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Investigating Different Endotracheal Tube Cuff Pressure Monitoring Methods and their Role in Postoperative Sore Throat among Tracheal Intubation Patients: A Randomized Study

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Abstract: ***Background: Postoperative sore throat (POST) is a common discomfort resulting from tracheal intubation in adults. The increased pressure exerted by the endotracheal tube (ETT) cuff often leads to local mucosal injury, causing sore throat. This study aimed to compare the impact of two different ETT cuff pressure monitoring systems versus no cuff pressure monitoring on the occurrence and severity of POST in adults. Methods: One hundred and five ASA I - III patients, aged 18–65 years, of any gender, undergoing surgeries requiring endotracheal intubation were enrolled. Patients were randomly allocated into three groups: control (C), cuff pressure gauge (G), and automated cuff controller (A). Intraoperatively, ETT cuff pressure was not monitored in group C, while it was monitored using a cuff pressure gauge and an automated cuff controller in groups G and A, respectively. Postoperatively, patients were assessed at 2, 24, and 48 hours for the presence and severity of POST, hoarseness, and cough. Result: Results One hundred patients completed the study. POST occurred in 67.6% of the patients in group C, 41.2% Patients in Group G and 21.6% of the patients in group A with statistically significant difference between them. There were no significant differences in hoarseness, coughing, and dysphagia acrossthe groups at any time. Conclusion: The study findings indicate that the utilization of a cuff pressure gauge or an automated cuff controller during tracheal intubation under general anesthesia can effectively decrease the incidence of postoperative sore throat (POST)***

Keywords: Postoperative sore throat (POST), Anesthesia, Endotracheal Tube

1. Introduction

Postoperative sore throat (POST) is a discomfort experienced by adults after endotracheal intubation, with an incidence ranging from 30% to 70% [1, 2]. This discomfort arises from mechanical stimulation of the airway mucosa due to the intubation process [3]. Factors such as intubation technique, tube size, and cuff pressures significantly influence its occurrence [4 - 6].

Maintaining optimal endotracheal tube (ETT) cuff pressure, typically between 25 and 30 cmH2O, is crucial during surgery to prevent regurgitant aspiration and airway damage [7]. Elevated cuff pressure above 30 cmH2O reduces local tracheal mucosal perfusion, escalating the risk of postoperative airway complications like POST, hoarseness, and dysphagia [8, 9]. Surprisingly, a substantial portion of anesthesia and intensive care personnel lack awareness of accurate ETT cuff pressure management, with few utilizing cuff pressure monitors [10].

Continuous monitoring of cuff pressure throughout surgery is imperative to avoid airway damage [11, 12]. Although cuff pressure gauges were traditionally used for this purpose, they are deemed insensitive and inefficient. The advent of automated cuff controllers allows real - time monitoring and automatic inflation or deflation of cuff pressure as needed [13 - 15]. However, current research predominantly examines their utilization in postoperative intensive care settings rather than the operating theater [16, 17]. The impact of automated cuff controllers on postoperative airway discomfort like sore throat remains largely unexplored.

This study aims to assess whether automated cuff controllers, compared to cuff pressure gauges, reduce the frequency and severity of POST and associated airway issues. The primary outcome is the incidence of POST within 48 hours post - surgery. Secondary outcomes include the occurrence and severity of postoperative hoarseness, cough, and dysphagia, along with POST incidence and severity at 2, 24, and 48 hours postoperatively. The hypothesis posits that both automated cuff controllers and cuff pressure gauges can mitigate the frequency of POST.

2. Methodology

This study, conducted in accordance with the CONSORT reporting guidelines [18], took place at the Department of. . . . . All participants provided written informed consent after approval from the hospital's Study Ethics Committee of the college.

Adult participants of either sex, aged between 18 and 65 years, with ASA physical status I, II, or III, and scheduled for elective procedures under general endotracheal anesthesia were included. Exclusion criteria comprised individuals with a body mass index below 19 kg/m− 2 or over 30 kg/m− 2, existing conditions such as sore throat, hoarseness, cough, bleeding in the laryngeal mucosa, asthma, chronic obstructive pulmonary disease, smoking history, difficult airway, respiratory tract infection within the past two weeks, recent nasogastric tube insertion, psychiatric disorders, or prior oral and ENT surgery.

Participants were enrolled one day before the operation and randomly assigned into groups at a 1: 1: 1 ratio through computer - generated random number tables. The anesthesiologist, overseeing procedures like intubation and cuff monitoring, accessed opaque envelopes containing allocation numbers.

Two independent investigator evaluated outcome measures post - surgery. Telephone follow - up was employed for post - operative monitoring if patients were discharged early. Neither patients, data analysts, nor outcome assessors were aware of the trial's intervention.

The endotracheal tube (ETT) cuffs were inflated using a 10 - ml syringe and the anesthesiologist's standard pilot balloon palpation method in all groups. Cuff pressure was not documented in the control (C) group. In the cuff gauge (G) group, ETT cuff pressure was monitored intraoperatively every hour using a cuff pressure gauge (Ambu*R, Germany), maintaining it at 25–30 cmH2O throughout the procedure. The automated (A) cuff controller group utilized an automated cuff controller (HPC - 1, Wuxi Huayao Biotechnology Co., Ltd) to sustain ETT cuff pressure constant at 25–30 cmH2O. Additionally, the initial cuff pressure was recorded during cuff inflation in groups G and A. Participants with a leaking ETT cuff were re - intubated and excluded.

Anesthesia induction included sufentanil (0.4 μg. kg− 1), rocuronium (0.6 mg. kg− 1), and ciprofol (0.4 mg. kg− 1), followed by guided endotracheal tube placement using visual laryngoscopy. Remifentanil (0.05 - 2.0 μg. kg− 1. min− 1), propofol (4.0–8.0 mg. kg− 1. h− 1), and cisatracurium (0.05 mg. kg− 1 every 30 min) maintained continuous general anesthesia.

The tidal volume (6–8 ml. kg− 1), respiratory rate (10–13 breaths/min), and peak airway pressure (25 mmHg) were determined based on the patient's ideal body weight. Mechanical ventilation was configured for volume control. Subsequently, patients were transferred to the post - anesthesia care unit (PACU) for postoperative resuscitation. The endotracheal tube was removed once patients exhibited spontaneous breathing and could follow directions by hand movement, with the cuff fully deflated after gentle oral cavity suction at a negative pressure of 50 cmH2O. [19]

Following surgery, patients underwent monitoring at 2, 24, and 48 hours to evaluate the prevalence and severity of postoperative sore throat (POST), hoarseness, and cough. Additionally, occurrences and intensities of dysphagia were recorded at 24 and 48 hours. POST was characterized as an unpleasant sensation of discomfort or irritation during rest or swallowing, categorized into four grades: absence (grade 0), milder than a common cold (grade 1), nearly equivalent to a common cold (grade 2), and severe (grade 3) [20]. Cough severity was graded from absent (0) to severe (3), while hoarseness severity ranged from none (0) to severe (3), with moderate (2) hoarseness observable by an observer [21]. Dysphagia severity was rated from no difficulty (grade 0) to severe difficulty (grade 3), with complications rated at ≥ 2 deemed significant [22].

Sample size and statistical analysis

The pre - test data indicated that 70% of group C patients, 50% of group G patients, and 30% of group A patients experienced POST within 48 hours after surgery. GPower was used to calculate the sample size, with $\alpha = 0.05$ and $\beta = 0.2$, respectively. The calculated sample size was 30 patients in each group. A dropout rate of 15% was considered during the study, resulting in 35 patients per group being enrolled. A total of 105 patients were included in the study

Continuous data are presented as mean ±standard deviation). Analysis of variance (ANOVA) was used was used to compare non - normally distributed data. Categorical data, including the rates of postoperative complications, are presented as frequencies (percentages). Statistical significance across groups was assessed using either the Chi - square test or the Fisher exact test. P - values < 0.05 were considered statistically significant. All data were analyzed using SPSS 25.0 (IBM Corp., Armonk, NY, USA).

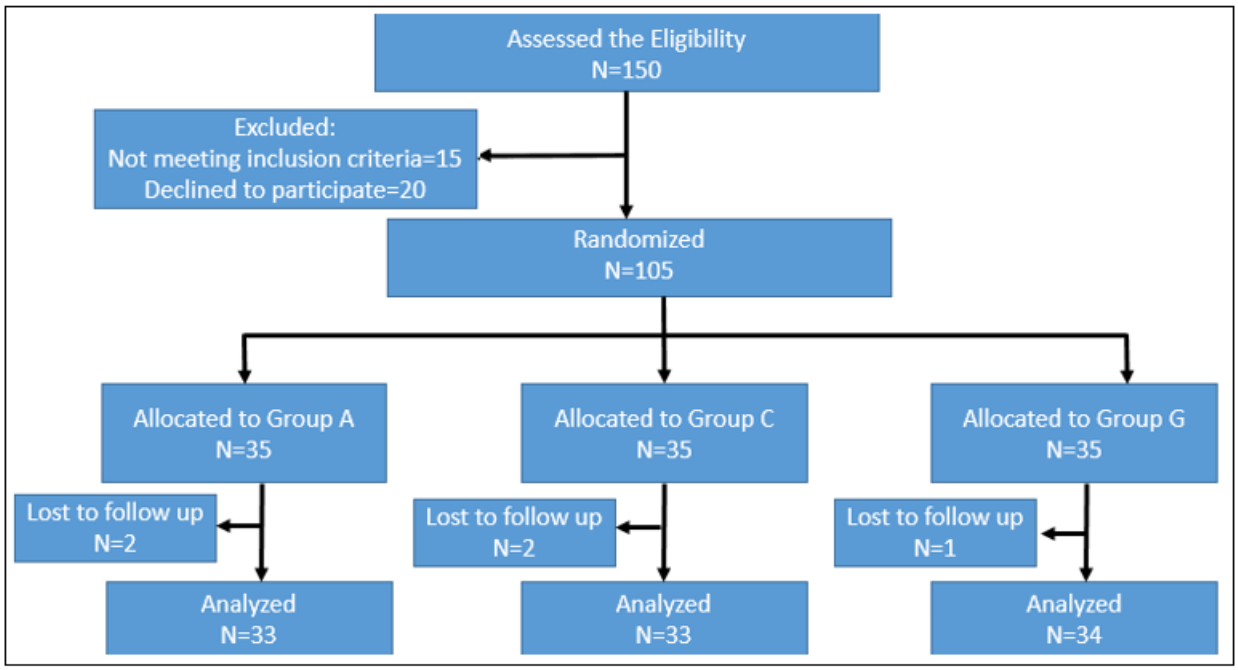

Figure 1: CONSORT flowchart

3. Result

Participants were enrolled between January and March 2023. Out of 150 potentially eligible patients, only 105 were included, with 5 patients excluded from analysis as they are lost to follow - up (see Fig.1). Age, sex, body mass index, ASA physical classification, Mallampati classification, surgery type, and surgical position were evenly distributed among the three groups (refer to Table 1). Additionally, there were no significant differences observed in endotracheal tube size, cuff inflation volume during intubation, duration of surgery, duration of anesthesia, or duration of intubation across the various groups (see Table 1 &2).

The proportion of patients who experienced at least one episode of significant airway complications during the 48 h after surgery was determined. In group A, 10.5% of patients experienced at least one significant episode of POST, which was less than that observed for groups C (41.7%, p = 0.002) and G (24.3%, p = 0.115) (p = 0.009 among groups). However, there was no statistically significant difference in the incidence of significant POST between groups G and C. Simlarly, in group A, 26.3% of patients experienced significant hoarseness at least once, which was also less than that seen in groups C (58.3%, p = 0.005) and G (40.5%, p = 0.191) (p = 0.02 among groups). None of the patients experienced significant coughing, and only one patient in group G suffered significant dysphagia. Details of the number of patients experiencing significant complications are provided in the supplemental materials.

During the 2 hours after surgery, 67.6% of patients in group C experienced POST; this was significantly higher than the patients in groups G and A (41.2% and 20.6%) and the result showed statistically significant difference between groups. At 24 h after the operation, the incidence of POST in group C (39.4%) was significantly higher than that in groups G (23.5%) and A (14.7%) and statistically significant difference between groups. At 48 h postoperatively, the difference in the incidence of POST also showed significant difference with higher prevalence in Group C. (Table 3).

The main symptoms of CAST include Horseness, cough and dysphagia. The symtoms of horseness was significantly greater in Group C in comparison to other groups at 2 hours time interval while it was not significantly high at 24 hours and 48 hours. There was non significant difference in prevalence of cough and dysphagia at all time intervals. (Table 4)

Table 1: Patients characteristics

Criteria		Group C (N=33)	Group G (N=33)	Group A (N=34)
Gender	Male	14 (42.4%)	13 (39.4%)	15 (44.1%)
	Female	19 (57.6%)	20 (60.6%)	19 (55.9%)
ASA classification,	I	1 (3.0%)	0 (0.0%)	0 (0.0%)
	II	31 (93.9%)	31 (93.9%)	33 (97.1%)
	III	1 (3.0%)	2 (6.1%)	1 (2.9%)
Mallampati classification	I	13 (39.4%)	14 (42.4%)	14 (41.2%)
	II	20 (60.6%)	19 (57.6%)	20 (58.8%)
Tube size	7	19 (57.6%)	17 (51.5%)	17 (50.0%)
	7.5	14 (42.4%)	16 (48.5%)	17 (50.0%)
	8	1 (3.0%)	0 (0.0%)	0 (0.0%)
Type of Surgery,	Spinal	15 (45.5%)	14 (42.4%)	15 (44.1%)
	Neurosurgical	6 (18.2%)	5 (15.2%)	7 (20.6%)
	Gynecological	6 (18.2%)	8 (24.2%)	7 (20.6%)
	Urological	2 (6.1%)	2 (6.1%)	1 (2.9%)
	Others	4 (12.1%)	3 (9.1%)	4 (11.8%)
Surgical position,	Supine	15 (45.5%)	14 (42.4%)	16 (47.1%)
	Prone	15 (45.5%)	15 (45.5%)	14 (41.2%)
	Lateral	2 (6.1%)	1 (3.0%)	2 (5.9%)
	Lithotomy	1 (3.0%)	3 (9.1%)	2 (5.9%)

Table 2: Operation Characteristics

Characteristics	Group C (N=33)	Group G (N=33)	Group A (N=34)	P Value
Operation duration (min)	140.24±4.87	148.48±6.54	138.79±2.56	0.37[#]
Intubation duration (min)	208.64±5.37	200.11±3.69	195.25±4.55	0.09[#]
Anaesthesia duration (min)	168.29±4.62	165.11±3.32	167.20±4.21	0.74[#]
Cuff inflation volume (ml)	4.05±0.21	4.17±0.19	4.11±0.21	0.89[#]

One way ANOVA, [#]Non significant

Table 3: Proportion of patients with POST over time

Time Period	Group C	Group G	Group A	P value
2 hours	23 (67.6%)	14 (41.2%)	7 (20.6%)	0.001*
24 hours	13 (39.4%)	8 (23.5%)	5 (14.7%)	0.001*
48 hours	8 (23.5%)	3 (9.1%)	1 (2.9%)	0.001*

Chi square test, *Significant

Table 4: Incidence of Hoarseness, cough and dysphagia

Symptoms	Time Period	Group C	Group G	Group A	P value
Hoarseness	2 hours	22 (66.7%)	18 (54.5%)	15 (44.1%)	0.04*
	24 hours	16 (48.5%)	14 (42.4%)	11 (32.4%)	0.39#
	48 hours	4 (12.1%)	1 (3.0%)	1 (2.9%)	0.40#
	Overall	22 (66.7%)	18 (54.5%)	15 (44.1%)	0.04#
Cough	2 hours	3 (9.1%)	2 (6.1%)	2 (5.9%)	0.89#
	24 hours	4 (12.1%)	2 (6.1%)	3 (8.8%)	0.77#
	48 hours	0 (0.0%)	1 (3.0%)	0 (0.0%)	0.97#
	Overall	7 (21.2%)	5 (15.2%)	5 (14.7%)	0.84#
Dysphagia	24 hours	2 (6.1%)	3 (9.1%)	2 (5.9%)	1.00#
	48 hours	0 (0.0%)	0 (0.0%)	0 (0.0%)	1.00#
	Overall	2 (6.1%)	3 (9.1%)	2 (5.9%)	1.00#

Chi square test, * Significant, #Non significant

4. Discussion

The findings of our study reveal that employing an automated cuff controller or cuff pressure gauge significantly reduces the occurrence of postoperative sore throat (POST) within 48 hours. Notably, the group utilizing the automated cuff controller also experiences a lower incidence of significant POST and hoarseness, validating our initial hypothesis.

Maintaining optimal pressure within the endotracheal tube (ETT) cuff post - intubation is vital for proper airway management [23]. Research indicates that when the ETT cuff pressure exceeds 30 cmH2O, blood flow in the tracheal mucosa diminishes, leading to ischemic damage if the pressure reaches 50 cmH2O for 15 minutes [24]. Additionally, there's a clear correlation between ETT cuff pressure and the development of postoperative airway symptoms like sore throat and hoarseness. Consistent with this, Zhao et al. [25] study revealed that 79.8% of patients had ETT cuff pressure exceeding 30 cmH2O, with 70.9% subsequently experiencing POST.

In our study, akin to previous investigations, cuff pressure gauges and manometers were employed for monitoring [11, 12]. However, relying solely on intermittent manual pressure measurements, as was done in Group G, resulted in a POST incidence of 40.5%. This suggests that hourly monitoring during surgery may overlook transient pressure increases due to procedural maneuvers or changes in patient positioning. For instance, Jung - Hee Ryu et al. [11] reported a 61% POST incidence in thyroid surgeries, indicating the procedure's association with higher risk. Hence, we opted for a diverse range of surgical procedures to capture a broader perspective.

The occurrence of postoperative sore throat (POST) as a secondary event was observed at rates of 20% and 8% in a study by Jain et al. [26], where they assessed two methods of monitoring endotracheal tube (ETT) cuff pressure using a manometer and an automated cuff controller, respectively, across 100 neurosurgery procedures. In contrast, our investigation revealed POST incidences of 40.5% and 23.7% when employing a gauge and cuff controller for monitoring, respectively. Notably, our study diverges by encompassing various surgical procedures, including neurosurgery. Additionally, our controller maintained a pressure range of 25 to 30 cmH2O, differing from the previous automated cuff controller, which sustained pressure solely at 25 cmH2O. Moreover, unlike prior studies, we assessed POST incidence at different time intervals. Utilizing POST and other postoperative airway complications as primary outcomes, we established a control group and observed a substantial reduction in POST incidence to 23.7% when monitored by an automated cuff controller, notably lower than both the control group and the cuff pressure gauge group.

Monsel et al. [27] discovered that consistent regulation of cuff pressure enhanced pressure stability and reduced variability while maintaining cuff integrity. Conversely, traditional manual pressure gauge measurement presents several limitations, including the inability to promptly adjust cuff pressure, potential gas loss during measurement, and low staff compliance with pressure monitoring. Although the cuff pressure gauge and automated cuff controller showed no significant variation in our study, a larger sample size might uncover nuanced differences.

Factors such as direct laryngoscopy, endotracheal tube (ETT) size, intubation duration, and the skill level of the anesthesiologist are all potential contributors to postoperative sore throat (POST) [2]. These variables were consistent across all study groups, underscoring the reliability of our findings. Additionally, there were no significant differences observed among the groups regarding the incidence of hoarseness, cough, and dysphagia within the initial 48 hours post - operation, which corroborates previous research [11]. However, our study identified a notable reduction in hoarseness severity among patients utilizing the automatic cuff controller. The application of high - pressure cuffs on the airway wall poses a risk of damaging the recurrent laryngeal nerve, which contributes to postoperative hoarseness and is situated between the esophagus and the trachea. Although the occurrence of dysphagia within 48 hours post - surgery did not exhibit significant variation among the three groups, it is widely recognized that maintaining appropriate cuff pressure during surgery helps prevent dysphagia [28 - 30].

This investigation offers several advantages. While existing studies on automated cuff controllers have primarily focused on individuals undergoing prolonged mechanical ventilation in intensive care units [16, 17], our research demonstrated routine application of the automated cuff controller, significantly reducing several postoperative complications, including sore throat. Moreover, it proved to be convenient for anesthesiologists. However, there are limitations to consider. Firstly, we did not collect intraoperative cuff pressure data because our cuff controller was designed to maintain pressure within a fixed range and couldn't measure the actual cuff pressure. Another limitation is the exclusion of

specific surgical procedures, as our primary aim was to assess the utility of cuff pressure monitoring across various surgical interventions. Certain surgeries, such as thyroid or cervical spine procedures, may carry a higher risk of POST development [31 - 33], warranting further investigation in subsequent studies.

5. Conclusion

The study findings suggest that employing a cuff pressure gauge or an automated cuff controller during tracheal intubation under general anesthesia can effectively reduce the incidence of postoperative sore throat (POST). It underscores the importance for anesthesiologists to prioritize patient monitoring and ensure precise regulation of intraoperative cuff pressure.

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