

ORIGINAL RESEARCH



Comparison of the Air-Q®sp versus the LMA® Supreme™ in patients undergoing laparoscopic gynecologic surgery: a single-blind, randomized controlled trial

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Abstract

Previous studies have reported the clinical utility of the LMA® Supreme™ (LMA Supreme) in laparoscopic surgery under general anesthesia, but there has been limited research on the effectiveness of the self-pressurized Air-Q® (Air-Q) in this clinical context. This study assessed the clinical performance of the Air-Q in laparoscopic gynecological surgeries by comparing its effectiveness, particularly in terms of oropharyngeal leak pressure (OLP), against that of the LMA Supreme. Fifty-two female patients (American Society of Anesthesiologists class I–II) scheduled for laparoscopic gynecologic surgery were randomly assigned to either the Air-Q group or the LMA Supreme group. The primary outcome was OLP, and secondary outcomes included the number of attempts required for device insertion, the time taken for insertion, difficulty of insertion, leakage rate, and complications associated with supraglottic airway device use. The Air-Q group exhibited a significantly lower OLP compared to the LMA Supreme group (19.5 ± 4.1 cmH₂O vs. 23.2 ± 6.0 cmH₂O, $p = 0.011$), with a mean difference of -3.8 cmH₂O (95% confidence interval, -6.6 to -0.9 cmH₂O). Analysis of secondary outcomes revealed no significant differences between the two groups. LMA Supreme could be preferred over Air-Q for airway management during general anesthesia in patients undergoing laparoscopic gynecologic surgery primarily due to its higher OLP. However, the Air-Q remains a viable alternative, exhibiting no significant differences in leakage rates compared to LMA Supreme.

Keywords

Supraglottic airway device; Laryngeal mask airway; Airway management; General anesthesia; Laparoscopic surgery; Gynecologic surgery

1. Introduction

Supraglottic airway devices (SADs) have proven to be a valuable alternative to endotracheal intubation for patients undergoing general anesthesia [1–5] as they provide safe and effective ventilation without the need for laryngoscopy, thereby reducing hemodynamic fluctuations and minimizing postoperative complications such as sore throat and hoarseness [6, 7]. While extensive evidence supports their safety and/or usefulness in various clinical scenarios [8–14], it is important to acknowledge the potential risk of aspiration, given that SADs do not offer complete airway protection [15]. This concern may be particularly relevant in certain situations, such as during laparoscopic surgery, where the presence of pneumoperitoneum could increase the risk of aspiration, prompting questions about the safety of SAD use [15, 16].

The LMA® Supreme™ (Teleflex Medical Europe Ltd, Westmeath, UK) is a second-generation SAD characterized by a preformed curved shaft that includes a dual lumen: a central

lumen for digestive tract access and an oval-shaped airway lumen, along with an integrated bite block [17]. Several studies have confirmed its effectiveness and safety when used as a standalone SAD [8, 18], and it has been recommended as an appropriate airway management tool for laparoscopic surgery [19, 20].

The Air-Q®sp (self-pressurizing) (Mercury Medical, Clearwater, FL, USA) is a newer SAD device, distinguished by its self-pressurizing cuff. This cuff is designed to automatically adjust to changes in airway pressure, allowing it to conform to the unique pharyngeal and peri-glottic structures of the patient. It has been reported to be effective in general anesthesia [21], suggesting potential advantages over traditional SADs [22]. However, data on its utility in laparoscopic surgical settings, particularly in gynecological laparoscopy, remains scarce.

Herein, we designed this present study to evaluate the clinical performance of the Air-Q in gynecological laparoscopic procedures, particularly in regard to oropharyngeal leak pressure (OLP) in comparison to LMA Supreme.

2. Materials and methods

2.1 Study design and participants

This study is a single-blind, randomized trial comprising female patients aged between 19 and 70 years, classified as American Society of Anesthesiologists (ASA) class 1 or 2, who were scheduled for laparoscopic gynecologic surgery under general anesthesia. The surgical procedures encompassed hysterectomy, myomectomy, salpingectomy, ovarian cystectomy and oophorectomy. Exclusion criteria comprised patients on medication for cardiovascular diseases (except hypertension), those who were pregnant, had a diagnosis of gastroesophageal reflux disease, a body mass index (BMI) >35 kg/m², or presented with conditions that could complicate airway management as identified during the preoperative physical examination, such as limited mouth opening, reduced head and neck mobility, a Mallampati score of 4, and micrognathia.

2.2 Anesthesia and airway management

Each patient was administered a 0.2 mg intramuscular injection of glycopyrrolate before entering the operating room. Subsequently, general anesthesia was initiated, accompanied by monitoring through electrocardiography, noninvasive blood pressure, pulse oximetry (SpO₂), pulse rate, and processed electroencephalogram signals. The induction phase of anesthesia began with an intravenous administration of propofol at 1.5–2.0 mg/kg, followed by rocuronium at 0.6 mg/kg and remifentanyl at 1.0 µg/kg. Upon verification of the absence of response to a jaw thrust maneuver, the patients were randomized to receive either Air-Q or LMA Supreme, in accordance with their group allocation (Fig. 1). Rocuronium was subsequently administered at an empirical rate of 10–20 mg/hr or as necessitated by clinical conditions.

The insertion of all SADs was conducted in accordance with the manufacturer's guidelines by an anesthesiologist experienced in SAD usage. Prior to the study, the anesthesiologist

had successfully inserted the Air-Q and LMA Supreme devices more than 20 times each. Lidocaine gel was applied to the posterior surface of each SAD prior to insertion. The selection of SAD sizes was based on the manufacturers' recommendations: for Air-Q, size 2.5 for individuals weighing 30–50 kg, size 3.5 for those between 50–70 kg, and size 4.5 for subjects weighing 70–100 kg. For LMA Supreme, size 3 was used for subjects weighing 30–50 kg, size 4 for those between 50–70 kg, and size 5 for individuals weighing 70–100 kg. As Air-Q has a self-inflating cuff, no manual inflation was required, whereas for LMA Supreme, a cuff pressure of 30 cmH₂O was maintained. This pressure is within the optimal range, being lower than the maximum recommended pressure of 60 cmH₂O [23] and higher than the minimum suggested pressure of approximately 12–13 cmH₂O for a classic LMA [24].

Successful SAD insertion was determined by the generation of at least two rectangular capnogram waves and visible thoracoabdominal movement, indicating effective ventilation. If significant air leakage occurred or adequate ventilation could not be established, the SAD was immediately removed for reinsertion, and if there were two successive unsuccessful attempts at insertion, the protocol mandated switching to endotracheal intubation.

After successful airway management, anesthesia was maintained with desflurane (4–6 vol%) and remifentanyl (0.05–0.2 µg/kg/min) and was adjusted accordingly to maintain an adequate anesthesia depth (bispectral index between 40 and 60) and to ensure blood pressure and pulse rate remained within $\pm 20\%$ of baseline values. Ventilation was maintained with an inspired oxygen fraction of 0.5, a respiratory rate of 10–20 breaths per minute, and a tidal volume of 6–8 mL/kg, targeting an end-tidal CO₂ partial pressure of 35–40 mmHg without applying positive end-expiratory pressure. Upon CO₂ insufflation into the abdominal cavity, the patient's position was altered to a 15-degree Trendelenburg, and the intra-abdominal pressure was maintained at 12 mmHg.

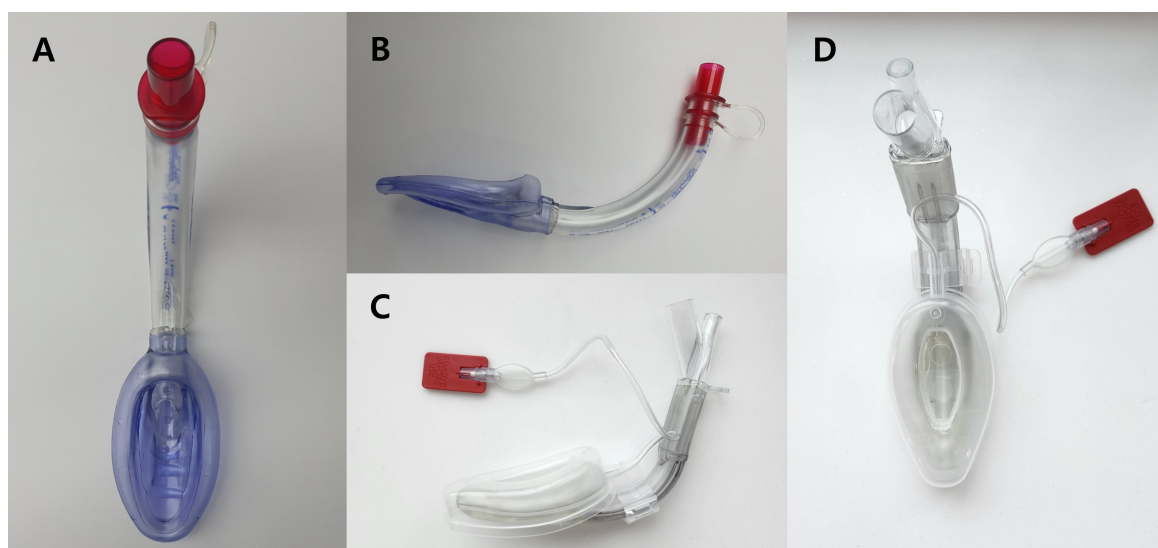


FIGURE 1. Supraglottic airway devices used in this study. Panels (A) and (B) show the Air-Q®sp device (self-pressurizing) (Mercury Medical, Clearwater, FL, USA), and panels (C) and (D) display the LMA® Supreme™ device (Teleflex Medical Europe Ltd, Westmeath, UK).

2.3 Outcome measures

The primary outcome was OLP measured immediately following SAD insertion. It was determined by closing the adjustable pressure-limiting valve while setting the fresh gas flow rate at 3 L/min and recording the airway pressure at which equilibrium was reached or when an audible air leak was detected around the mouth [25], with the maximum pressure capped at 40 cmH₂O. Trained physicians conducted the OLP measurement and used a stethoscope to check for any air leakage.

Secondary outcomes included the number of attempts required for SAD insertion, time taken for insertion, difficulty of insertion (rated on a scale from 1 to 4, where “1” indicates easy insertion without resistance; “2” denotes successful insertion on the first attempt but with resistance encountered; “3” reflects successful insertion on the second attempt; and “4” represents failure on the second attempt), rate of air leakage, and complications related to SAD use such as laryngeal spasm, sore throat, dysphagia and hoarseness. The leakage rate was assessed by calculating the ratio of leakage volume (the difference between inspired and expired tidal volumes) to the inspiratory volume, with data acquired from the anesthesia machine. To adjust for the expansion of gas due to increased temperature and humidification, the inspired tidal volume was multiplied by a factor of 1.12 for the leakage volume calculation [26]. Leakage rates were documented at the following intervals: (1) 10 minutes post-SAD insertion; (2–4) immediately, 15 and 25 minutes after pneumoperitoneum initiation; and (5) subsequent to CO₂ removal. Additionally, the peak inspiratory pressure (PIP) at each aforementioned time point was recorded.

2.4 Randomization and blinding

The study participants were randomly assigned to groups using a computer-generated 1:1 random number table. Due to the distinctive features of the SADs, both the individuals performing the procedure and the researchers conducting intra-operative measurements were aware of the group assignments. Nonetheless, the patients and the evaluators assessing postoperative outcomes were blinded to the study allocation.

2.5 Sample size

The required sample size was calculated based on an assumed OLP of 20 ± 5 cmH₂O in patients with LMA Supreme [8, 27]. To detect a 5 cmH₂O (25%) difference in OLP between groups, with a risk of 5% type 1 error and 90% power, a minimum of 23 patients in each group was required, resulting in a total of 46 participants. To account for a potential 10% dropout rate, the total number of participants targeted for recruitment was increased to 52.

2.6 Statistical analysis

Continuous variables were analyzed using Student’s *t*-test or the Mann-Whitney U test, based on data normality assessed by the Shapiro-Wilk test, and the results are presented as mean ± standard deviation (SD) or median (first quartile, third quartile), accordingly. The effect size and 95% confidence interval (CI) for the primary outcome were computed and

reported as the mean or median difference as appropriate. Categorical variables are expressed as counts (percentage) and assessed using the chi-square test or Fisher’s exact test. The group difference in repeated measurements were evaluated with linear mixed models. All statistical analyses were conducted using R software, version 4.2.2 (R Project for Statistical Computing, Vienna, Austria), and a two-tailed *p*-value < 0.05 was used to indicate statistical significance.

2.7 Post-hoc exploratory analysis

The difference between PIP and OLP was computed for each time point as PIP minus OLP. Pearson’s correlation coefficient was then calculated to assess the relationship between these differences (PIP – OLP) and the leakage rates at each corresponding time point.

3. Results

A total of 55 patients were initially assessed for eligibility, and 3 were excluded according to the inclusion criteria. The remaining 52 participants were randomized and underwent the assigned intervention. One patient in the LMA Supreme group necessitated endotracheal intubation for the maintenance of adequate ventilation during the surgery. This conversion occurred between the initial and the second measurement of leakage volume during pneumoperitoneum. There were no cases requiring unexpected conversion to open surgery (laparotomy). All patients who were allocated interventions were included in the final analysis (Fig. 2). The clinical characteristics of the included patients are summarized in Table 1.

TABLE 1. Clinical characteristics stratified by group.

Characteristics	Air-Q (n = 26)	LMA Supreme (n = 26)
Age (yr)	45.5 (36.0, 51.0)	47.0 (36.0, 51.0)
Weight (kg)	56.1 (50.0, 62.0)	59.5 (54.3, 65.9)
Height (cm)	159.3 ± 6.0	158.9 ± 5.7
BMI (kg/m ²)	22.3 (19.2, 25.8)	23.5 (21.8, 26.6)
ASA 2	8 (30.8)	7 (26.9)
Surgery duration (min)	99.0 (79.0, 140.0)	96.0 (79.0, 124.0)

Values are presented as mean ± SD, median (IQR), or number (%). Abbreviations: BMI: body mass index; ASA: American Society of Anesthesiologists physical status.

The OLP was significantly lower in the Air-Q group than in the LMA Supreme group (19.5 ± 4.1 cmH₂O vs. 23.2 ± 6.0 cmH₂O, *p* = 0.011, Fig. 3), with a difference of mean of –3.8 cmH₂O (95% CI, –6.6 to –0.9 cmH₂O). Most SAD insertions were successful on the first attempt (100% vs. 92.3% in Air-Q and LMA Supreme group, *p* = 0.490), with none requiring more than two attempts. No significant differences were observed in insertion time and difficulties between the two groups (Table 2).

There were 4, 6 and 1 missing measurements of leakage vol-

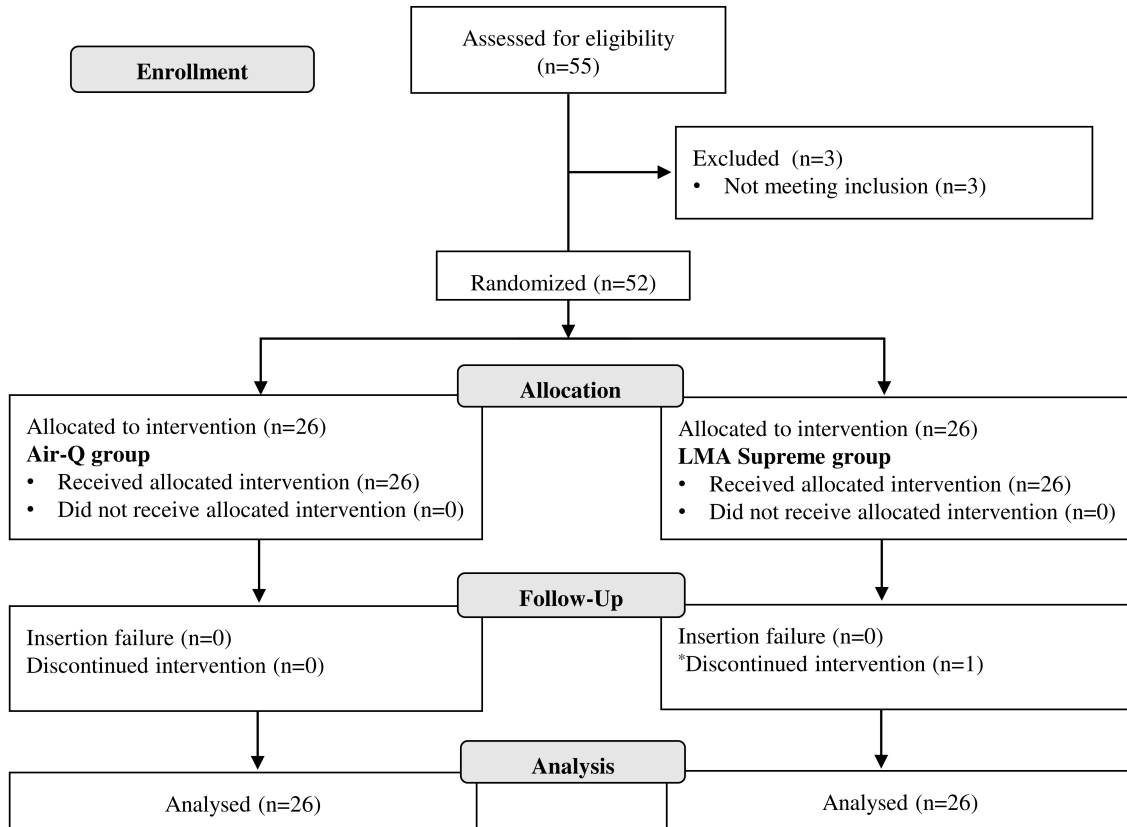


FIGURE 2. Patient flow diagram. Note: One patient in the LMA Supreme group required endotracheal intubation due to the inability to maintain adequate ventilation intraoperatively. This conversion occurred after the initial measurement of leakage volume immediately after CO₂ inflation and before the second measurement 15 minutes after CO₂ inflation. All enrolled patients were included in the primary outcome analysis.

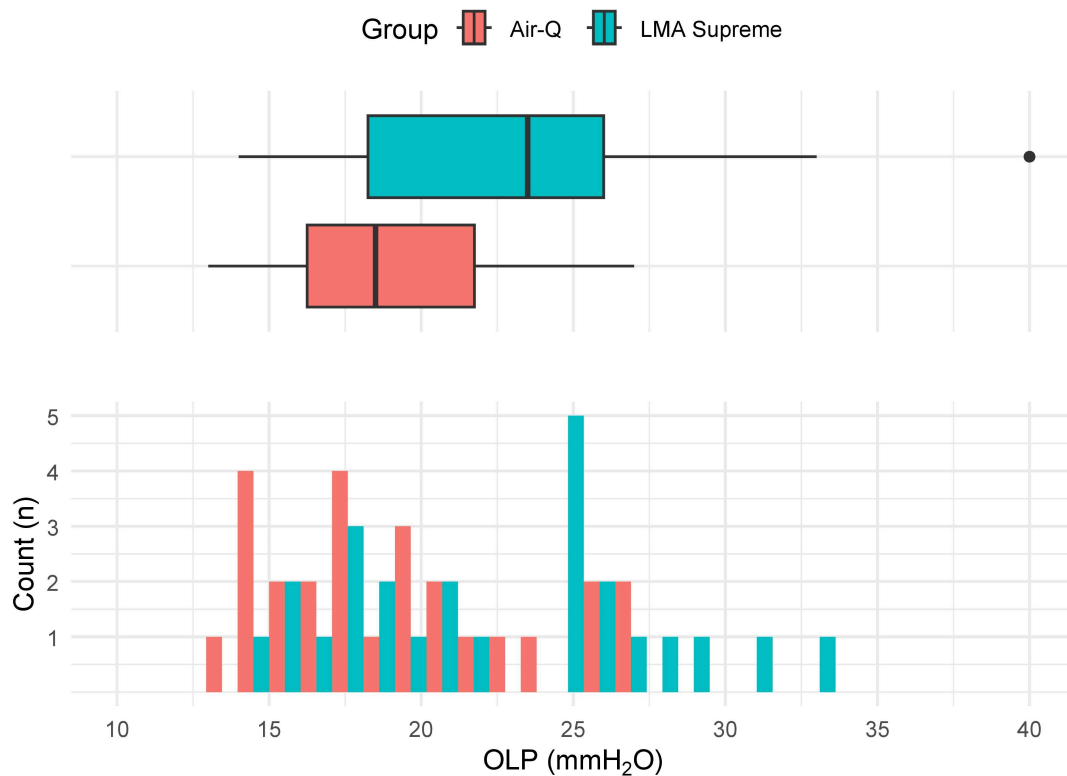


FIGURE 3. Oropharyngeal leak pressure (OLP) stratified by group.

TABLE 2. Secondary outcomes stratified by group.

Outcomes	Air-Q (n = 26)	LMA Supreme (n = 26)	<i>p</i>
SAD insertion attempts			
First	26 (100.0)	24 (92.3)	
Second	0 (0.0)	2 (7.7)	0.490
Third	0 (0.0)	0 (0.0)	
Insertion time (sec)	33.5 (26.0, 40.0)	29.0 (24.0, 33.0)	0.190
Insertion difficulty*			
Grade 1	21 (80.8)	22 (84.6)	
Grade 2	5 (19.2)	2 (7.7)	0.256
Grade 3	0 (0.0)	2 (7.7)	
Grade 4	0 (0.0)	0 (0.0)	

Values are presented as median (1Q, 3Q) or number (%). *Rated on a scale of 1 to 4: “1”, easily inserted without resistance; “2”, success on the first attempt but with resistance; “3”, success on the second attempt; “4”, failure on the second attempt. SAD: Supraglottic airway device.

ume and peak inspiratory pressure during the 15, 25-minute, and immediately after the end of pneumoperitoneum, respectively. Data analysis revealed no significant difference in leakage rates across the investigated time points ($p = 0.167$). Also, there was no significant difference in PIPs across time points ($p = 0.099$). The comparison of leakage rates and PIPs between the groups at each time point is shown in Table 3. Two patients in the Air-Q group and one in the LMA Supreme group reported sore throat in the post-anesthesia care unit, and none experienced laryngeal spasm, dysphagia or hoarseness.

The results of the *post-hoc* exploratory analysis revealed significant positive correlations between PIP – OLP values and leakage rates at 10 minutes after SAD insertion and immediately after the initiation of pneumoperitoneum (Fig. 4). However, the significance of these correlations diminished over time with the emergence of several outliers.

4. Discussion

This study revealed that the OLP of the LMA Supreme was higher than that of Air-Q. Since OLP is an essential metric for evaluating the performance and safety of SADs, this finding suggests that LMA Supreme may offer greater reliability and safety for laparoscopic gynecological surgeries. Nevertheless, the Air-Q remains an important alternative, as it showed comparable results to the LMA Supreme in terms of insertion attempts, insertion time, difficulty of insertion, leakage rate, and complications.

The primary outcome of this investigation is consistent with the inherent differences in cuff mechanisms between the two evaluated devices. The Air-Q utilizes a self-pressurizing cuff that automatically adjusts its pressure in response to the surrounding airway pressure, negating the need for manual inflation. In contrast, the LMA Supreme’s cuff requires manual

inflation, with the achieved cuff pressure directly impacting the effectiveness of the peri-glottic seal. This relationship between cuff pressure and OLP was previously established in studies focusing on the LMA Supreme, indicating that higher manually set cuff pressures correlate with increased OLP [27]. Specifically, a study noted an OLP of 18 cmH₂O at a cuff pressure of 40 cmH₂O, with an increase to 25.6 cmH₂O when the cuff pressure was elevated to 80 cmH₂O. In our research, we utilized a cuff pressure of 30 cmH₂O for the LMA Supreme, which is below the lower benchmark set in prior investigations. Nevertheless, it is reasonable to infer that the LMA Supreme’s cuff pressure during general anesthesia would be at least equivalent to, if not surpassing, that of the Air-Q’s. Despite employing a lower cuff pressure than that reported in earlier LMA Supreme studies [8, 27], our findings indicate an OLP within a comparable range, highlighting the efficacy of the LMA Supreme in maintaining a robust airway seal under these conditions.

The self-pressurizing mechanism of the Air-Q device is designed to automatically adjust cuff pressure, potentially minimizing risks of tissue ischemia or discomfort associated with over-pressurization [28]. Despite this theoretical advantage, existing literature has not conclusively shown that the Air-Q outperforms other SADs in reducing such complications [29, 30]. Our findings are consistent with these observations, suggesting no distinct advantage of the Air-Q in this aspect. However, it should be acknowledged that the overall low incidence of postoperative complications observed with SAD use in our study limits the ability to conduct meaningful comparative analyses. Additionally, the use of lidocaine gel as a lubricant could serve as a confounding variable, potentially influencing the outcome.

The exploratory analysis conducted in this study revealed important notable findings regarding the relationship between

TABLE 3. Leakage rates and peak inspiratory pressures stratified by group.

Measurements	Air-Q (n = 26)	LMA Supreme (n = 26)	<i>p</i> *
Leakage rates (%)			
10 mins after SAD insertion	8.0 ± 5.1	9.1 ± 4.4	0.404
Right after PP	8.4 ± 6.0	9.4 ± 4.7	0.530
15 mins after PP**	4.8 (3.6, 7.0)	9.0 (4.1, 11.4)	0.100
25 mins after PP**	4.9 (3.1, 8.1)	6.5 (3.7, 11.7)	0.332
Right after the end of PP*	5.9 ± 5.2	8.2 ± 4.3	0.099
Peak inspiratory pressure (cmH ₂ O)			
10 mins after SAD insertion	10.0 (8.0, 13.0)	11.5 (9.0, 16.0)	0.118
Right after PP	14.9 ± 5.0	17.0 ± 5.4	0.158
15 mins after PP**	15.0 (12.0, 19.0)	18.0 (15.0, 22.0)	0.089
25 mins after PP**	15.9 ± 5.3	18.3 ± 4.3	0.098
Right after the end of PP**	11.5 (10.0, 18.0)	15.0 (12.0, 19.0)	0.153

Values are presented as mean ± SD or median (I_Q, 3_Q). Leakage rate was determined by calculating the ratio of the leakage volume (the difference between the inspired and expired tidal volume) to the inspiratory volume. A factor of 1.12 was multiplied by the inspired tidal volume for the calculation of the leakage volume. *No overall significant difference across time points was observed, and unadjusted *p* values are provided. **There were 4, 6 and 1 missing measurements of leakage volume and peak inspiratory pressure during the 15, 25-minute, and immediately after the end of pneumoperitoneum, respectively. Abbreviations: SAD: supraglottic airway device; PP: pneumoperitoneum.

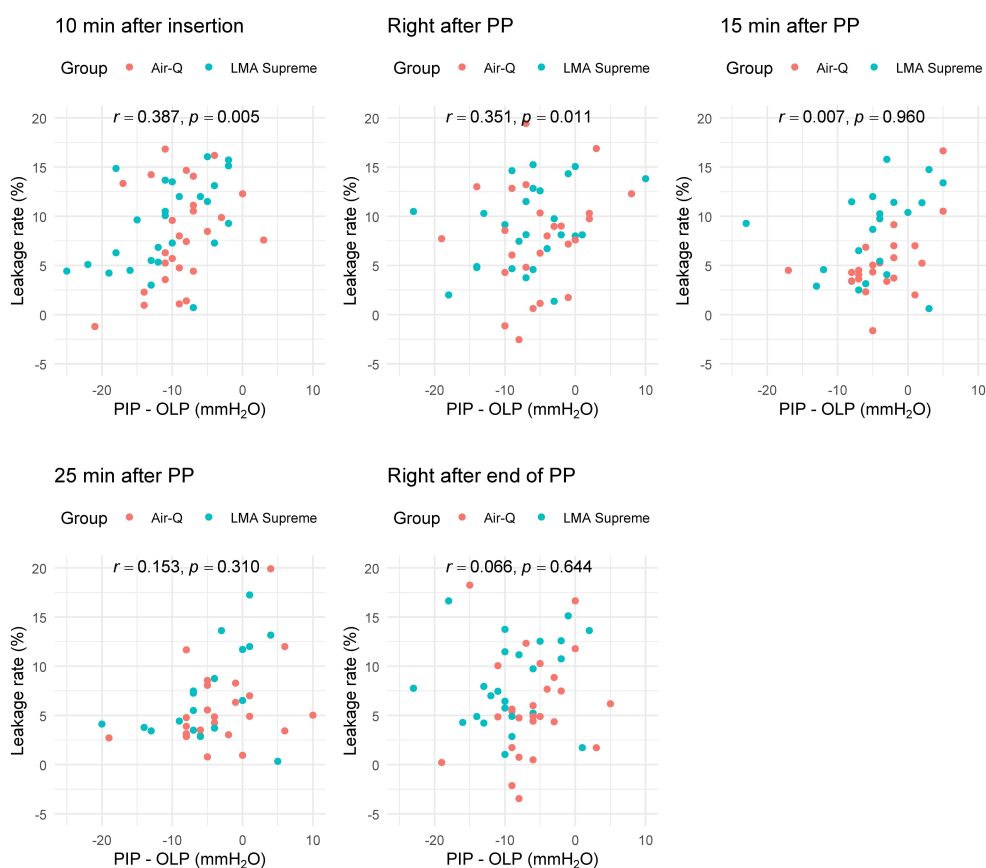


FIGURE 4. Correlations between the differences between peak inspiratory pressure (PIP) and oropharyngeal leak pressure (OLP) and the leakage rates at different intraoperative time points. The positive correlations were significant at 10 minutes after SAD insertion and right after the initiation of pneumoperitoneum. Abbreviations: PP: pneumoperitoneum.

PIP – OLP and airway sealing efficiency. PIP – OLP reflects the margin by which the PIP exceeds the OLP. Essentially, OLP gauges the buffer against airway leakage that occurs when airway pressures rise above the seal’s integrity. A lower OLP suggests a greater risk of air leakage if airway pressures surpass this threshold (Fig. 4). However, the interpretation of this positive correlation should be cautiously interpreted due to its potential variability and the influence of outliers. The absence of significant correlations during later surgical stages may be attributable to occasional leakage incidents, likely related to factors such as surgical manipulations, fluctuations in intra-abdominal pressures, or the partial reversal of neuromuscular blockade, thereby highlighting the complexity of maintaining effective airway seals and the impact of dynamic surgical conditions on airway management.

Current evidence supports the suitability of SADs for laparoscopic surgery, with several studies confirming their clinical significance [7, 16, 19, 20, 31–34]. Notably, a randomized trial comparing LMA Supreme with endotracheal intubation for laparoscopic gynecologic procedures found the former to be superior and advantageous in airway management duration and lower rates of postoperative pharyngolaryngeal complications [7]. Despite these benefits, the use of SADs is not without potential challenges in airway security [15]. This was evident in our study, where a participant assigned to the LMA Supreme group required an unexpected switch to endotracheal intubation. Such occurrences indicate the necessity for vigilance in cases that complicate airway management, including patient positioning that restricts access to the airway or procedures near the head and neck that may disrupt SAD placement. Thus, meticulous patient selection is important to avoid or manage incidences requiring emergent conversion to endotracheal intubation [35].

The study has several limitations worth noting. First, it only included patients classified as ASA class 1 or 2 and those with a relatively lean physique, which may limit the extrapolation of findings to individuals with reduced respiratory compliance or those presenting a difficult airway. Furthermore, the study design did not account for patient comorbidities such as a history of smoking or chronic pulmonary disease. While such conditions are uncommon in the patient population undergoing gynecologic surgery at our institution, this omission may affect the generalizability of the results to wider populations with these conditions. Second, the LMA Supreme group was subjected to a lower cuff pressure setting, potentially not reflecting those that might be observed under conditions of higher cuff pressures. Lastly, the inability to blind the clinician performing the SAD insertions to group assignment might introduce bias into subjective measures such as the number of insertion attempts, insertion time, and perceived difficulty of insertion. However, the primary outcome, largely determined by inherent patient characteristics and device specifications, is expected to be minimally influenced by this lack of blinding [25].

5. Conclusions

In conclusion, this study suggests LMA Supreme as a more suitable choice for airway management under general anesthe-

sia in laparoscopic gynecologic procedures, mainly because of its superior OLP. Nevertheless, Air-Q remains a viable alternative, as it showed no significant differences in leakage rates compared to LMA Supreme.

AVAILABILITY OF DATA AND MATERIALS

The data presented in this study are available on reasonable request from the corresponding author.

AUTHOR CONTRIBUTIONS

CN, SL, JL, YHK, CO and SYL—designed the research study. CN, JL, BH, WC and YK—performed the research. CO and BH—analyzed the data. CN, SL, JL and CO—wrote the manuscript. All authors read and approved the final manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The study protocol was approved by the Chungnam National University Hospital Institutional Review Board (IRB CNUH 2016-08-007-002) and was registered prior to patient enrollment at cris.nih.go.kr (KCT0003904). Written consent was obtained from all patients before anesthesia after explaining the purposes and methodology of the study.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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