Comparison of Supreme laryngeal mask airway versus endotracheal intubation for airway management during general anesthesia for Cesarean section: a randomized controlled trial

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Research article

Keywords: Laryngeal Mask Airway, Obstetric, Cesarean Section, General Anesthesia

Posted Date: May 20th, 2019

DOI: https://doi.org/10.21203/rs.2.287/v2

Version of Record: A version of this preprint was published on July 8th, 2019. See the published version at https://doi.org/10.1186/s12871-019-0792-9.

Abstract

Background The obstetric airway is a significant cause of maternal morbidity and mortality. Endotracheal intubation is considered the standard of care but the laryngeal mask airway (LMA) has gained acceptance as a rescue airway and has been incorporated into the obstetric airway management guidelines. In this randomized controlled equivalence trial, we compared the Supreme LMA (SLMA) with endotracheal intubation (ETT) in managing the obstetric airway during cesarean section. Methods Parturients who underwent elective cesarean section under general anesthesia were randomized to receive either an SLMA or ETT as their airway device. Our primary outcome was first-attempt insertion success. Successful insertion was defined as adequate bilateral air entry with auscultation and the presence of end-tidal carbon dioxide on the capnogram. The first-attempt insertion success rate was compared using the Chi-Square test. Secondary outcomes included time-to-ventilation, seal pressure, ventilation/hemodynamic parameters, occurrence of clinical aspiration, foetal outcomes, and maternal side effects associated with the airway device. Results We recruited 920 parturients (460 SLMA, 460 ETT) who underwent elective Caesarean section under general anesthesia. Patient characteristics were similar between the groups. First attempt success was similar (Odds Ratio–ORSLMA/ETA: 1.00 (95%CI: 0.25, 4.02), p = 1.0000). SLMA was associated with reduced time to effective ventilation (Mean Difference–MD -22.96; 95%CI: -23.71, -22.21 seconds) compared to ETT group (p<0.0001). Ventilation parameters, maternal and fetal outcomes were similar between the groups, and there was no aspiration. Conclusions SLMA could be an alternative airway management technique for a carefully selected low-risk obstetric population, with similar insertion success rates, reduced time to ventilation and less hemodynamic changes compared with ETT. Our findings are consistent with the airway guidelines in recommending the second line use of LMA in the management of obstetric airway.

Background

Airway complications are one of the main causes of anesthetic-related obstetric adverse events in developed countries, with the incidence of failed intubation estimated to be around 0.4%[1-5]. Obstetric airway management is complex, due to the unique challenges posed by the physiological changes of pregnancy, including reduced oncotic pressure, oxytocin-related water retention, and Valsalva maneuver during labor leading to mucosal capillary engorgement and edema. This is often confounded by inadequate fasting time, urgency of cesarean section requiring general anesthesia, and the need to balance the potential conflicting needs of the mother and fetus[6-8].

The introduction of second-generation supraglottic airway devices (SAD) such as the Proseal Laryngeal Mask Airway (LMA) and Supreme LMA (SLMA) with a double-lumen specifically designed to physically separate the respiratory and alimentary tract, reduces the risk of aspiration[8-12] and has changed obstetric airway management. The first Difficult Airway Society (DAS) guideline for managing an unanticipated difficult intubation published in 2004 incorporated the LMA as a second-line rescue device, though obstetric patients were specifically excluded[13]. Subsequently, the important role of the LMA in obstetric

difficult airway management was recognized in the first obstetric-specific guideline jointly released by Obstetric Anaesthetists' Association (OAA) and DAS[14]. In addition, the OAA-DAS guideline recommends an active decision process that takes into consideration the maternal risk of proceeding without endotracheal intubation versus the fetal risk of delayed surgery. The guideline also drew attention to the traditional notion that general anesthesia for cesarean section is unacceptable without endotracheal intubation, due to concerns of increased risk of pulmonary aspiration.

The practice of rapid sequence induction (RSI) and ETT as the standard of care for obstetric airway management originated from concerns of pulmonary aspiration of gastric contents following general anesthesia[15]. Current obstetric anesthesia practice is associated with a low but significant incidence of pulmonary aspiration of about 0.1%[3]. The increasing use of neuraxial anesthesia, aspiration prophylaxis, stricter adherence to fasting guidelines, and airway control via RSI and ETT for general anesthesia are factors that may enhance the margin of safety in this respect. However, rising rates of obesity and other risk factors for pulmonary aspiration may necessitate endotracheal intubation as standard of care.

Recently, the efficacy and safety of LMA use in selected patients undergoing cesarean section under general anesthesia has been demonstrated in several prospective and retrospective cohort studies[12, 16-18]. However, to date, there are no randomized controlled trials comparing airway outcomes of the LMA compared to ETT in cesarean section. This prospective, randomized controlled trial aims to evaluate the first insertion attempt success rate of the SLMA compared to ETT in elective cesarean section under general anesthesia.

Methods

This study was approved by the Institutional Review Board (approval obtained on 25th October 2012) at the Quanzhou Women's and Children's Hospital, Fujian Province, China (clinical trials registration number: NCT01858467). At the time of the study, the majority of cesarean sections at Quanzhou Women's and Children's Hospital were performed under general anesthesia largely due to patient request, with routine airway management using the SLMA in both elective and urgent cases[18]. The hospital cesarean section rate is 35% and the SLMA technique for general anesthesia is used in about 2000 deliveries annually, with endotracheal intubation employed as an alternative airway management.

We recruited parturients with singleton pregnancies aged 18 to 50 years old with healthy or well-controlled medical conditions (American Society of Anesthesiology; ASA 2) undergoing elective cesarean section under general anesthesia at Quanzhou Women's and Children's Hospital, China between May 2013 and July 2014. Written informed consent was obtained from every participant. Parturients with body mass index (BMI) $\geq$ 35 kg/m^2, potentially difficult airway (modified Mallampati grade 4, upper respiratory tract or neck pathology) or gastro-esophageal reflux disease (self-reported) were excluded from the study. All parturients were fasted for at least 6 hours. Once enrolled in the study, the parturients were randomized into 2 groups and allocation concealed using sealed opaque envelopes prepared by a statistician not involved in the study recruitment. The 2 groups were (1) SLMA group; and (2) ETT group.

The parturients were blinded to their assigned group, but the investigators managing the airway were not blinded.

Premedication with intravenous ranitidine was administered to all parturients. Electrocardiography, pulse oximetry, capnography and non-invasive blood pressure measurements were applied. After preoxygenation for three minutes, RSI was carried out with cricoid pressure applied by a trained anaesthetic nurse. Anesthesia was induced with intravenous propofol (2-3mg/kg) and 100mg succinylcholine. After the airway device was inserted, rocuronium (0.5mg/kg) was used to maintain muscle relaxation and fentanyl (100mcg) was administered for intraoperative analgesia after the fetus was delivered. All cases regardless of assigned study groups were induced in similar fashion.

The size of SLMA used was based on manufacturer's recommendations, however, at the discretion of the attending anesthesiologist, a more appropriate size could be selected based on parturient's weight, BMI and mouth opening. ETTs of intraluminal diameters between 6.5 to 7.0 millimeters were used, chosen at the investigators' discretion. Three investigators (Yao, Li, and Yuan), each with more than 5 years of experience in the use of both SLMA and ETT as well as difficult airway management in general anesthesia, managed the airway for all parturients enrolled in this study.

In the SLMA group, the SLMA was inserted using the single-handed rotational technique recommended by the manufacturer until resistance was met with the cricoid pressure maintained. The cuff was then inflated with air to a pressure of 60 cmH_2O as measured by an intracuff pressure monitor, and the volume of air needed to achieve this pressure was recorded. Next, the ability to ventilate was confirmed as evidenced by the presence of auscultation of bilateral air entry and carbon dioxide trace on capnography. The cricoid pressure was then released. After successful placement, a pre-mounted #14 orogastric tube was advanced through the gastric drainage aperture and placement was confirmed by: (1) aspiration of gastric contents; or (2) injection of air into orogastric tube via the large lumen whilst auscultating the epigastrium for a "swoosh". The number of orogastric tube insertion attempts and failure to pass the orogastric tube were recorded. Suctioning of the orogastric tube was performed at the beginning of the surgery and at the end before emergence. Finally, the seal pressure was determined by recording the peak airway pressure after closing the adjustable pressure-limiting valve and insufflating the closed breathing system with 3L/min of fresh gas flow.

The investigators were allowed to use additional maneuvers (chin lift, jaw thrust, head extension) or reposition the SLMA if necessary to achieve airway patency. If successful placement could not be achieved (1) after 2 attempts, (2) within 60 secs, or (3) before desaturation occurred (oxygen saturation < 92%), the airway would then be secured using direct laryngoscopy and endotracheal intubation. The surgical procedure was allowed to proceed if the following criteria were met: (1) a square-wave capnograph tracing was present; (2) the pilot cuff was inflated to 60cmH_2O and checked with a manometer; (3) the bite block of the SLMA was sitting between the incisors; (4) the gastric tube was inserted into the drain tube, and the position confirmed using insufflation of 5mL of air and auscultation

over the epigastric region, followed by active/passive suction and then passive drainage of the gastric tube; and (5) the seal pressure was checked and ≥ 20cmH_2O.

In the ETT group, oral endotracheal intubation via direct laryngoscopy was performed using a Macintosh blade (size 3-4 based on anesthesiologist's preference). The cuff was inflated with air to a pressure of about 25 cmH_2O as measured by an intracuff pressure monitor, and the volume of air needed to achieve this pressure was recorded. Cricoid pressure was then released after ability to ventilate was confirmed, as evidenced by the presence of auscultation of bilateral air entry and carbon dioxide trace on capnography. A #14 orogastric tube was inserted, and the position was confirmed as above.

For all parturients, successful placement of the airway device was confirmed by auscultation and the presence of end-tidal carbon dioxide on the capnogram. The number of attempts required to achieve successful placement, with an attempt defined as insertion and complete withdrawal of the device from the airway was recorded. The time to effective airway placement, defined as the interval from when the device was picked up until appearance of the first end-tidal carbon dioxide waveform, was also measured and recorded.

Anesthesia was maintained with 1.5 to 2.0% sevoflurane and 50% nitrous oxide in oxygen. All parturients were placed in the left lateral tilt position using a wedge. During maintenance of anesthesia, complications including loss of airway, desaturation, inadequate ventilation and bleeding into the airway device were recorded. The tidal volume was set from 6 to 10mL/kg, and the respiratory rate ranged from 10 to 16 breaths/min to maintain an end-tidal carbon dioxide concentration of 30 to 40 mmHg. If there were signs of aspiration (perioperative hypoxemia, wheezing, crepitations upon lung auscultation, postoperative dyspnea), the parturient would be investigated with bronchoscopy or chest X-rays.

The obstetricians were instructed to reduce fundal pressure during delivery regardless of device used. Upon completion of surgery, muscle paralysis was reversed and the orogastric tube was suctioned and removed. After return to spontaneous respiration and consciousness (defined as when parturient was able to follow instructions to open eyes and mouth) was achieved, the airway devices were removed and inspected for blood. The incidence of sore throat and hoarseness were assessed by an independent assessor before discharge from the post anesthesia care unit.

Our primary outcome was the first insertion attempt success rate of the airway devices. Secondary anesthetic outcomes included:

1. time to effective ventilation; seal pressure;

2. ventilation parameters (tidal volume, respiratory rate, peak airway pressure) to maintain effective oxygenation and ventilation, defined as the ability to maintain SpO_2 ≥ 92% and an end-tidal carbon dioxide concentration of < 50mmHg, using inspired oxygen concentration ≤ 0.5 with respiratory rate 10 to 16 breaths/min and tidal volume 6 to 10 mL/kg; and

3. hemodynamic parameters (heart rate and blood pressure) for 6 minutes after induction.

The amount and pH of gastric aspirate; incidence of regurgitation (clear or bile stained fluid seen during procedure or removal of airway device); incidence of aspiration (bile stained fluid seen in the lung during bronchoscopy or postoperative radiological evidence) and pH of the laryngeal surface of the SLMA and ETT cuff were also recorded. Apart from neonatal weight, the obstetric outcomes recorded were neonatal Apgar score at 1 and 5 min and umbilical cord venous pH. Maternal satisfaction with the anesthetic experience (question asked “how would you rate your overall satisfaction with your anesthetic care from 0 to 100%”), the presence of sore throat and voice hoarseness were assessed one day after surgery by an independent assessor.

Statistical Analysis

The primary outcome measure of first attempt insertion success rate in SLMA insertion and secondary outcomes, namely incidence of regurgitation, aspiration, blood stain on SLMA and hoarseness were treated as categorical data, with categories “*yes*” or “*no*”. All demographic, anesthetic and clinical categorical variables were summarized as frequency with corresponding proportion; and continuous variables were expressed as mean (standard deviation (SD)) or median [interquartile range (IQR)], whichever applicable with respect to two study groups SLMA and ETT. Difference in outcomes between ETT and SLMA were represented as odds ratio (OR) and mean difference or median difference, whichever applicable, with 95% confidence interval for categorical and continuous data respectively. Difference in categorical and continuous variables between SLMA and ETT were tested using Chi-Square test and Student’s t-test or Mann-Whitney U test, whichever applicable, respectively. Significance level was set at p-value < 0.05 and all tests were two-sided. Data analysis was generated using SAS 9.3 software (SAS Institute Inc., Cary, NC, USA).

We performed a sample size calculation based on our previous experience estimate of 98% in first attempt insertion success rate of SLMA insertion[18]. An equivalence boundary of 0.034 i.e. (96.3%, 99.7%) as the maximum difference between maximum likelihood estimates of the true proportions in the first attempt insertion success rate in SLMA and ETT use was considered as clinical equivalence. A sample size of 916 parturients (458 per group) would achieve 80% power with the above-mentioned equivalence limits, based on a one-sided test with a significance level of 2.5% and retrospective estimate in the first attempt success rate of 98%. We aimed to recruit a total of 920 parturients in this study.

Results

We screened 998 parturients between May 2013 and July 2014. There were 49 parturients who did not give consent and 29 parturients did not meet the recruitment criteria. A total of 920 parturients were randomized (460 assigned to each group) and there was no withdrawal or dropout (Fig. 1 consort diagram).

Demographic and clinical characteristics of the parturients are summarized in Table 1. There were no significant differences in maternal age, weight, height, ASA scores, Mallampati score and fetal gestational age. There was no significant difference in duration from the time of anesthesia to delivery and the overall duration of surgery.

The anesthesia outcomes are presented in Table 2. The primary outcome first attempt success was similar in in both groups: SLMA 456/460 (99.1%), ETT 456/460 (99.1%), with OR of 1.00 (95%CI: 0.25, 4.02; p = 1.0000) when SLMA was compared with respect to ETT. We found there was a statistically significant reduction in time to effective ventilation (defined as the duration from when the device was picked up to appearance of first end-tidal carbon dioxide waveform) with MD of -22.96 (95%CI: -23.71, -22.21; p < 0.0001) in SLMA insertion compared to ETT. There was a significant difference in seal pressure obtained (MD: -0.77; 95%CI: -1.25, -0.30; p = 0.0014). The rest of the ventilation parameters were similar between the groups, in terms of lowest tidal volume, lowest respiratory rate, highest peak airway pressure, seal minus highest peak airway pressure and lowest SpO_2 achieved. No episodes of hypoxemia, laryngospasm or bronchospasm were observed intra-operatively. Although the baseline heart rate and systolic blood pressure were similar, we found that SLMA insertion was associated with less hemodynamic alterations compared to endotracheal intubation, with lower heart rate and systolic blood pressure during the airway insertion period.

Maternal and fetal outcomes are summarized in Table 3. There were no significant mean differences in fetal weight, or median differences in APGAR scores at 1 and 5 minutes, and umbilical venous cord pH. The volume of gastric aspirate was similar between the groups, but the SLMA group had a lower pH with MD of -0.06 (95%CI: -0.11, -0.02) compared to the ETT group (p = 0.0309). More importantly, the pH of the SLMA laryngeal surface was similar to that of the ETT cuff, suggesting the absence of gastric contents in the airway (-0.001; 95%CI: -0.004, 0.002 for both ETT and SLMA groups, p = 0.5613). There was no clinical suggestion of pulmonary aspiration.

The incidence of airway complications was low in this study. Odds of blood on SLMA was lower compared to ETT insertion with OR of 0.76 (95%CI: 0.46, 1.27; p = 0.2999). The incidence of sore throat was similar (OR 0.59; 95%CI: 0.26, 1.37, p = 0.2146), and there was no voice hoarseness reported in both groups. Patient satisfaction scores were also similar between the groups (MD 0.86; 95%CI: -0.14, 1.86; p = 0.0931).

Discussion

This large prospective randomized controlled trial involving parturients receiving general anesthesia for cesarean section showed similar first attempt insertion success rates in both SLMA and ETT groups. However, SLMA use was associated with a significant reduction in the time to effective ventilation and less hemodynamic fluctuation in the immediate period after airway insertion. The respiratory, airway and fetal outcomes were similar between both groups. No evidence of pulmonary aspiration was detected,

and the incidence of complications were low in both groups (blood on the airway device, sore throat, voice hoarseness). Maternal satisfaction was also similar.

The first attempt SLMA insertion success rate of 99.1% is comparable to rates previously reported in LMA studies in obstetric general anesthesia (97.7% to 98.0%)[12, 17-19]. The high success rate could be attributed to use of the technique recommended by manufacturers, insertion by experienced anesthetists, and the routine use of SLMA for general anesthesia in cesarean section at the study site. Of note, we achieved a high SLMA insertion success rate despite maintenance of cricoid pressure, which could impede the LMA insertion into the post-cricoid hypopharyngeal space. This issue could have been attenuated by the relative rigidity of the SLMA. The high success rate of SLMA insertion in obstetrics further strengthens our hypothesis that the use of second-generation LMAs such as the Supreme is suitable in selected parturients, and this is consistent with the OAA-DAS recommendations for use in difficult and failed intubation.

The obstetric population is considered to be at higher risk for gastric regurgitation and pulmonary aspiration. The risk could be exacerbated especially with concomitant obesity, labor pain or opioid analgesia administration. Although this study was not powered to investigate the risk of pulmonary aspiration, we did not detect any clinical evidence of regurgitation or aspiration, including no significant acidification of SLMA laryngeal surface to reflect gastric pH, which is a surrogate indication of the presence of gastric contents in the trachea[20]. The lack of clinical aspiration is possibly due to: (1) the ability of the double-lumen system of second-generation LMAs that facilitate gastric tube insertion and attenuation of intra-gastric fluid volume; (2) a better pharyngeal seal that prevents stomach insufflation and gastric fluid at the hypopharynx from entering the airway; (3) performance of rapid sequence induction and cricoid pressure; (4) careful patient selection with exclusion of parturients at risk of gastric regurgitation; and (5) adherence to the minimum recommended fasting time. We also requested the obstetricians to reduce fundal pressure for all cases, though the benefit of this in terms of aspiration risk is uncertain.

Our results concurred with previous studies evaluating the role of supraglottic airway devices in parturients receiving general anesthesia for cesarean section. The prospective study using the Classic™ LMA in 1067 parturients undergoing elective cesarean section by Han et al. in 2001 detected no aspiration or regurgitation[19]. The use of the ProSeal LMA in 3000 parturients by Halaseh et al. reported a single event of gastric regurgitation after LMA insertion, but with no clinical evidence of aspiration[17]. More recently, our team demonstrated the safety of SLMA use for airway management in obstetric general anesthesia, in a cohort study involving 700 low-risk parturients undergoing elective and urgent cesarean section[12], followed by a higher-risk 584 women requiring emergent Category 2 or 3 cesarean section, of which 38.4% were in active labor[18]. Both studies reported a high first attempt success rate of SLMA insertion of 98% and no clinical evidence of regurgitation or aspiration.

There are several limitations in our study. Our participants were carefully selected to reduce the risk of gastric regurgitation and our study was not powered to detect such rare events. By extension, we are also

unable to extrapolate our findings to parturients who are at a higher risk of pulmonary aspiration. Based on a previous study by Halaseh et al, with a baseline risk of aspiration of 1:1000, at least 3000 cases is required based on a cohort study.[17] This would make the study feasibility difficult given the large numbers. The cesarean section rate is 35% in our institution and the SLMA technique for general anesthesia is used in 2000 deliveries annually. Since we have adopted the SLMA in airway management of selected parturients, we have not noted any adverse events (aspiration). However, the current practice of endotracheal intubation for cesarean section should still be advocated as pulmonary aspiration is one of the main concerns with SLMA use in obstetrics, for which our study was not powered to detect. We noted that the familiarity with the use of SLMA in general anesthesia for cesarean section and less familiarity with endotracheal intubation could have led to faster time to ventilation and high success insertion rate with SLMA in this study center. Thus, these findings may not be applicable to other centers. Also, cricoid pressure was applied by the anesthetic nurses, who were briefed on the study and the need for consistency. They applied cricoid pressure according to routine hospital practice, but cricoid pressure was not directly measured. Although the obstetricians were not blinded, they were instructed to reduce fundal pressure uniformly for all cases. Lastly, there is no reliable method to blind the anesthesiologists who performed the airway management in this study. Hence, outcome measures including the primary outcome could be influenced by the experience and familiarity with the airway devices used.

The faster speed to establish a secure airway and the reduced risk of hemodynamic fluctuations renders potential justification for future studies on the effectiveness of second-generation LMAs in the obstetric population especially in difficult obstetric airway management. Higher-risk obstetric parturients with medical conditions such as preeclampsia and cardiac disease could benefit from reduced hemodynamic alterations associated with SLMA use[21, 22]. Furthermore, during emergency airway management, a shorter time to ventilation could prevent potential hypoxia[8, 23].

Conclusions

We found that in parturients undergoing elective cesarean section under general anesthesia, the SLMA has similar high first attempt success rate, while potentially reducing the time taken to achieve effective ventilation and less hemodynamic changes, as compared to endotracheal intubation. However, there is still limited information of the safety of SLMA use, especially pertaining to pulmonary aspiration risk. Given the higher incidence of difficult and failed intubation in obstetrics, our findings support the current DAS-OAA guidelines in recommending the use of second-generation LMAs as a second line airway device, in place of persistent attempts at endotracheal intubation.

Abbreviations

American Society of Anesthesiology — ASA; body mass index — BMI; confidence interval — CI; Difficult Airway Society — DAS; endotracheal intubation — ETT; interquartile range — IQR; laryngeal mask airway — LMA; mean difference — MD; Obstetric Anaesthetists' Association — OAA; odds ratio — OR; rapid

sequence induction — RSI; supraglottic airway devices — SAD; standard deviation — SD; Supreme laryngeal mask airway — SLMA.

Declarations

Ethics approval and consent to participate

This study was approved by the Institutional Review Board (approval obtained on 25th October 2012) at the Quanzhou Women's and Children's Hospital, Fujian Province, China (clinical trials registration number: NCT01858467). Written informed consent has been obtained from every participants.

Consent for publication

Not applicable

Availability of data and materials

The datasets generated and analyzed for this manuscript are not publicly available, but could be obtained from the corresponding author on reasonable request.

Competing interests

Dr Ban Leong SNG is associate editor of BMC Anesthesiology. The other authors declare that they have no competing interests.

Funding

No external funding was used in this study.

Author's contributions

BLS: study design, data collection, data analysis, revising the article critically for important intellectual content and final approval of the version to be submitted. WYY: data collection, patient recruitment and final approval of the version to be submitted. SYL: study design, data collection, patient recruitment and final approval of the version to be submitted. YJY: data collection, patient recruitment and final approval of the version to be submitted. HST: data analysis, revising the article and final approval of the version to be submitted. NLH: data analysis, revising the article and final approval of the version to be submitted. RS: data analysis, revising the article and final approval of the version to be submitted. PNA: data analysis, revising the article and final approval of the version to be submitted. ATS: study design, data analysis, revising the article critically for important intellectual content and final approval of the version to be submitted. All authors read and approved the final manuscript.

Acknowledgement

The authors would like to acknowledge the staff of Quanzhou Women's and Children's Hospital for their help in patient care for this study.

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Tables

Table 1: Baseline patient demographics and clinical characteristics of participants receiving SLMA or ETT while undergoing Caesarean section under general anesthesia. Categorical values are compared using Chi-Square test and continuous variables are compared using two-sample Student's t-test. P-values of 0.05 or less are considered significant.

Characteristics	SLMA (n = 460)	ETT (n = 460)	p value
Age (years), mean (SD)	28.4 (4.1)	28.4 (4.0)	0.9869
Weight (kg), mean (SD)	65.6 (6.5)	65.0 (6.5)	0.1230
Height (cm), mean (SD)	158.9 (5.0)	158.1 (4.7)	**0.0130**
BMI (kg/m2), mean (SD)	26.0 (2.27)	26.0 (2.33)	0.9875
Mallampati, n (%)			0.8644
Mallampati 1	183 (39.8)	177 (38.5)	
Mallampati 2	244 (53.0)	252 (54.8)	
Mallampati 3	33 (7.2)	31 (6.7)	
Gestational age (weeks), mean (SD)	38.1 (1.2)	38.3 (1.2)	0.7422
Duration from anesthesia to delivery (min), mean (SD)	12.0 (7.9)	12.5 (7.9)	0.3307
Duration of surgery (min), mean (SD)	33.1 (10.5)	32.1 (10.1)	0.1524

Table 2: Anesthetic outcomes of participants receiving either SLMA or ETT while undergoing Caesarean section under general anesthesia. Difference between two categories were expressed as mean difference or median difference and odds ratio with 95% confidence interval for continuous and categorical values respectively. Categorical values are compared using Chi-Square test and continuous variables are compared using two-sample Student's t-test or Wilcoxon test. P-values of 0.05 or less are considered significant. + refers to type 3 p – value.

Characteristics	SLMA (n = 460)	ETT (n = 460)	Mean Difference / Odds ratio (95%CI)	p value
Number of insertion attempts, n (%)				
First attempt	456 (99.1)	456 (99.1)	Reference	-
Second attempt or more	4 (0.9)	4 (0.9)	1.00 (0.25, 4.02)	1.0000
Time to effective ventilation (s), mean (SD)	16.1 (3.9)	39.1 (7.2)	-22.96 (-23.71, -22.21)	**< 0.0001**
Seal pressure (cmH2O), mean (SD)	27.1 (3.8)	27.9 (3.6)	-0.77 (-1.25, -0.30)	**0.0014**
Lowest tidal volume (ml), mean (SD)	430.9 (39.2)	429.2 (39.3)	1.76 (-3.32, 6.84)	0.4965
Lowest respiratory rate (breaths /min), median (IQR)	12 (12.0, 12.0)	12 (12.0, 12.0)	0.00 (0.00, 0.00)	0.7957
Highest peak airway pressure (cmH2O), mean (SD)	16.8 (3.4)	17.0 (3.6)	-0.14 (-0.59, 0.31)	0.5320
Seal pressure minus highest peak airway pressure (cmH2O), mean (SD)	10.3 (4.2)	10.9 (4.3)	-0.63 (-1.18, -0.08)	**0.0250**
Lowest SpO2 (%), median (IQR)	99.0 (97.0, 99.0)	98.5 (97.0, 99.0)	0.50 (0.00, 0.00)	0.2109
Baseline systolic blood pressure (mmHg), mean (SD)	116.8 (8.6)	116.8 (11.2)	-0.002 (-1.297, 1.292)	0.9974
Systolic blood pressure 2 min after induction (mmHg), mean (SD)	114.0 (11.1)	133.9 (18.2)	-19.96 (-21.91, -18.01)	**< 0.0001**
Systolic blood pressure 5 min after induction (mmHg), mean (SD)	103.7 (10.4)	111.2 (13.3)	-7.51 (-9.06, -5.97)	**< 0.0001**
Baseline heart rate (beats /min), mean (SD)	84.4 (10.3)	85.5 (10.1)	-1.04 (-2.36, 0.28)	0.1210
Heart rate 2 min after induction (beats /min), mean (SD)	93.6 (12.9)	105.4 (11.7)	-11.75 (-13.34, -10.16)	**< 0.0001**
Heart rate 5 min after induction (beats /min), mean (SD)	88.0 (13.3)	92.9 (11.9)	-4.87 (-6.5, -3.24)	**< 0.0001**

Figures

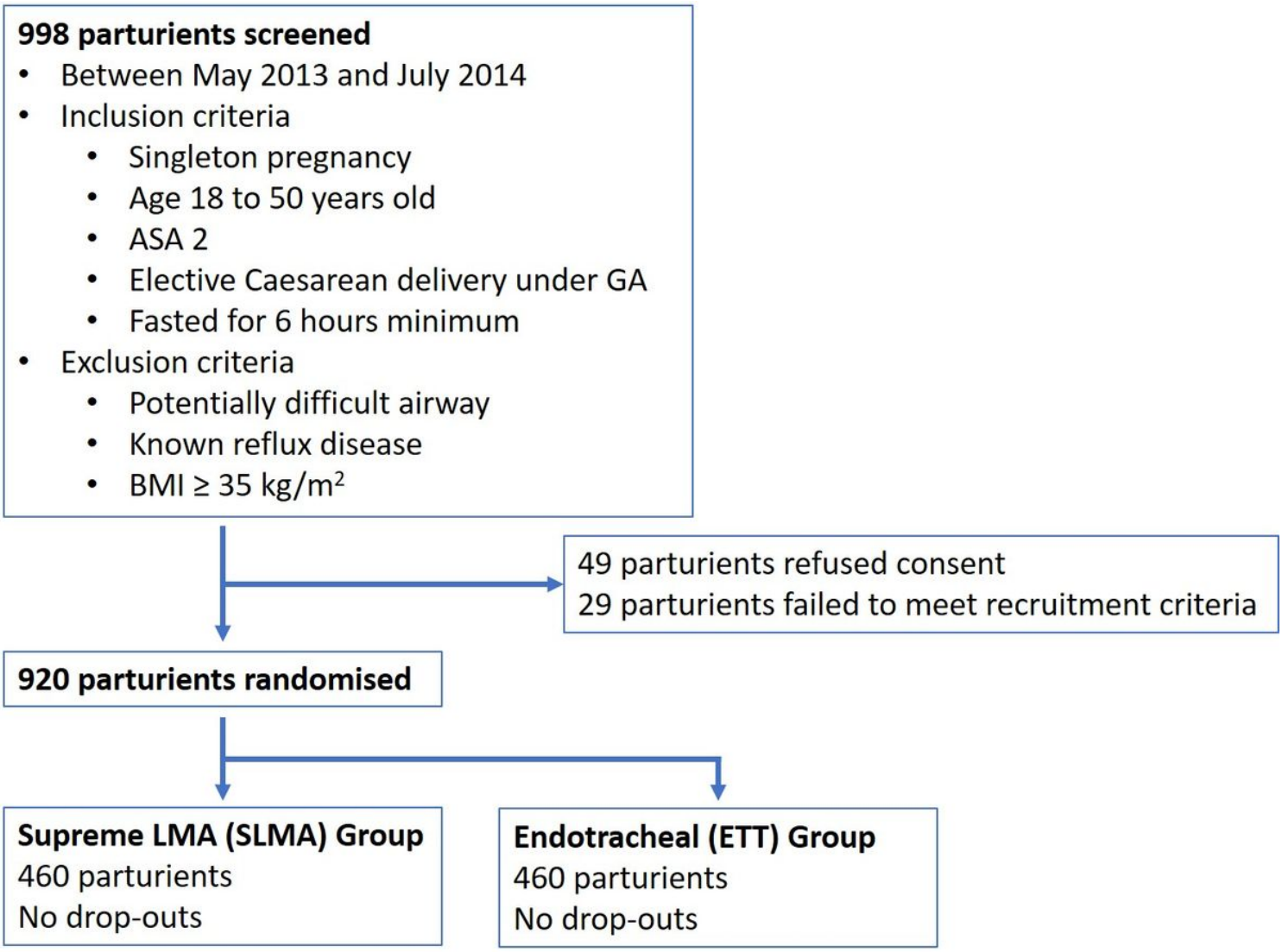

Figure 1

Consort diagram. 998 parturients who were planned for elective Caesarean section in Quanzhou Women's and Children's Hospital were screened between May 2013 and July 2014. Inclusion criteria: singleton pregnancy, aged 18 to 50 years old, ASA 2, and fasted for at least 6 hours. Parturients with potentially difficult airway, known reflux disease, or with BMI ≥ 35 kg/m2 were excluded. 49 parturients refused consent, and 29 did not meet the recruitment criteria. The remaining 920 parturients were randomized by opaque envelope to obtain 460 in each group. There were no dropouts or withdrawal.