



Original Contribution



Gastric regurgitation in patients undergoing gynecological laparoscopy with a laryngeal mask airway: a prospective observational study[☆]

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Abstract

Objective: The use of pneumoperitonium and the placement of patients in Trendelenburg position are commonly cited reasons for the potential development of intraoperative regurgitation of gastric contents and the need for an endotracheal tube in laparoscopic surgery. The main objective of the current investigation was to evaluate the presence of regurgitation of gastric contents in the oropharynx of patients having laparoscopic gynecological surgery with a laryngeal mask airway (LMA).

Design: Prospective, observational clinical investigation.

Interventions: Not applicable.

Measurements: Healthy subjects having a laparoscopic gynecological surgery under general anesthesia with a ProSeal LMA were included in the study. An insufflation pressure of 15 mm Hg was established as the maximum intra-abdominal pressure for the pneumoperitonium, and patients were placed in Trendelenburg position at a 15° angle. The pH of secretions extracted from subjects' hypopharynx was measured at multiple time points during the surgical procedure. A pH of oropharynx secretions ≤ 4.1 indicated the regurgitation of gastric contents.

Main results: Eighty subjects were recruited and completed the study. The median (range) of pH measurements at any time (T3-T9) was 6.5 (5.5-7.0). The median (range) for the lowest pH for each subject was 6.0

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(5.5–7.0). The lowest detected pH in the hypopharynx was not correlated (Spearman ρ) with total surgical time ($P = .9$), total pneumoperitonium time ($P = .17$), or total Trendelenburg position time ($P = .47$).

Conclusions: Our current results suggest that the use of an LMA in healthy patients undergoing laparoscopic gynecological surgery may be safe. Future studies to confirm or refute our findings are warranted.

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1. Introduction

Patients having surgery under general anesthesia have better postsurgical recovery when a laryngeal mask airway (LMA) is used compared with an endotracheal tube [1]. Nonetheless, the risk of aspiration pneumonitis frequently leads clinical practitioners to choose an endotracheal tube instead of an LMA for patients undergoing laparoscopic procedures [2–4]. The use of pneumoperitonium and the placement of patients in Trendelenburg position in laparoscopic surgery are commonly cited reasons for the potential development of intraoperative regurgitation of gastric contents and the need for an endotracheal tube [5].

Several studies have evaluated the use of LMA for laparoscopic surgery. Nevertheless, prior studies have focused on the examination of the adequacy of ventilation using the LMA rather than safety aspects related to aspiration of gastric contents. Safety analyses have been limited to report the absence of clinical aspiration and very few studies have systematically evaluated the presence of gastric regurgitation. The need for more studies evaluating the presence of gastric regurgitation in patients undergoing laparoscopic procedures with an LMA has also been suggested by a systematic review of the literature [6].

The main objective of the current investigation was to evaluate the presence of regurgitation of gastric contents in the oropharynx of patients having laparoscopic gynecological surgery with an LMA. We specifically sought to determine the pH of oropharynx secretions at multiple times during the surgical procedure.

2. Methods

This study was a prospective, observational clinical investigation. Study approval was obtained from the Royal Spanish Charitable Society/Hospital (Real Sociedade Espanhola de Beneficência/Hospital), and written informed consent was obtained from all the study participants. The study is reported following the STROBE guidelines [7]. The study was performed between August 2012 and October 2013. Eligible subjects were consecutive healthy women undergoing gynecological laparoscopy. Patients with a history of full stomach, gastroesophageal reflux disease, hiatal hernia, body mass index $> 30 \text{ kg/m}^2$, diabetes mellitus, or any other conditions that might delay the passing of the gastric contents were excluded.

Reasons to drop out after inclusion in the study were the need to use an endotracheal tube or conversion to an open incision.

After fasting for at least 6 hours, subjects were taken to the operating room and standard American Society of Anesthesiologists monitors were applied. Subjects did not receive any premedication. Anesthesia was induced with fentanyl ($2\text{--}4 \mu\text{g kg}^{-1}$), propofol ($1.5\text{--}2.5 \text{ mg kg}^{-1}$), and rocuronium (0.6 mg/kg). An LMA (ProSeal; Teleflex, San Diego, CA) size 3 or 4 following the manufacturer's recommendation according to subjects' weight was inserted by an experienced anesthesiologist, and the cuff inflation pressure was kept $\leq 60 \text{ cm H}_2\text{O}$. A maximum total of 3 attempts were made to place the device, and in the case of failure, orotracheal intubation was used. Anesthesia maintenance was achieved using propofol ($4\text{--}12 \text{ mg kg}^{-1} \text{ h}^{-1}$), remifentanyl ($0.1\text{--}2.0 \mu\text{g kg}^{-1} \text{ min}^{-1}$), and rocuronium (0.15 mg kg^{-1}). Patients were ventilated with intermittent positive pressure ventilation with a tidal volume of 8 mL kg^{-1} and 10–12 breaths per minute were used for this study. An insufflation pressure of 15 mm Hg was established as the maximum intra-abdominal pressure for the pneumoperitonium and patients were placed in Trendelenburg position at a 15° angle.

Secretions in the hypopharynx were collected via a suction probe (one for each aspirate) inserted into the esophageal drainage tube of the LMA-ProSeal at 1 cm from its distal end at various defined times, as follows: T1 (baseline), after the placement of the LMA; T2, after insufflation of the abdominal cavity (pneumoperitoneum); T3, before the head-down positioning; T4, after the head-down positioning; T5, after the end of insufflation; T6, after returning to a horizontal position; T7, at the end of surgery; and T8, after removing the LMA (measured on the outside of the LMA shell near the end of the drainage tube on both sides).

To measure the pH of the secretions in the hypopharynx, we used pH test strips, pH 0–9 (Merck, Darmstadt, Germany), due to their reliability, high accuracy, and for already having been validated in other studies [8–10]. If the secretions were pigmented, such as in the presence of blood, which would make the pH test strip measurements less reliable, the collected material was measured using a bench top pH meter in the central laboratory for a more reliable measurement. Based on prior studies, a pH of ≤ 4.1 was considered to indicate the regurgitation of gastric contents into the secretions in the hypopharynx [11].

A sample of 80 patients evaluated at 7 points of the surgical procedure (T2 through T8) would generate 560 data points. This would allow us to establish a maximum incidence of

regurgitation <0.8% using the Clopper-Pearson exact method for binomial interval estimations. The Shapiro-Wilk test was used to test the hypothesis of normal distribution. Normally distributed interval data are reported as mean (SD). Nonnormally distributed interval and ordinal data are reported as median (interquartile range) and it was evaluated using Mann-Whitney *U* test [12]. The 95% binomial confidence interval (CI) for the incidence of regurgitation was calculated using the Jeffreys' method. The coverage properties of that method are similar to others, but it has the advantage of being equal-tailed (eg, for a 95% CI, the probabilities of the interval lying above or below the true value are both close to 2.5%) [13]. Nonparametric correlations were performed with the Spearman ρ correlation coefficient. An analysis of changes in the pH across time was performed by using Friedman test. Two-tailed *P* values <.05 were used to reject null hypotheses. Statistical analyses were performed using STATA v13 (Stata-Corp, College Station, TX).

3. Results

Of 97 patients initially screened, 80 subjects were recruited and all completed the study. Nine patients refused to participate and 8 did not meet inclusion and/or exclusion criteria. Subjects' demographics and surgical characteristics are presented in Table 1. The median (range) of pH measurements at any time (T3-T9) was 6.5 (5.5-7.0). The median (range) for the lowest pH for each subject was 6.0 (5.5-7.0). The oropharynx pH values did not significantly change across different measurement times as presented in Fig. 1.

An exploratory analysis by grouping and comparing lower aspiration risk times (T1, T2, T7, and T8) to higher aspiration risk times (T3, T4, T5, and T6) did not demonstrate a significant difference in the pH values between the lower aspiration risk times, median (interquartile range) of 6.5 (6-7) and higher aspiration risk times of 6.0 (6-7; *P* = .07). The lowest detected pH in the hypopharynx for each subject was not correlated (Spearman ρ) with total surgical time (*P* = .9), total pneumoperitonium time (*P* = .17), or total Trendelenburg position time (*P* = .47).

Table 1 Subjects' demographics and surgical characteristics (n = 80)

Age (y)	33 (28-37)
Body mass index (kg/m ²)	24 (22-27)
Fasting time (min)	642 (521-790)
Surgical time (min)	59 (49-80)
Pneumoperitonium time (min)	40 (29-55)
Trendelenburg time (min)	35 (27-47)

Data are described as median (interquartile range).

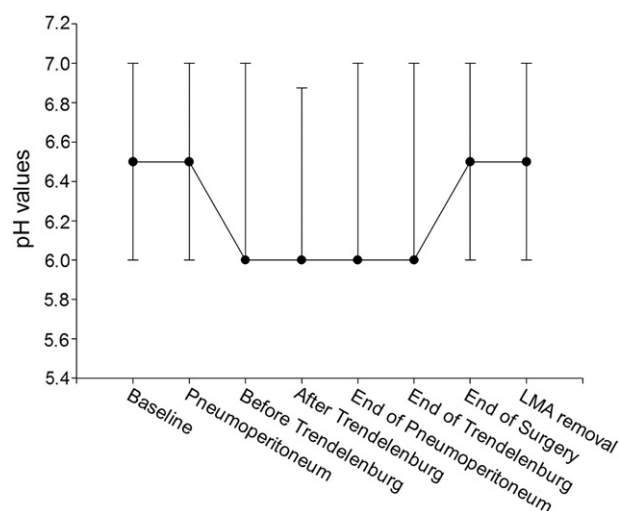


Fig. 1 Box plots demonstrating hypopharynx pH values across study times. Black dots represent median values. The limits of the boxplots denote 95% confidence limits. Data were analyzed using repeated measure for nonparametric data (Friedman test). There was no association between pH values and the different times of measurement, *P* = .66.

The estimated incidence (95% CI) of regurgitation at any surgical time was 0% (0-0.8%). The estimated incidence (95% CI) of regurgitation per study subject was 0% (0.1-5%).

4. Discussion

The most important finding of the current investigation was the lack of gastric regurgitation in patients having a gynecological laparoscopy with an LMA. We did not detect any hypopharynx pH values consistent with gastric regurgitation across different times of the surgical procedure. Our current results support the safety of using the LMA for airway management in patients undergoing laparoscopic gynecological procedures.

Our findings are clinically important because the use of the LMA for laparoscopic procedures remains controversial [6]. Although several studies have demonstrated adequate ventilation of patients undergoing laparoscopic surgery with an LMA, very few have systematically examined the presence of gastric regurgitation. The safety of using an LMA in laparoscopic surgery has relied mainly in the lack of cases in the literature reporting adverse events such as aspiration [14,15].

It was interesting to note in our study a change in the hypopharynx pH across different times of the surgical procedure. We noticed a decrease of 0.5 in the hypopharynx pH that happened concomitantly with the pneumoperitonium insufflation and a return to baseline values at the end of surgery. It is possible that the development of respiratory acidosis or the diffusion and mixture of carbon dioxide with pharyngeal secretions could have contributed to the detected changes. Nevertheless,

all the pH measurements were still not consistent with regurgitation of gastric contents (pH > 4.0).

The results of the current study support prior studies that systematically examined the presence but did not detect regurgitation in patients having laparoscopic surgery with an LMA [16,17]. In contrast, prior studies have used a regular LMA, instead of the Proseal LMA used in the current investigation. The use of a regular LMA may limit the ability to reliably access hypopharynx secretions, and this could have led to false-negative results in prior studies. The Proseal LMA provides a high seal pressure and a built-in drain tube designed to channel fluid away that easily permits gastric access [18,19]. These characteristics of the Proseal LMA are advantageous for laparoscopic procedures requiring positive pressure ventilation when compared with the regular LMA.

Both volume and pH of gastric contents are important factors in the development of aspiration. Although we did not precisely measure the volumes of the aspirate content in the current study, we did not observe any sample that had a volume greater than 2 mL. This value is substantially lower than the values associated with the development of aspiration pneumonitis. Nonetheless, future studies should precisely measure not only pH values but also the volume of aspirate content.

Our study should only be interpreted within the context of its limitations. We only examined healthy patients; therefore, our results cannot be generalized to patients with other comorbidities (eg, obese, gastroesophageal reflux, diabetes). Although we did not detect any regurgitation of gastric contents at any time, we could only determine a maximum incidence of 5% of regurgitation per subject in our cohort. When our results are combined with a previous study [17], a maximum incidence of regurgitation of 2.5% can be established. Nonetheless, more studies are warranted to further examine the presence of gastric regurgitation in patients undergoing laparoscopic procedures with an LMA.

Despite prior evidence demonstrating better recovery in patients having surgery with an LMA, clinical practitioners often avoid the use of LMA due to the potential risk for regurgitation of gastric contents in patients undergoing laparoscopic surgery. Our current results suggest that the use of an LMA in healthy patients undergoing laparoscopic gynecological surgery may be safe. Future studies to confirm or refute our findings are warranted. Future studies comparing the risk of complications derived from endotracheal intubation with the use LMA in this patient population and also to confirm or refute our current findings are needed.

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