



# Effect of continuous measurement and adjustment of endotracheal tube cuff pressure on postoperative sore throat in patients undergoing gynecological laparoscopic surgery: a randomized controlled trial

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## Abstract

**Background:** Postoperative sore throat (POST) is a common complication following endotracheal tube removal, and effective preventive strategies remain elusive. This trial aimed to determine whether actively regulating intraoperative cuff pressure below the tracheal capillary perfusion pressure threshold could effectively reduce POST incidence in patients undergoing gynecological laparoscopic procedures. **Methods:** This single-center, randomized controlled superiority trial allocated 60 patients scheduled for elective gynecological laparoscopic procedures into two groups: one designated for cuff pressure measurement and adjustment (CPMA) group, and a control group where only cuff pressure measurement was conducted without any subsequent adjustments. The primary outcome was POST incidence at rest within 24 h post-extubation. Secondary outcomes included cough, hoarseness, postoperative nausea and vomiting (PONV) incidence, and post-extubation pain severity. **Results:** The incidence of sore throat at rest within 24 h after extubation in the CPMA group was lower than in the control group, meeting the criteria for statistically significant superiority based on a one-sided test (3.3% vs. 26.7%,  $P < 0.025$ ). No statistically significant differences were observed in cough, hoarseness, or pain scores within 24 h post-extubation between the two groups. However, the CPMA group had a higher incidence of PONV compared to the control group. Additionally, the control group reported higher sore throat severity scores within 24 h post-extubation. **Conclusions:** Continuous monitoring and maintenance of tracheal tube cuff pressure at 18 mmHg were superior to merely monitoring without adjustment, effectively reducing the incidence of POST during quiet within 24 h after tracheal tube removal in gynecological laparoscopic surgery patients.

**Trial registration:** The study was registered at [www.chictr.org.cn](http://www.chictr.org.cn) (ChiCTR2200064792) on 18/10/2022.

**Keywords** Anesthesia · Postoperative complications · Sore throat · Endotracheal tube cuff pressure · Pressure transducer · Monitor

## 1 Introduction

One of the prevalent complications following endotracheal intubation is postoperative sore throat (POST). The incidence of POST has been reported to range between 14 and 62% [1–3] and is known to significantly impair patient comfort and satisfaction. POST denotes pharyngolaryngeal discomfort, which may arise from the procedural manipulations during the insertion of an airway device or as a consequence of mucosal irritation or trauma to the airway structures engendered by the device itself. Prior meta-analyses indicate that determinants including female gender, elevated cuff pressures, and the utilization of incorrectly sized

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tubes correlate with the incidence of POST [3, 4]. Nevertheless, existing literature has yet to conclusively ascertain the primary etiological factor of POST. Consequently, the predominant objective of contemporary studies is to elucidate this chief determinant to facilitate effective intervention and mitigation of POST.

Several scholarly investigations propound that high cuff pressure within the endotracheal tube can be a paramount determinant contributing to POST [5, 6]. The optimal cuff pressure is the one that maintains unimpaired blood perfusion to the tracheal mucosa while ensuring no escape of air during the process of ventilation and concurrently thwarting ventilator-associated pneumonia (VAP) by precluding the aspiration of subglottic secretions. In light of these considerations, the prevailing recommendation is to sustain cuff pressure within the confines of 25–30 cmH<sub>2</sub>O (18–22 mmHg) subsequent to inflation, a measure that is subordinated to the tracheal mucosal capillary perfusion pressure [7, 8]. Currently, two prevalent methodologies are commonly employed to monitor endotracheal cuff pressure within clinical settings. A substantial proportion of anesthesiologists exhibit a preference for utilizing the pilot balloon palpation technique to approximate the cuff pressure, despite the concomitant risk of inadvertently inducing overinflation of the endotracheal cuff [9]. Conversely, the predominant choice among respiratory physicians for assessing cuff pressure tends to be the implementation of an endotracheal cuff pressure manometer. While the manometer offers precision in measuring cuff pressure, it necessitates manual intermittent measurement coupled with close-range observation of readings. It is imperative to note that each connection and subsequent disconnection of the manometer to the pilot balloon induces a decrement in cuff pressure, typically within a range of 2–3 cmH<sub>2</sub>O [10]. Additionally, some scholarly researches have showed that a pressure transducer presents a superior methodology for cuff pressure measurement, as compared to the previously mentioned techniques [11–13].

Cuff pressure measurement utilizing a manometer has been shown to enhance the prevention of POST in laparoscopic gynecological surgery patients [14]. Until now, there have been no studies investigating the differential effects of pressure-guided cuff pressure measurements by pressure sensors on POST in this patient population with and without adjustment. The objective of this research is to investigate the efficacy of continuous monitoring and maintenance of the recommended range of tracheal cuff pressure (18–22 mmHg) in reducing the incidence of POST, compared to passive measurement without adjustment in this demographic.

## 2 Materials and methods

### 2.1 Study design and study population

This was a single-center, randomized controlled trial approved by the Ethics Committee of Beijing Chaoyang Hospital (serial number 2022-ke-472) on September 5, 2022. The trial was subsequently registered with the Chinese Clinical Trial Registry (registration number ChiCTR2200064792) on October 18, 2022. The comprehensive study protocol is accessible online [15]. Subjects must meet all of the following criteria simultaneously: aged between 18 and 65 years; body mass index within the range of 18.0 to 30.0 kg/m<sup>2</sup>; classified as American Society of Anesthesiologists grade I or II; scheduled for elective laparoscopic gynecological surgery requiring general anesthesia with endotracheal intubation and mechanical ventilation. Subjects must provide informed consent for the study before participation and voluntarily sign a written informed consent form. Exclusion criteria included the presence of a preoperative upper respiratory tract infection, cough, or sore throat; a history of nausea and vomiting; a history of smoking; prior insertion of a nasogastric tube; any previous oropharynx or larynx surgeries; or any other conditions that, in the researcher's judgment, would make participation in the trial not in the best interest of the individual.

### 2.2 Randomization and blinding

On the surgical day, participants were randomly allocated to either the study or control group in a 1:1 ratio using Ericure, an online service that generates computer-based central randomization [16]. To decrease the predictability of the allocation sequence, blocked randomization with permuted blocks of varying sizes (4 or 6) was employed. An independent statistician, who was not involved in the research, managed the allocation sequence in the central randomization system. Investigators who were blinded to the assignment sequence received randomization codes through a central randomization system during the operation day, after screening and all baseline measurements had been performed, to ensure concealment of assignment. The allocation sequence remained concealed, preventing selection bias, until database analysis was completed. The patients, outcome assessors, the statistician, and data collectors were all blinded to the allocation information.

### 2.3 Study interventions

No preoperative medication was administered to any of the patients. Upon entering the operating room, standard monitoring measures were established, including non-invasive



**Fig. 1** A tracheal tube with a pressure transducer for continuously monitoring the cuff pressure

arterial blood pressure, pulse oxygen saturation, electrocardiogram, and end-expiratory carbon dioxide. Patients were then provided with inhaled oxygen via a mask. Following peripheral venous catheterization, a combination of midazolam (0.02–0.05 mg/kg; Nhwa Pharma, Jiangsu, China), sufentanil (0.2–0.5  $\mu$ g/kg; Yichang Humanwell

Pharma, Hubei, China), propofol (2–3 mg/kg; Fresenius Kabi AB, Uppsala, Sweden), and rocuronium (0.6–0.8 mg/kg; Star Pharma, Hainan, China) was injected intravenously to induce general anesthesia. Anesthesiologists with a minimum of two years' experience selected polyvinyl chloride tracheal tubes with a 7.0 mm internal diameter (Tuoren, Henan, China) for visual laryngoscope intubation. The anesthesiologist used a three-way stopcock to connect the pressure sensor (Tuoren, Henan, China) to the spring-loaded one-way valve pilot balloon in the cuff pressure measurement and adjustment (CPMA) group (Fig. 1). The tube cuff was then inflated or deflated with a 10 ml syringe, also connected to the stopcock, to maintain an intraoperative cuff pressure of 18–22 mmHg. Conversely, in the control group, cuff pressure adjustment was based on the anesthesiologists' tactile experience, gauging the pilot balloon by finger palpation pre-operation. This pressure was not adjusted during the surgery, but it was blindly monitored on a fully-covered portable monitor screen (Fig. 2). Metrics such as the number of endotracheal intubation attempts, the coughing during intubation, and the implementation of cricoid compression were recorded.

Upon successful tracheal intubation, volume controlled ventilation was initiated with parameters set as follows: tidal volume of 6–8 ml/kg, an inspired oxygen fraction of 80%, a respiratory rate of 12–18 breaths per minute, and an inspiratory-to-expiratory ratio of 1:2. This was done to maintain an end-tidal carbon dioxide partial pressure between 30 and 40 mmHg. The anesthesia was maintained by total intravenous anesthesia with propofol (4–6 mg/kg/h) and remifentanil (0.1–0.25  $\mu$ g/kg/min; Yichang Humanwell Pharma, Hubei, China), and additional rocuronium bromide (10–20 mg) and sufentanil (5–10  $\mu$ g) were administered as necessary throughout the procedure. Post-carbon



**Fig. 2** In the control group, the cuff pressure was recorded using the blind method during the surgery (shown in the bottom left of the image), and post-surgery, photographs were taken to record changes in the cuff pressure displayed on the portable monitor screen

dioxide pneumoperitoneum establishment, patients from both groups were positioned in the Trendelenburg posture, necessary for laparoscopic gynecological surgeries, with pneumoperitoneum pressure maintained at 14 mmHg. Hemodynamic parameters were consistently monitored and logged at 5-minute intervals. Both operation duration and duration of endotracheal intubation with a tube were noted.

Post-operation, oropharyngeal secretions were gently suctioned from patients in both groups, using wall suction pressures ranging between  $-80$  to  $-120$  mmHg. The decision to administer an intravenous muscle relaxant antagonist, neostigmine ( $40 \mu\text{g}/\text{kg}$ ; Sine Jinzhu Pharma, Shanghai, China), was based on muscle strength recovery evaluations. Once patients regained full consciousness, achieved normal tidal volume, and sustained adequate oxygen saturation, the endotracheal tube was removed. Furthermore, the coughing before extubation was documented. Postoperative pain relief for all participants was managed using an analgesic pump that dispensed sufentanil at a rate of  $2 \mu\text{g}/\text{h}$ , with a total dosage of  $100 \mu\text{g}$ . Symptoms like sore throat, its severity, hoarseness, cough, nausea, vomiting, and pain scores were recorded immediately post-extubation (0 h post-extubation) and 24 h post-extubation.

## 2.4 Outcome measures

The primary outcome assessed was the incidence of sore throat at rest within 24 h following extubation. We recorded the total number of patients who reported a sore throat at rest at two time points: immediately after extubation (0 h) and 24 h post-extubation. The secondary outcomes encompassed the following: (1) the incidence of cough within 24 h post-extubation; (2) the incidence of hoarseness within 24 h post-extubation; (3) the incidence of postoperative nausea and vomiting (PONV) within 24 h post-extubation; (4) the severity of POST during 24 h post-extubation, which was graded on pain scores from 0 to 3: 0 denoting no sore throat, 1 for mild sore throat (milder than a cold), 2 for moderate sore throat (comparable to a cold), and 3 indicating severe sore throat (more intense than a cold) [17–20]; (5) An 11-point Numerical Rating Scale for pain intensity during 24 h post-extubation, where 0 represents no pain and 10 signifies the worst pain imaginable [21].

## 2.5 Statistical analysis

The sample size estimation was based on the incidence of post-extubation sore throat at resting during 24 h. For the superiority study with a 1:1 allocation ratio, we aimed to achieve 80% power with a one-sided significance level ( $\alpha$ ) of 0.025. The previous randomized controlled trial on laparoscopic gynecologic surgery [14], reported a POST

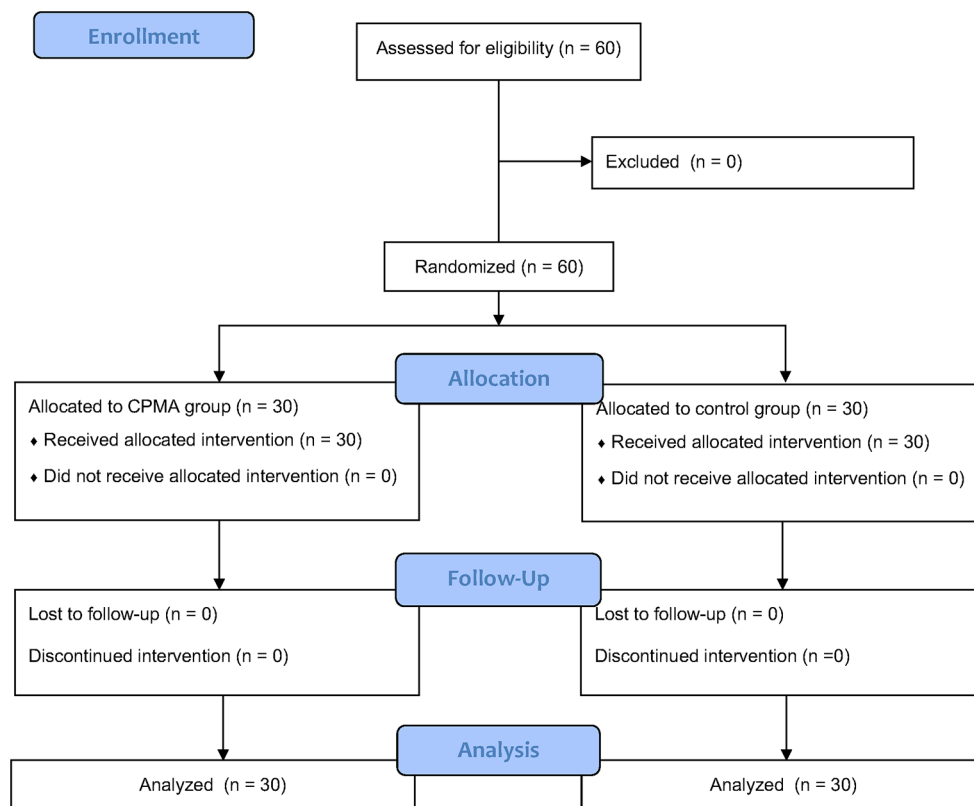
incidence of 31.7% (19/60) for the cuff pressure adjusted to  $25 \text{ cmH}_2\text{O}$  group (measured via a manometer) and 68.3% (41/60) for the control group (measured via palpation of the pilot balloon). Extrapolating from this data for a similar surgical context, we projected a sore throat incidence of 32% in the CPMA group and 68% in the control group. Using these estimates, we determined that 54 participants would be needed to meet the conditions specified. To account for a potential 10% dropout rate, we recruited a total of 60 patients (30 in each group). The sample size was determined using tests for two proportions in the PASS software (version 15, NCSS, USA).

All data were analyzed using SPSS software (version 26, IBM, USA). Both per-protocol and intention-to-treat analyses were conducted for the primary outcome. For the primary outcome, a one-sided significance level was set at  $P < 0.025$ . For other statistical tests, a two-sided significance level was set at  $P < 0.05$ . Continuous variables were presented as either the mean with standard deviation (for normal distribution) or the median with interquartile range (for skewed distribution). The Student's t-test was employed to compare normally distributed continuous variables, while the Mann-Whitney U test was employed for non-normal distribution variables. Categorical variables, such as the incidence of POST, PONV, hoarseness, and cough during 24 h following extubation, were expressed as counts and percentages. Differences between groups for the categorical variables were assessed using the  $\chi^2$  analysis or Fisher's exact test.

## 3 Results

A total of 60 patients were included in the study conducted during the period from November 2022 to May 2023. Due to the absence of dropouts and loss to follow-up in both the experimental and control groups, a total of 60 patients were included in the per-protocol analysis and intention-to-treat analysis, as depicted in the CONSORT (Consolidated Standards of Reporting Trials) 2010 flowchart (Fig. 3). The differences in age, body mass index, comorbidity (hypertension, diabetes, coronary artery disease, and other diseases), history of allergies, and surgical history between the two patient groups (30 in each group) were not statistically significant ( $P > 0.05$ ), as shown in Table 1. In addition to one patient in the CPMA group who underwent two attempts of endotracheal intubation, the remaining patients in both groups were successfully intubated on the first attempt. The reason for multiple intubation attempts was improper angulation of the distal end of the tracheal tube, facilitated by the stylet, resulting in difficulty in placing the tracheal tube at the glottic opening and necessitating repeated intubation attempts. The number of attempts at tracheal intubation,

**Fig. 3** CONSORT 2010 flow diagram. CONSORT, consolidated standards of reporting trials; CPMA, cuff pressure measurement and adjustment



**Table 1** Baseline characteristics of patients in two groups. CPMA, cuff pressure measurement and adjustment; BMI, body mass index; CAD, coronary artery disease. Data are represented as mean ± SD or number of patients (%)

	CPMA (n=30)	Control (n=30)	P value
Age (year)	42.5 ± 10.1	41.2 ± 11.0	0.635
BMI (kg/m <sup>2</sup> )	22.9 ± 3.2	23.3 ± 2.9	0.602
Comorbidity			
Hypertension	8 (26.7%)	4 (13.3%)	0.197
Diabetes Mellitus	2 (6.7%)	2 (6.7%)	1.000
CAD	1 (3.3%)	0 (0.0%)	1.000
Other diseases	10 (33.3%)	8 (26.7%)	0.573
Allergic history	8 (26.7%)	9 (30.0%)	0.774
Surgical history	24 (80.0%)	23 (76.7%)	0.754

**Table 2** Intraoperative characteristics of the two groups. CPMA, cuff pressure measurement and adjustment. Data are represented as median (IQR), mean ± SD or number of patients (%)

	CPMA (n=30)	Control (n=30)	P value
Tracheal intubation attempts	1 (1–1)	1 (1–1)	0.317
Coughing during intubation	0 (0.0%)	1 (3.3%)	1.000
Implementation of cricoid pressure	3 (10.0%)	2 (6.7%)	1.000
Duration of tracheal intubation (min)	190 ± 50	185 ± 84	0.782
Duration of operation (min)	135 ± 46	129 ± 66	0.732
Coughing before extubation	6 (20.0%)	2 (6.7%)	0.254

coughing during intubation, cricoid pressure application, duration of tracheal intubation with a tube, operation duration, and coughing before extubation showed no statistical differences between the two groups ( $P > 0.05$ ), as shown in Table 2.

In the CPMA group, the volume of air injected into the tracheal tube cuff via the syringe was lower than that in the control group ( $P < 0.05$ ). In the CPMA group, the syringe was used to adjust and maintain the tracheal tube cuff pressure not exceeding 18 mmHg during the procedure. In contrast, the control group used the method of feeling the pilot balloon with the thumb and index finger to determine the appropriate cuff pressure, and during the procedure, its value was higher than that of the CPMA group ( $P < 0.05$ ). In terms of the primary outcome measure, the incidence of POST while resting during 24 h post-extubation, the CPMA group had a lower incidence than the control group, which was consistent with the results of a superiority study with statistical significance (one-sided test  $P < 0.025$ ). As for the secondary outcome measures, there was no statistical difference between the two groups in the incidence of hoarseness and cough during 24 h post-extubation, as well as the pain score within 24 h post-extubation ( $P > 0.05$ ). However, the incidence of PONV within 24 h after extubation was higher in the CPMA group than in the control group ( $P < 0.05$ ). The POST score at rest during 24 h after extubation was higher in

the control group compared to the CPMA group ( $P < 0.05$ ). The results mentioned above were detailed in Table 3.

## 4 Discussion

This study is a parallel-group randomized controlled superiority trial that confirmed maintaining the tracheal cuff pressure below the tracheal mucosal capillary perfusion pressure during surgery can effectively reduce the occurrence of POST in laparoscopic gynecological surgery patients. Our findings will not only contribute to the existing body of knowledge regarding the impact of endotracheal tube cuff pressure on POST but also provide clear guidelines for clinical practice, optimizing patient comfort and safety.

The optimal range for endotracheal tube cuff pressure remains controversial. In this study, the optimal cuff pressure range adopted was 25–30 cmH<sub>2</sub>O (18–22 mmHg), although some research suggests a range of 20–30 cmH<sub>2</sub>O (15–22 mmHg) [22]. To maximize the reduction in the incidence of POST, the cuff pressure for patients in the CPMA group was maintained at 18 mmHg. This study found that this cuff pressure value not only prevented air leakage around the endotracheal tube cuff during ventilation but also

effectively reduced the incidence of POST in laparoscopic gynecological surgery patients.

During laparoscopic surgery, pneumoperitoneum can lead to an increase in cuff pressure, which is associated with an elevated incidence of POST [14, 23, 24]. The increase in cuff pressure caused by pneumoperitoneum might be due to the raised abdominal pressure from carbon dioxide insufflation, elevation of the diaphragm, decreased lung compliance, and the pressure being transmitted to the thorax through the diaphragm. This then results in an increased pressure on the tracheal wall and tracheal tube cuff. The contact area between the cuff and the tracheal wall doesn't notably change, leading to an elevated cuff pressure [25–27]. The increased incidence of POST in laparoscopic surgery is closely related to the elevated tracheal tube cuff pressure, which also indicates that cuff pressure is a significant influencing factor for POST. In laparoscopic surgeries, anesthesiologists should pay more attention to the changes in cuff pressure, observing whether continuous monitoring and timely adjustments can effectively reduce the incidence of POST. This is also the reason why patients undergoing laparoscopic surgery are chosen as subjects for this study.

In addition to the excessive pressure inside the endotracheal tube cuff, the relationship between females and POST still requires further research for validation. Most studies have shown that the incidence of POST after tracheal intubation under general anesthesia in females is higher than in males [1, 28, 29]. However, a few studies have not found gender differences in the occurrence of POST [19, 30]. One possible reason for this gender difference is that females might be more articulate in describing their pain or more willing to discuss it, hence they are more likely to report any postoperative complications, leading to a reporting bias [28]. Another reason might be that the variance in tracheal diameter among females is larger than in males, which makes them more susceptible to the effects of different endotracheal tube sizes [20]. In the studies where no gender difference in POST was found, most female patients under general anesthesia used a size 6.0 endotracheal tube. Some reviews have also pointed out that sizes 7.0 or 7.5 endotracheal tubes are recommended for females under general anesthesia, but this might increase the risk of POST [31]. This risk can be mitigated by using smaller size tubes (6.0 or 6.5), but these smaller tubes are not safe for use in patients with high risk of aspiration or limited airflow. It's essential to balance the risks and benefits according to the clinical situation and choose an endotracheal tube size that ensures safety while minimizing the incidence of POST. In this study, we consistently used a size 7.0 endotracheal tube, which is close to the tube size (7.5) used in the reference literature for our estimated sample size. In our study, the incidence of POST at rest during 24 h after extubation in the

**Table 3** Comparison of preoperative syringe inflation volume, intraoperative tracheal tube cuff pressure, and postoperative data between the two groups. Data are represented as median (IQR) or number of patients (%). \*The Fisher's exact probability test was used, with a one-tailed test  $P < 0.025$

	CPMA ( <i>n</i> = 30)	Control ( <i>n</i> = 30)	<i>P</i> value
Volume of air injected into cuff (ml)	3 (3–4)	6 (4–7)	<0.001
Cuff pressure (mmHg)	18 (18–18)	30 (18–45)	<0.001
POST at rest immediately after extubation	0 (0.0%)	7 (23.3%)	0.011
POST at rest within 24 h after extubation	1 (3.3%)	8 (26.7%)	0.013*
Cough immediately after extubation	0 (0.0%)	0 (0.0%)	
Cough within 24 h after extubation	3 (10.0%)	2 (6.7%)	1.000
Hoarseness immediately after extubation	3 (10.0%)	6 (20.0%)	0.472
Hoarseness within 24 h after extubation	3 (10.0%)	6 (20.0%)	0.472
PONV immediately after extubation	1 (3.3%)	0 (0.0%)	1.000
PONV within 24 h after extubation	19 (63.3%)	9 (30.0%)	0.010
POST score at rest immediately after extubation	0 (0–0)	0 (0–0)	0.005
POST score at rest at 24 h after extubation	0 (0–0)	0 (0–0)	0.030
Pain NRS at rest immediately after extubation	2 (1–2)	2 (1–4)	0.308
Pain NRS at rest at 24 h after extubation	1 (1–2)	1 (1–3)	0.927

control group was 26.7%. Using a size 6.5 endotracheal tube for both the experimental and control groups in our research might further reduce the incidence of POST at rest during 24 h post-extubation, but more randomized controlled trials are needed to confirm this.

Given that this study is a single-center research, the external validity of the research findings is a significant concern. There's a need for more research centers and a larger sample size to generalize the results to other healthcare settings and patient groups. The discoveries from this study can serve as a valuable reference for forthcoming multi-center investigations aiming to assess the influence of cuff pressure on the occurrence of POST.

## 5 Conclusion

The continuous monitoring and maintenance of tracheal tube cuff pressure at 18 mmHg proves superior to simply monitoring without adjustment. This method effectively lowers the incidence of POST within 24 h following tracheal tube removal in patients undergoing gynecological laparoscopic surgery.

**Author contributions** Study design: CW, XY, SML. Patient recruitment: CW and XY. Data collection: DB, CG, SML. Writing of paper: CW, XY, SML. Manuscript revision: JJ and ASW. Statistical analysis: DZ. Data interpretation: DZ, CW, XY. Final approval of the version to be published: all authors.

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**Data availability** No datasets were generated or analysed during the current study.

## Declarations

**Ethics approval and consent to participate** This trial was approved by the Ethics Committee of Beijing Chaoyang Hospital (serial number 2022-ke-472) on September 5, 2022. All participants voluntarily provided a signed written informed consent.

**Competing interests** The authors declare no competing interests.

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