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The application of reinforced endotracheal tubes with pressure indicators in preventing postoperative airway-related complications in neurosurgical patients: a randomized controlled study

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Abstract

Background Excessive cuff pressure can lead to complications associated with endotracheal intubation. This study aims to compare the effects of cuff inflation guided by a pressure indicator versus the tactile estimation method on postoperative airway-related complications in neurosurgical patients.

Methods This study employed a prospective, randomized, double-blind, controlled design. Blinding was implemented for the subjects and data collectors. Subjects were randomly divided into two groups. The intervention group used tracheal tubes with pressure indicators. The control group used standard reinforced tracheal tubes. The primary outcome measure was the score of tracheal mucosal injury in two groups of subjects under bronchoscopy assistance with extubation. Secondary outcome measures included: (1) the incidence of tracheal mucosal injury assessed by bronchoscopy at the time of extubation; (2) the incidence of blood-stained cuff during extubation; (3) the incidence and severity of sore throat, and the incidence of hoarseness, blood-stained sputum, and coughing at 1 h and 24 h post-extubation.

Results The intervention group demonstrated a significantly lower tracheal mucosal injury score before extubation compared to controls (1.4 ± 0.274 vs. 2.7 ± 0.335; $P = 0.009$). There were no significant differences in immediate post-extubation complications or short-term (1-hour) postoperative symptoms. Notably, while the majority of 24-hour post-extubation outcomes remained comparable between groups, the intervention group exhibited significantly reduced sore throat severity at this timepoint ($P = 0.044$).

Conclusion The use of tracheal tubes with pressure indicators to control intraoperative cuff pressure could reduce postoperative airway mucosal damage in neurosurgical patients and alleviated post-extubation pharyngeal pain after 24 h.

Trial registration ChiCTR2200065315, first registered on 02/11/2022. The study was retrospectively registered.

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Keywords Neurosurgical operations, Endotracheal tube cuff pressure, Pressure indicator, Manual palpation, Airway complication

Introduction

Tracheal intubation is the standard technique for perioperative airway management in most patients undergoing general anesthesia in clinical settings [1, 2]. However, this technique has numerous disadvantages [3]. Common postoperative complications include coughing, sore throat, and hoarseness, with severe cases presenting tracheal stenosis, tracheoesophageal fistula, tracheal rupture, and obstructive fibrinous pseudomembrane formation [4, 5]. These complications are often associated with tracheal mucosal damage due to excessive cuff inflation [3]. It is generally recommended that the pressure of the endotracheal tube cuff (ETTCP) be maintained between 20 and 30 cmH_2O [6–8]. Excessive cuff pressure (> 30 cmH_2O) may lead to ischemic injury or even necrosis of airway mucosa, tracheoesophageal fistula may occur in severe cases [9]. Insufficient cuff pressure (< 20 cmH_2O) may cause microaspiration and lead to airway leakage and reduced mechanical ventilation quality, affecting clinical treatment [10].

Previous research indicates that continuous cuff pressure monitoring can significantly reduce the incidence of ventilator-associated pneumonia (VAP) [11]. Clinically, the palpation method or manometry are commonly used to assess ETTCP. The palpation method is subjective, heavily reliant on individual clinical experience, and not highly accurate [12]. Although manometry can objectively and accurately reflect the cuff pressure at the time of measurement, intermittent repeated measurements carry a risk of cuff leakage, which can lead to decreased cuff pressure [13, 14]. For neurosurgical patients, almost all require endotracheal intubation and general anesthesia, with longer durations of surgery and mechanical ventilation compared to other surgeries, increasing the risk of tracheal intubation-related airway complications [15].

We hypothesize that continuous intraoperative monitoring using pressure-controlled manometry will better maintain optimal ETTCP (20–30 cmH2O) compared to conventional manual palpation, thereby reducing both the severity of tracheal mucosal injury and the incidence of post-extubation complications in neurosurgical patients.

We hypothesize that continuous intraoperative monitoring using pressure-controlled manometry will better maintain optimal ETTCP (20–30 cmH2O) compared to conventional manual palpation, thereby reducing both the severity of tracheal mucosal injury and the incidence of post-extubation complications in neurosurgical patients. Therefore, this study aims to employ a randomized controlled trial design to: (1) analyze the effects of controlling endotracheal tube cuff pressure between 20 and 30 cmH2O using a pressure gauge compared to manual palpation on postoperative airway mucosal injury scores in neurosurgical patients; (2) investigate the incidence of airway complications following extubation in both groups.

Methods

Study design

This study was designed as a single-center, prospective, randomized, double-blind controlled trial, with the research protocol and outcome reporting adhering to standard specifications. The study received approval from the Biomedical Ethics Committee of West China Hospital, Sichuan University (document No.345, Review 2022) and registered on Chinese Clinical Trial Registry (registration number: ChiCTR2200065315).

Selection of subjects

Inclusion criteria

This study enrolled 48 patients who underwent elective neurosurgical operations at West China Hospital, Sichuan University, between August 2022 and November 2022. Inclusion criteria were as follows: (1) ASA (American Society of Anesthesiologists) classification I-III; (2) aged 18–65 years; (3) informed consent form signed by the participant or their legal guardian; (4) intubation duration of ≥ 4 h.

Exclusion criteria

Exclusion criteria were as follows: (1) history of preoperative cough, sore throat, or hoarseness; (2) difficult airway; (3) tracheostomy; (4) endonasal surgery; (5) pregnant or lactating women.

Random allocation

On the day of surgery, a research coordinator used a computer-generated random sequence in the operating room to randomly assign subjects to either the intervention group or the control group. The coordinator and the chief anesthesiologist were not blinded to the group assignments, while blinding was maintained for the subjects, the bronchoscopy assessors (who also conducted the follow-ups). This study employed total intravenous anesthesia (TIVA), with routine monitoring of electrocardiogram, blood pressure, heart rate, and blood oxygen saturation for all subjects upon entering the operating room. Both groups received the following intravenous induction agents: midazolam 0.03 mg/kg, penehyclidine hydrochloride 0.01 mg/kg, sufentanil 0.3–0.4 μg/kg,

rocuronium bromide 0.9 mg/kg, and propofol with a Target-Controlled Infusion (TCI) effect compartment concentra postoperative airway mucosal damagetion of 4 μg/ml for intubation. The intervention group used an endotracheal tube with a pressure indicator (AccuCuff™, Medis, China) (Fig. 1), whereas the control group used a standard reinforced endotracheal tube. Male and female patients were intubated with endotracheal tubes of 7.5 mm and 7.0 mm internal diameter, respectively. The vocal cords are positioned between the two black lines on the endotracheal tube. In the intervention group, the cuff pressure of the endotracheal tube was maintained between 20 and 30 cmH_2O, as indicated by the pressure indicator, and was checked and adjusted to the specified range every half hour during the surgery. The control group used the tactile estimation method to inflate the cuff, with the firmness of the cuff adjusted to the feel of a normal person's nose tip, and the cuff pressure was not adjusted perioperatively. In the control group, cuff pressure was measured using a manometer at two time points: after inflation and at the end of the surgery.

Mechanical ventilation was conducted using an anesthesia ventilator, with a tidal volume of 8–10 ml/kg, a respiratory rate of 8–10 breaths per minute, and a mixture of oxygen 1 L/min and air 1 L/min (final oxygen concentration 60%). Invasive arterial blood pressure (ABP) monitoring was established, and intraoperative adjustments to the propofol effect-site concentration (3–6 μg/ml), remifentanil (0.1–0.2 μg/kg·min), and intermittent administration of rocuronium and sufentanil were made based on changes in the subject's ABP and heart rate (HR), maintaining blood pressure within ± 20% of the preoperative baseline. The control group's expiratory end cuff pressures were recorded immediately after cuff inflation and at the end of the surgery. Before transferring to the recovery room or ICU, the external surface of the endotracheal tube and the inflation balloon were covered with non-woven material to ensure that the subsequent airway evaluation was blinded, meaning the evaluator was unaware of which type of endotracheal tube was used. Extubation of the patients in the ICU or recovery room were performed upon achieving complete recovery of spontaneous respiration, defined by a respiratory rate of 12–20 breaths per minute, regular breathing pattern, tidal volume > 6 ml/kg, and end-tidal CO2 levels of 35–45 mmHg. 1 mg/kg of propofol was administered intravenously in response to bucking or coughing, and the condition of the tracheal mucosa was assessed by a bronchoscopic evaluator.

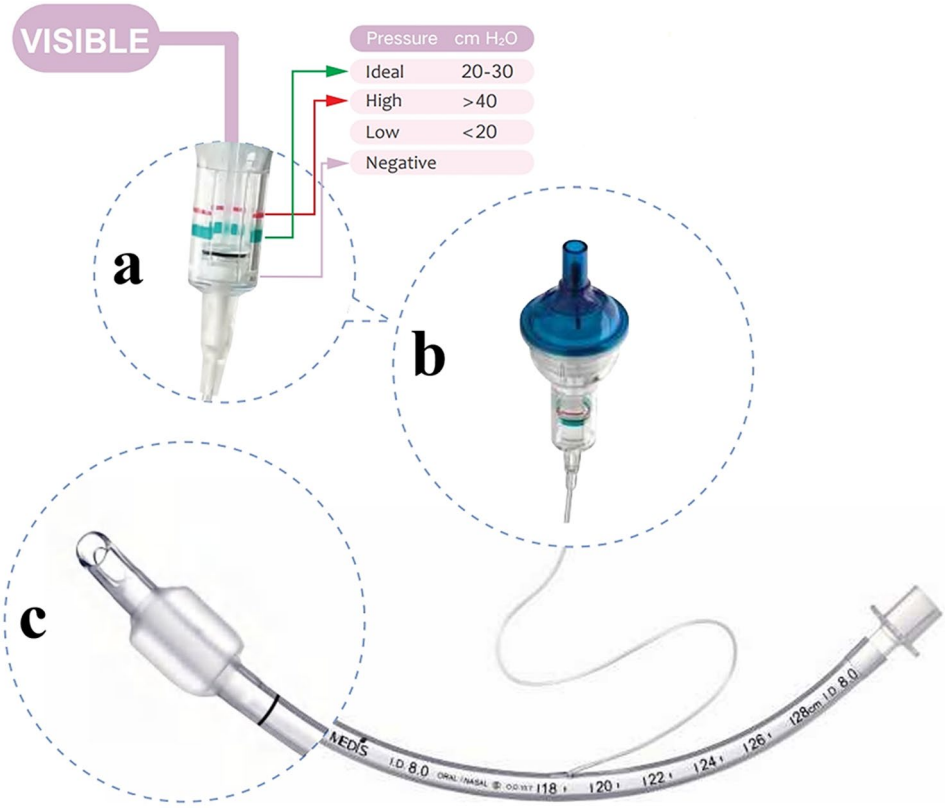

Fig. 1 Reinforced tracheal tube with Pressure Indicator. **a**: visualized pressure indicator, the green area is the safe perimeter, above this area indicates excessive stress, below this area indicates insufficient stress; **b**: pressure detector; **c**: inflatable balloon

Outcome

Primary outcome measurement

Primary outcome measure: Evaluation of tracheal mucosal damage in two groups of subjects under bronchoscopic assistance before and during extubation. The tracheal mucosal damage was classified into 5-point: Grade 0 (no apparent damage), Grade I (edema), Grade II (congestion), Grade III (hemorrhage), and Grade IV (tracheal rupture, obstructive fibrinous pseudomembrane, tracheal stenosis, tracheal fistula, etc.).

Secondary outcomes

Secondary outcome measures include: (1) the incidence of tracheal mucosal injury as assessed by bronchoscopy at the time of extubation in both groups of subjects; (2) the incidence of blood-stained cuff in both groups during extubation; (3) the incidence and severity of sore throat, and the incidence of hoarseness, blood-stained sputum, and coughing at 1 h and 24 h post-extubation in both groups.

Data collection

Patient-related information was obtained through the surgical anesthesia system and the Hospital Information System (HIS) of West China Hospital. Collected baseline data included patient age, gender, height, weight, body mass index (BMI), ASA classification, intended surgical procedure, surgical position, anesthesia method, and endotracheal tube size. Perioperative indices for the subjects were collected as follows: A researcher recorded the cuff pressure values at the cuff inflation and at the end of surgery in the control group, tracheal mucosal damage was observed via fiberoptic bronchoscopy before extubation and classified according to the extent of injury (Fig. 2): Grade 0, no apparent damage; Grade I, edema (defined as excessive fluid accumulation in the tracheal mucosa and submucosal tissue at the cuff contact site, leading to mucosal swelling); Grade II, congestion (defined as localized congestion in the tracheal mucosa at the cuff contact site due to compression, with uneven reddening of the congested area); Grade III, hemorrhage (defined as localized blood accumulation in the tracheal mucosa at the cuff contact site, forming red or dark red hemorrhagic spots); Grade IV, tracheal rupture, obstructive fibrinous pseudomembrane, tracheal stenosis, tracheoesophageal fistula, etc. (tracheal rupture refers to the disruption of the integrity of the tracheal wall; an obstructive fibrinous pseudomembrane is a thick tube-like, rubbery, white pseudomembrane that forms on the tracheal wall at the cuff contact site; tracheal stenosis

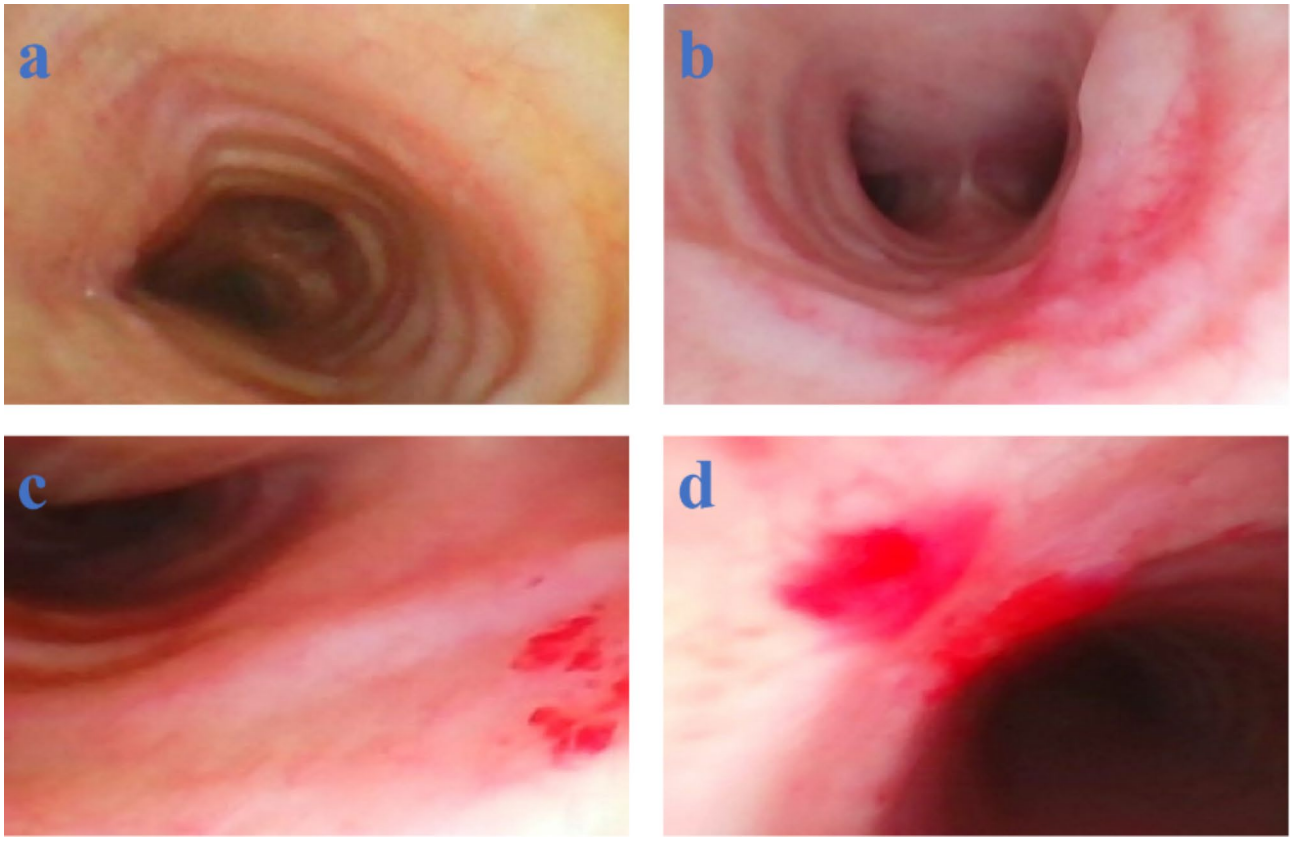

Fig. 2 Classification of Tracheal Mucosal Injury. **a**: Grade 0 (no apparent damage); **b**: Grade I (edema); **c**: Grade II (congestion); **d**: Grade III (hemorrhage)

refers to the narrowing of the tracheal lumen compared to normal due to ulceration and subsequent scar proliferation at the cuff contact site; tracheoesophageal fistula is a pathological state where an abnormal channel forms between the trachea and adjacent spaces or organs like the pleural cavity or esophagus). The incidence of cuff-related bleeding in both groups was assessed (observing the oropharyngeal condition under fiberoptic guidance to exclude the possibility of bleeding). At 1 h and 24 h post-extubation, a designated medical staff member (blinded to the study) conducted follow-up assessments of endotracheal intubation-related complications (sore throat, hoarseness, coughing, and blood-stained sputum) through patient interviews. Post-operative sore throat (POST) was described as pain, prickling, or irritation in the throat, further categorized using a visual analogue scale (VAS) from 0 to 10 into mild (VAS score 1–3), moderate (VAS score 4–7), and severe (VAS score 8–10); hoarseness was described as an abnormal change in voice, such as raspiness, strain, or alterations in volume or pitch; coughing was described as either intermittent or persistent.

Sample size calculation

The sample size was calculated using PASS 15 software. Based on the results of a pilot study, the incidence of tracheal mucosal injury was 50% in the intervention group versus 93.75% in the control group. Given a test power of 80% and a two-sided significance level of $\alpha = 0.025$, it was estimated that each group would need 20 subjects. The subjects were all perioperative patients, with follow-up occurring during their hospital stay, and there were no major events such as death. There were no lost-to-follow-up patients in this study; hence, 20 subjects were recruited for each group.

Statistical analysis

This study is a prospective, double-blind, randomized controlled trial. For descriptive statistical analysis, categorical variables are presented as n (%), intubation time continuous variables are evaluated for normality (through the Shapiro–Wilk's test) and homogeneity of variance (Levene's test), with normally distributed data presented as mean ± standard deviation, and non-normally distributed data represented by median and interquartile range. Statistical analysis is conducted using the Student's t-test or Mann-Whitney U test as appropriate. Outcome measures are reported as percentages along with 95% confidence intervals (CIs). All statistical analyses are performed using SPSS Statistics version 26.0, with a two-tailed *P*-value of < 0.05 considered statistically significant.

Results

Baseline information

This study enrolled 48 subjects scheduled for neurosurgical operations, of which 8 were excluded due to not meeting the inclusion criteria: 2 were due to the cancellation of surgery, 1 experienced intubation difficulties during anesthesia induction, 3 preoperatively refused to continue participation, and 2 underwent percutaneous tracheostomy. Ultimately, 40 subjects were included, with 20 in the intervention group and 20 in the control group. All patients completed the follow-up and were incorporated into the statistical analysis (Fig. 3).

Baseline characteristics of the two groups are detailed in Table 1. There were no statistically significant differences in the baseline characteristics between the two groups.

The comparison of tracheal mucosal injury scores between two groups of subjects before extubation

In the primary outcome measures, there was a significant statistical difference in the tracheal mucosal damage scores assessed by bronchoscopy before extubation between the two groups (intervention group: 1.4 ± 0.274 vs. control group: 2.7 ± 0.335, $P = 0.009$). The intervention group primarily exhibited Grade I injuries (edema, 65%), while the control group showed predominance of Grade I (edema) and Grade II injuries (congestion). There was a statistically significant difference in the incidence of airway congestion between the two groups (intervention group: 35% vs. control group: 75%, $P = 0.012$); however, no Grade IV damage was observed in either group.

The comparison of the incidence of tracheal mucosal injury before and during extubation between two groups of subjects

The incidence of tracheal mucosal injury in the intervention group was 70%, representing a decrease compared to the control group, which had an incidence of 95%. However, there was no statistically significant difference between the two groups ($P = 0.091$).

The cuff pressure (cmH_2O) of the endotracheal tube in the control group after inflation and at the end of the surgery

In the control group, endotracheal tube cuff inflation was conducted using the digital palpation method. Only 10% of the patients had cuff pressures within the ideal range, with over 65% of the patients exhibiting cuff pressures exceeding 50 cmH_2O. At the conclusion of the surgery, 85% of the patients still had cuff pressures exceeding 30 cmH_2O (Fig. 4).

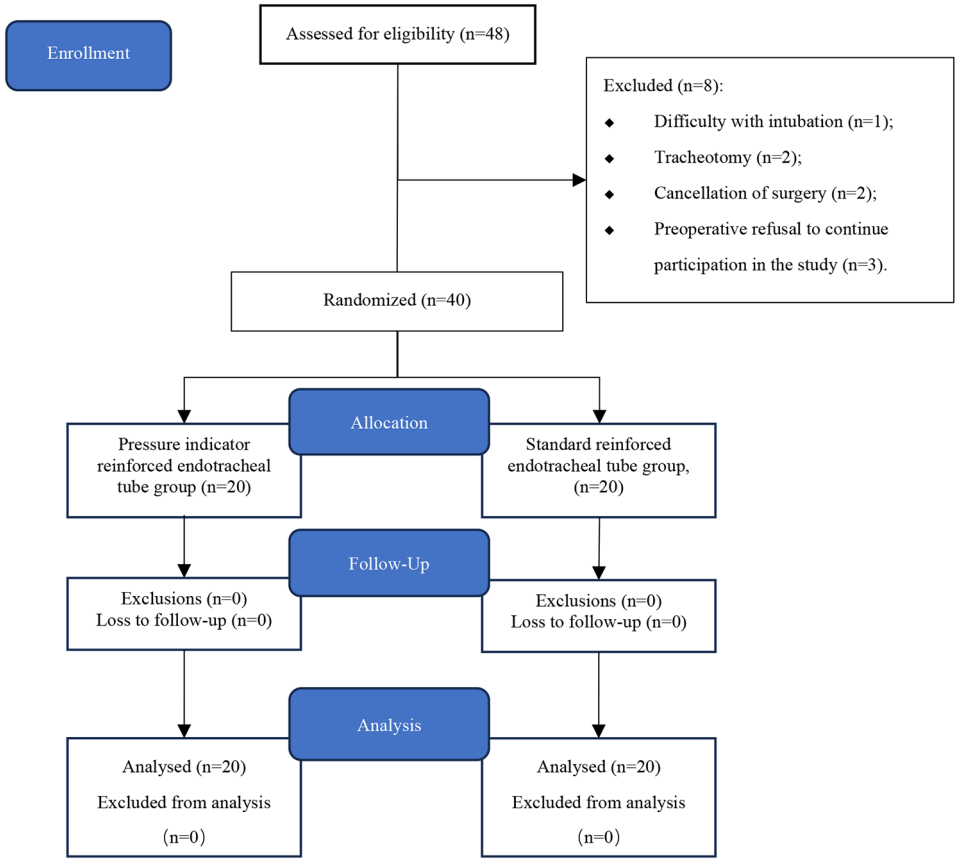

Fig. 3 Research flowchart

Comparison of airway-related complications after extubation between the two groups

Upon extubation, the incidence of cuff blood in the two groups of patients was evaluated (intervention group: 0% vs. control group: 10%, $P=0.244$). 1-hour post-extubation, the incidence of pharyngalgia (intervention group: 70% vs. control group: 85%, $P=0.500$), hoarseness (intervention group: 45% vs. control group: 35%, $P=0.424$), blood-tinged sputum (intervention group: 0% vs. control group: 5%, $P=0.500$), cough (intervention group: 5% vs. control group: 10%, $P=0.500$), and the severity of pharyngalgia showed no significant statistical differences ($P=0.633$). However, the incidence of blood-stained cuffs during extubation was 10% in the control group, while no such complication was observed in the intervention group (Table 2).

At 24 h post-extubation, the rates of pharyngeal pain (intervention group: 20% vs. control group: 40%, $P=0.301$), hoarseness (intervention group: 15% vs. control group: 25%, $P=0.317$), blood-tinged sputum (intervention group: 0% vs. control group: 0%), and cough (intervention group: 5% vs. control group: 5%, $P=0.756$) did not show significant statistical differences. However, there was a significant statistical difference in the severity of pharyngeal pain between the two groups after 24 h of extubation ($P=0.044$) (Table 2).

Discussion

Our study is conducted directly under the guidance of a bronchoscope, which can assess the impact of the cuff pressure of the tracheal tube on tracheal mucosal injury. It utilized endotracheal tubes with pressure indicators to restrict cuff pressure during neurosurgical procedures. We observed significant differences in cuff pressure between the two groups of patients after intubation and at the end of surgery. Strict intraoperative control of cuff pressure was found to significantly reduce airway mucosal injury scores. Patients in the control group experienced more severe pharyngeal pain 24 h after extubation. Previous research has predominantly focused on evaluating patient symptoms such as sore throat, cough, and hoarseness through scoring, with the assessment criteria being subjective and failing to precisely reflect the condition of airway mucosal damage [16, 17]. This study, utilizing bronchoscopy, identified various signs of airway mucosal damage in patients, including edema, congestion, and hemorrhage. Based on the bronchoscopic findings, targeted treatments (such as decongestion or hemostasis) can be administered, thereby enhancing the

Table 1 Baseline characteristics of patients

Parameters	Intervention group ($n=20$)	Control group ($n=20$)	*P*
Sex (man)	10 (50%)	11 (55%)	0.752
Age (y)	49.5 (23,65)	43.5 (21,59)	0.114
ASA			0.705
II	5 (25%)	4 (20%)	
III	15 (75%)	16 (80%)	
Height (cm)	161.2 ± 1.736	164.3 ± 2.113	0.289
Weight (kg)	64.7 ± 2.214	64.4 ± 3.625	0.883
BMI	24.9 ± 0.818	23.6 ± 1.071	0.221
Type of surgery			0.564
Intracranial space occupying surgery	17 (85%)	14 (70%)	
Surgery for spinal canal lesions	1 (5%)	3 (15%)	
Surgery for cerebrovascular disease	2 (10%)	3 (15%)	
Surgical position			1
Supine position	15 (75%)	16 (80%)	
Lateral position	1 (5%)	1 (5%)	
Prone position	4 (20%)	3 (15%)	
Time of operation (min)	274.9 ± 19.924	245.4 ± 18.321	0.265
Intubation time (min)	365.5 (268,1507)	313.5 (259,940)	0.127

$P<0.05$ was considered statistically significant. The type of surgery, sex, ASA, type of surgery, and surgical position are shown as n (%), or number. The Age and 95% are shown as confidence intervals (CIs). The height, Weight, BMI and time of operation are shown as mean ± SD unless otherwise indicated; ASA indicates American Society of Anesthesiologists. BMI indicates Body Mass Index

Table 2 Comparison of Outcome measures between the two groups

Parameters	Intervention group ($n=20$)	Control group ($n=20$)	*P*
Primary outcome measures			
Tracheal mucosal injury score	1.4 ± 0.274	2.7 ± 0.335	0.009
Edema (1 point)	13 (65%)	17(85%)	0.137
Congestion (2 points)	7(35%)	15 (75%)	0.012
Hemorrhage (3 points)	0 (0%)	2 (10%)	0.244
Other Severe Injuries (4 points)	0 (0%)	0 (0%)	
Secondary outcome measures			
Tracheal mucosal injury	14 (70%)	19 (95%)	0.091
Cuff leakage with blood	0 (0%)	2 (10%)	0.244
Complications within 1 h post-extubation			
Hoarseness	9 (45%)	7 (35%)	0.424
Cough	1 (5%)	2 (10%)	0.5
Hemoptysis	0 (0%)	1 (5%)	0.5
Pharyngeal pain	14 (70%)	17 (85%)	0.451
the severity of pharyngeal pain			0.633
0	6 (30%)	3 (15%)	
1	12 (60%)	14 (70%)	
2	2 (10%)	3 (15%)	
3	0 (0%)	0 (0%)	
Complications within 24 h post-extubation			
Hoarseness	3 (15%)	5 (25%)	0.317
Cough	1 (5%)	1 (5%)	0.756
Hemoptysis	0 (0%)	0 (0%)	/
Pharyngeal pain	4 (20%)	8 (40%)	0.301
the severity of pharyngeal pain			0.044
0	16 (80%)	12 (60%)	
1	4 (20%)	4 (20%)	
2	0 (0%)	3 (15%)	
3	0 (0%)	1 (5%)	

$P<0.05$ was considered statistically significant. The tracheal mucosal injury score, the severity of pharyngeal pain are shown as mean ± SD. The other data are shown as n (%)

standardization and effectiveness of clinical diagnosis and treatment.

Previous research has demonstrated that the traditional palpation method may be unreliable to some extent. For instance, a study on medical personnel employing the palpation technique for cuff inflation found that nearly 90% of the cuff pressures exceeded 30 cmH_2O, with only less than 6% within the recommended range [12]. Meanwhile, our study revealed that in the control group

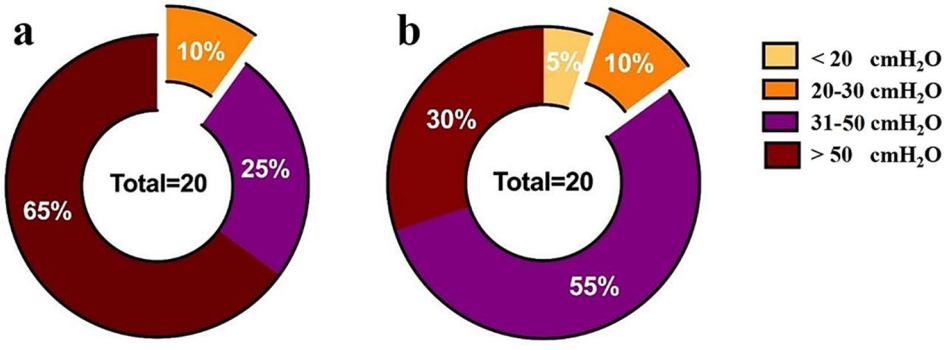

Fig. 4 The percentage for different range of cuff pressure in the control group. **a**: the control group after intubation, 10% of the patients had cuff pressures within the ideal range, with over 65% of the patients exhibiting cuff pressures exceeding 50 cmH_2O; **b**: the control group at the end of the surgery, 85% of the patients still had cuff pressures exceeding 30 cmH_2O

using the palpation method for cuff inflation, 90% of the patients had cuff pressures exceeding 30 cmH_2O. Patients with overinflated cuffs often experienced changes in cuff pressure postoperatively, yet the overall cuff pressure remained persistently high. Wujtewicz and colleagues categorized anesthesiologists based on their work experience [18]. The results indicated that experienced anesthesiologists (with over 10 years of experience) were more prone to overinflation. All these studies suggested that relying solely on experience and the palpation method for cuff inflation was unreliable. Therefore, alternative objective methods of inflation and monitoring should be adopted, with strict perioperative cuff pressure control to reduce the incidence of airway mucosal ischemia.

Our study found that using reinforced endotracheal tubes with pressure indicators to control intraoperative cuff pressure could reduce postoperative airway mucosal injury in neurosurgical patients and alleviated the severity of pharyngeal pain 24 h after extubation. However, the incidence of tracheal mucosal injury postoperatively was not low (≥ 70%) in both groups, and the occurrence of airway injury-related complications remained high (predominantly hoarseness and sore throat), with no significant improvement observed in the intervention group. Our findings are consistent with previous research. Controlling the cuff pressure with a manometer has been found that it could significantly reduce the incidence of short-term airway complications postoperatively, such as sore throat, hoarseness, and blood-streaked sputum, compared to the manual palpation method [19]. Similarly, it has been reported that controlling cuff pressure significantly reduced the incidence and severity of sore throat 24 h postoperatively ($P < 0.001$), as well as the symptoms of hoarseness 1 h postoperatively and coughing at 1 and 12 h postoperatively ($P < 0.005$) [20]. The reason for this may be related to the generally longer intubation duration in neurosurgical patients, the frequent need for intraoperative neuromonitoring, and restricted use of muscle relaxants. Meanwhile, our study was consistent with previous study, which found automated cuff controller could significantly reduce the postoperative sore throat at postoperative 2 h [17]. Cuff pressure may not be the sole factor affecting post-neurosurgical airway mucosal injury and airway-related complications. Further large-scale, multicenter studies are needed to comprehensively analyze the factors contributing to tracheal mucosal injury, to enhance the understanding of airway mucosal damage post-intubation.

Our study also has certain limitations. Due to the small sample size, our analysis results may lack stability. Furthermore, no patients with Grade IV airway mucosal injury were identified in this study, which precluded an exploration of the specific manifestations and management strategies for such high-risk patients. Lastly, the lack of blinding for coordinators and anesthesiologists could introduce potential bias into the research.

Conclusions

In conclusion, the use of reinforced endotracheal tubes with pressure indicators to control intraoperative cuff pressure could alleviate postoperative airway mucosal damage in neurosurgical patients, and could reduce the severity of pharyngeal pain 24 h after extubation.

Abbreviations

ETTCP	The pressure of the endotracheal tube cuff
VAP	Ventilator-associated pneumonia
ASA	American Society of Anesthesiologists
TIVA	Total intravenous anesthesia
ABP	Arterial blood pressure
HR	Heart rate
ICU	Intensive Care Unit
HIS	Hospital Information System
BMI	Body mass index
POST	Post-operative sore throat
VAS	Visual analogue scale
Cis	Confidence intervals

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12871-025-02967-6 .

Supplementary Material 1

Supplementary Material 2

Supplementary Material 3

Acknowledgements

Not applicable.

Author contributions

All authors contributed to the study conception and design. Material preparation was performed by XQG, YT and JQY. Data collection was performed by XQG, YT, YYJ and XQL. Analysis was performed by YL. The first draft of the manuscript was written by CC and XQG. All authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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Data availability

The data used and analyzed during our study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

The study received approval from the Biomedical Ethics Committee of West China Hospital, Sichuan University (Document No. 345, Review 2022) and registered on Chinese Clinical Trial Registry (registration number: ChiCTR2200065315). All participants provided written informed consent.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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