA	0.005
MAP preinduction (mmHg)	112.81 (48.13) (96.52–129.09)	100.09 (29.51) (89.79–110.39)	12.72 (-6.27–31.70)	0.185
MAP postinduction (mmHg)	97.61 (46.44) (81.90–113.33)	88.94 (28.02) (79.16–98.72)	8.67 (-9.57–26.91)	0.345
MAP maintenance (mmHg)	72.78 (11.33) (68.94–76.61)	72.18 (13.18) (67.58–76.78)	0.60 (-5.28–6.48)	0.849
MAP postextubation (mmHg)	84.72 (14.60) (79.78–89.66)	81.47 (12.72) (77.03–85.91)	3.25 (-3.27–9.77)	0.323

Data expressed as mean (standard deviation) (95% confidence interval) or numbers. ETT=endotracheal tube, MAP=mean arterial pressure, RLMA=reinforced laryngeal mask airway, SD=standard deviation, μg=micrograms, min=minute, mmHg= mm of mercury, n=number of patients

to zero in the RLMA group, required a rescue bolus of fentanyl outside TCI ($P = 0.005$). Metaraminol was also required in one patient in the ETT group to control blood pressure, while no patients in the RLMA group required this additional medication. Magnesium sulphate and esmolol as adjuvants were needed in two and three patients in the ETT group, respectively. Only one patient in the RMLA group required esmolol. Grade 1 contamination was noticed in five patients, grade 2 in 21 and grade 3 in four patients in the RLMA group. There were no instances of grade 4 contamination.

There were statistically significantly more adverse events in the ETT group (14 vs. 4, $P = 0.013$), with coughing and postoperative throat discomfort being the most reported adverse events. Specifically, 10 patients in the ETT group reported either cough or sore throat as adverse events, as opposed to two in the RLMA group ($P = 0.022$). No patients required further airway intervention during the procedure, and there were no reported aspiration events in either group.

DISCUSSION

In this study, there was no significant difference between RLMA and ETT groups regarding the time for emergence from anaesthesia. A significantly longer duration of anaesthesia and adverse events were observed in the ETT group.

No randomised trials specifically aim for eye opening emergence in sinus surgery using ETT versus RLMA. A non-randomised study that compared these devices in sinus surgery using sevoflurane and remifentanil infusion reported no difference in emergence time.[8] This study's emergence time was from completion of surgery to operating room exit, but not until eye opening. Remifentanil use was noted to be significant in the ETT group, and this is attributable to the more noxious stimuli incurred with the device. Supraglottic RLMA is a less-stimulating airway device than the subglottic ETT, so it potentially requires less anaesthetic and analgesic agents intraoperatively and may offer a better balance in the zone of permissive hypotension.[1] The RLMA group also needed less bolus rescue dosing with fentanyl or metaraminol, suggesting improved ease of maintaining a stable anaesthetic.

The decreased overall duration of surgery in the RLMA group may reflect better intraoperative conditions from tighter MAP control, leading to improved surgical efficiency. Other factors potentially contributing to longer anaesthetic time in the ETT group include the increased time associated with laryngoscopy and the additional time required to apply or antagonise residual neuromuscular blockade. However, it is also possible that the overall operating time was influenced by a difference in the complexity of the sinonasal cases between the two groups, with the ETT group having a higher proportion of sinus surgery (46% vs. 35%).

The goal of any anaesthetic is to provide safe conditions for surgery, and there is a well-established link between anaesthesia and the field of sinus surgery.[1,10,11] There is a direct correlation between hypotensive anaesthesia and good surgical field conditions during endoscopic sinus procedures.[11] This results in a careful balancing

act between an optimised surgical field and adequate cerebral and end-organ perfusion.[1]

A perceived pitfall of the RLMA is that it may provide a less secure airway, which is prone to air leaks and potentially requires repositioning or replacement midway through the case. The need to reinsert an airway mid-surgery, with difficult access and contamination of the field, is an understandable concern. The authors have found the device highly reliable and demonstrated a 97.14% success rate in using RLMA for endoscopic sinus surgery. This study is consistent with the high success rates previously demonstrated in using RLMA for nasal surgery.[3,4] However, it is vital to be vigilant of the function of RLMA throughout its application.[12]

A higher rate of sore throat in the ETT group was observed in this study. This discomfort would have resulted from overinflation of the cuff (if not monitored) and the pressure effects of the throat pack. A meta-analysis reported similar adverse events; however, another study reported no difference in airway irritation between the two airway maintenance methods.[3,8] A throat pack was used in all ETT group patients due to the preference of the authors and institution. While traditionally inserted for airway protection against aspiration of blood, surgical debris and irrigation fluid during surgery, a systematic review showed no benefit obtained from using throat packs in airway soiling or postoperative nausea and vomiting.[13] Furthermore, throat packs have the risk of a retained airway foreign body if not removed postsurgery[14] and have been shown to worsen throat pain[15] and have the theoretical potential to limit venous drainage, thus worsening the surgical field in endoscopic sinus surgery.

Our study has several strengths. A strict anaesthetic protocol was applied, and various meaningful parameters were assessed. Although interruptions occurred during the COVID pandemic, the authors continued the study and completed recruitment as per the sample size estimate. Our study had a few shortcomings. It was a single-centre study; therefore, the results may not apply to other settings. The anaesthetist who administered the anaesthetic was not blinded to the airway device. Likewise, the postoperative parameters were not extracted in a blinded fashion. The sample size did not account for dropouts. However, the attrition rates were too low. A further large study may be required in the future.

CONCLUSION

This study demonstrated that RLMA use for endoscopic sinonasal surgery was comparable to ETT in terms of emergence time. Total remifentanil use and adverse events such as sore throat are reduced by using an RLMA.

Study data availability

De-identified data may be requested with reasonable justification from the authors (email to the corresponding author) and shall be shared upon request.

Financial support and sponsorship

Nil.

Conflicts of interest

Professor Alkis J Psaltis is a consultant for Medtronic and Neurent and is on the speakers bureau for GlaxoSmithKline, Sanofi, Karl Storz and Sequiris. He is a shareholder in Chitogel.

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