

# Tube Exchanges and Respiratory Adverse Events in Infants up to 3 Months of Age Using Microcuff and Uncuffed Endotracheal Tubes: A Randomized Study

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## ARTICLE INFO

### Article history:

Received 11 December 2025

Revised 03 January 2026

Accepted 17 January 2026

### Keywords:

Airway management;  
Infant;  
Intubation;  
Newborn;  
Patient safety;  
Stridor

## ABSTRACT

**Background:** Optimal sizing of endotracheal tubes (ETTs) in pediatric patients may lead to repeated laryngoscopies, intubations, and ETT exchanges. The subglottis is functionally the narrowest part of the pediatric airway and is prone to edema, tracheal lumen narrowing, and post-extubation stridor due to repeated airway manipulations. Objectives: To compare the proportion of infants up to 3 months of age who require ETT exchanges and who develop postoperative respiratory adverse events (PRAEs) following intubation with Microcuff versus uncuffed ETTs.

**Methods:** This prospective randomized study included 100 patients up to 3 months of age. They were randomized into two groups of 50 each: Gp M: intubated with microcuff ETT. Gp U: intubated with uncuffed ETT. A leak test was done after intubation. In Gp U, excessive leak at 10 cm of water pressure required a 0.5-size bigger ETT. A minimal leak at 10-20 cm of water was acceptable. No leak at 20 cm of water required downsizing ETT by 0.5. In Gp M, the cuff was inflated until minimal leak at 10-20 cm of water. No leak with the deflated cuff at 20 cm of water warranted exchange with an uncuffed ETT of size 3.0.

**Results:** In Gp U, 12/50 (24%) patients underwent tube exchanges, and 6/50 (12%) had post-extubation stridor. In group M, 4/50 (8%) patients required tube exchange to size 3.0 uncuffed ETT, and one patient (2%) had post-extubation stridor.

**Conclusion:** Microcuff ETTs have a lesser incidence of tube exchange and post-extubation stridor as compared to uncuffed ETTs in infants up to three months of age.

## Introduction

Glottis is the smallest measured part of the pediatric airway, but it is distensible. In contrast, cricoid cartilage at the level of the subglottis is the first non-distensible, complete cartilaginous ring, which is covered with pseudostratified columnar epithelium. This makes the subglottis prone to edema and tracheal lumen narrowing if irritated, hence making it functionally the narrowest part of the pediatric airway [1]. An endotracheal tube (ETT) that passes easily through the glottis may not advance beyond the cricoid in

pediatric patients [2]. The narrowing of the tracheal lumen caused by mucosal edema can result in post-extubation stridor, a common complication in neonates and infants. Traditionally, uncuffed ETTs have been recommended in infants due to concerns about potential airway injury from cuff inflation with cuffed ETTs. Uncuffed ETTs provide a larger internal diameter, resulting in lower resistance to airflow. However, choosing the appropriate tube size is a challenge frequently necessitating multiple attempts at laryngoscopy and intubation. This further increases the risk of airway trauma, edema, and subsequent complications. Using uncuffed ETTs requires higher gas

The authors declare no conflicts of interest.

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DOI:

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flows, has increased chances of aspiration, and causes OR pollution [3]. The advent of microcuff ETTs has raised interest in their use in the pediatric population. The cuffs of these tubes are soft and made of polyurethane, inflate symmetrically, and exert less pressure on the tracheal wall (<15 cm of water). Murphy's eye is absent in these tubes, allowing cuff position to be distal. Hence, preventing it from lying at the level of the cricoid, resulting in lesser chances of airway edema. They provide a reliable airway seal, reducing the need for repeated laryngoscopy and intubation attempts. Microcuff ETTs allow use of lower gas flows and reduce OR pollution [4]. The use of uncuffed ETTs results in increased chances of tube exchanges, as the exact size of tube is difficult to ascertain; smaller-sized tubes result in leaks, causing inadequate ventilation, and larger-sized tubes cause increased chances of airway edema, which may lead to stridor. Microcuff ETT limits the number of laryngoscopies and intubations, as its cuff can be inflated to provide adequate seal and ventilation. Thus, avoiding repeated attempts at securing a definitive airway [4]. Although some studies have evaluated the safety and efficacy of Microcuff ETTs in older children, their use in infants under 3 months of age remains limited. Hence, this randomized prospective study was planned to compare the proportion of infants requiring ETT exchanges and developing postoperative respiratory adverse events (RAE), which include post-extubation stridor, desaturation ( $SpO_2 < 95\%$ ), laryngospasm, bronchospasm, and soft tissue airway obstruction, while securing the airway with microcuff ETTs and uncuffed ETTs.

## Methods

This prospective randomized study included term neonates, preterms with post-conceptual age more than 37 weeks at the time of surgery, and infants up to three months of age requiring endotracheal intubation for general anesthesia for elective and emergency procedures to be done in the supine position. Recruitment of patients was conducted after obtaining approval from the Institutional Ethics Committee (F.1/IEC/CNBC/27/02/2024/155) and registration with the Clinical Trials Registry of India (CTRI/2024/07/071236). Children with congenital syndromes, children with airway anomalies, children with tracheo-esophageal fistula, and those requiring postoperative ventilation were excluded from the study. Objectives: To compare the proportion of infants up to 3 months of age who require ETT exchanges and who develop postoperative respiratory adverse events (PRAEs) following intubation with Microcuff versus uncuffed ETTs. Sample size: Sample size was estimated based on a previous study [5], assuming a 15% absolute difference in the incidence of stridor between Microcuff

and uncuffed groups (expected rates: 17.2% vs 7.5%). A total of 49 infants per group would provide 80% power to detect this difference at a one-sided alpha of 0.05. Therefore, we enrolled 50 patients in each group. Randomization: Patients were randomized into two groups of 50 patients each by using permuted blocks of varying sizes using a web randomization tool—<http://www.randomization.com>. After the randomization sequence, allocation was concealed using sequentially numbered, opaque sealed envelopes. The envelope was opened by the anesthesiologist performing the laryngoscopy. Due to the nature of the intervention, the anesthesiologist could not be blinded. The parents of the child were blinded to the group allocation.

After taking written informed consent, the infant was taken into the operating room. The intravenous route for induction of anesthesia was chosen for patients who had an existing intravenous catheter in situ; otherwise, a volatile inhalational anesthetic agent was given to facilitate intravenous cannulation. After securing an IV catheter, Inj. Fentanyl at a dose of 2.0 mcg/kg IV, Inj. Propofol at a dose of 1.0-2.5 mg/kg IV, and Inj. Atracurium at a dose of 0.5 mg/kg IV were given. All cases were conducted using sevoflurane with oxygen and air. Direct laryngoscopy was done, and oral endotracheal intubation was performed by a trained pediatric anesthesiologist as per the group assigned. The two groups were: Gp M: patients were intubated with size 3 microcuff ETTs [6]. Gp U: patients were intubated with the size of tube decided by the trained anesthesiologist performing laryngoscopy on visual estimation of glottic diameter.

## Leak test

It was conducted with the stethoscope's bell placed over the patient's larynx and the patient being hand ventilated in the manual mode of the anesthesia workstation with a fresh gas flow of 3 liters per minute. The adjustable pressure limiting (APL) valve was gradually closed up to a pressure of 20 cm of water, and auscultation on the larynx was continuously done. Loud conducted sounds and inadequate ventilation ( $TV < 6$  ml/kg) demonstrated excessive leak, and soft rustling sounds allowing adequate ventilation ( $TV = 6$  ml/kg) depicted minimum leak. In Gp U, patients were intubated with an uncuffed ETT size as per the decision of the trained anesthesiologist performing laryngoscopy, following which leak was checked. In cases of excessive leak at a pressure of 10 cm of water, a 0.5-size bigger ETT was inserted. In case of persistent leak after increasing the tube size, oral packing was done. Minimal leak at pressures of 10-20 cm of water was accepted, and GA was proceeded with the same. No leak at pressures of 20 cm of water required downsizing the ETT by 0.5. In Gp M, a size 3.0 microcuff ETT was inserted, and the leak was assessed with a deflated cuff. In the presence of

excessive leak, the cuff was inflated with incremental volumes of 0.5 ml until a minimal leak was auscultated at pressures of 10-20 cm of water, indicating an appropriate size tube. Anesthesia was proceeded with this microcuff ETT, and cuff pressure was monitored hourly. In case there is no leak around the deflated cuff at a pressure of 20 cm of water, the microcuff ETT was exchanged with an uncuffed ETT of size 3.0. At the end of surgery, once the spontaneous respiratory efforts were present, neuromuscular blockade was reversed and the trachea was extubated. The number of patients requiring tube exchanges to ascertain the appropriate size tube, post-extubation stridor, desaturation ( $SpO_2 < 95\%$ ), laryngospasm, bronchospasm, coughing, and soft tissue obstruction was noted. Use of CPAP (continuous positive airway pressure), IV steroids, adrenaline nebulization, and reintubations if needed for managing these complications was noted. The patients were followed up for up to 24 hours for stridor and postoperative RAE.

### Statistical Methods

Continuous variables are presented as mean $\pm$ SD or median (IQR) for non-normally distributed data. Between-group comparisons are made using Student's t-test for normally distributed variables and the Mann-Whitney U test for non-normal data. Categorical variables are expressed as frequencies and percentages and analyzed using the chi-squared test or Fisher's exact test, as appropriate. A P value  $< 0.05$  indicates statistical significance.

## Results

A total of 108 were screened for eligibility. Of these, five parents declined consent, and seven were excluded as per the predefined exclusion criteria. Thus, a total of 100 patients were recruited for the study. Fifty patients in each of Gp U and Gp M. The demographic profile and gender distribution of the patients have been depicted in (Table 1,2). The ASA status and CL grading of the patients are depicted in (Table 3). A p-value  $< 0.05$  is considered statistically significant. In group U, thirty patients were intubated with uncuffed ETT of size 3.5, and twenty were intubated with uncuffed ETT of size 3.0. However, 12/50 (24%) patients of group U had to undergo tube exchanges. Seven patients who were initially intubated with size 3.0 had excessive leakage; therefore, tube size was upsized to 3.5.

Five patients who were intubated with a 3.5-sized tube had no leak as per the leak test; therefore, the tube was downsized to size 3.0 to have a permissible leak to prevent injury to the subglottis. Desaturation was seen in 10/50 (20%); four (8%) had transient desaturation immediately after extubation, which was managed with CPAP of 10-20 cm of water and 100%  $O_2$ . Six (12%) with persistent desaturation developed post-extubation stridor, which was treated with CPAP along with inj. dexamethasone (0.1 mg/kg) and adrenaline nebulizations (3 ml of 1:1000).

All the patients were relieved with the above-mentioned modalities and did not require reintubation and mechanical ventilation (Table 4). In group M, all 50 patients were intubated with a size 3.0 microcuff ETT. After performing a leak test, 30/50 (60%) patients required cuff inflation to have a permissible leak.

**Table 1- Demographic profile of recruited patients**

	Group U (Mean $\pm$ SD)	Group M (Mean $\pm$ SD)	P value
Age (days)	29.33 $\pm$ 20.19	28.8 $\pm$ 21.08	0.9
Weight (kg)	2.86 $\pm$ 0.67	2.79 $\pm$ 0.53	0.655
Surgery Duration (hr)	2.02 $\pm$ 0.5	2.11 $\pm$ 0.57	0.518

**Table 2- Gender distribution between Group U and Group M**

Gender	Group U	Group M	P value
Male	30/50=60%	27/50=54%	0.53
Female	20/50=40%	13/50=46%	

P value $<0.05$  is considered statistically significant.

**Table 3- ASA status and CL Grading of Group U and Group M**

ASA STATUS	Group U	Group M	P value
2	15/50 (30%)	13/50 (26%)	0.318
3	27/50 (54%)	20/50 (40%)	
4	8/50 (16%)	17/50 (34%)	
CL GRADING			
2a	32/50 (64%)	24/50 (48%)	
2b	15/50 (30%)	23/50 (46%)	

3a	3/50 (6%)	3/50 (6%)
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P value<0.05 is considered statistically significant, ASA: American Society of Anesthesiologists, CL: Cormack-Lehane

Ten of 16/50 (32%) patients did not require cuff inflation, as ventilation was adequate with a permissible leak in the deflated state of the cuff. And four 4/50 (8%) patients required a tube exchange, as there was no leak even with the deflated cuff. These four patients were intubated with an uncuffed ETT of size 3.0, and a permissible leak was established.

Desaturation was observed in five (10%) patients; it was transient in 4 patients, while one (2%) patient developed post-extubation stridor, managed conservatively with the same protocol. No patients in either group developed laryngospasm, bronchospasm, or soft tissue obstruction (Table 4).

**Table 4- Statistical Data of Group U and Group M**

	Group U	Group M	P value
Stridor	6/50 (12%)	1/50 (2%)	0.02
Tube exchange	12/50 (24%)	4/50 (8%)	0.02
Cuff Inflation	NA	30/50 (60%)	-
Laryngospasm	0/50	0/50	-
Bronchospasm	0/50	0/50	-
Desaturation	10/50 (20%)	5/50 (10%)	0.16

P value<0.05 is considered statistically significant.

## Discussion

The comparison of the number of patients who required ETT exchanges between both groups was found to be statistically significant ( $p=0.02, < 0.05$ ). In Group U, tube exchanges were done either due to excessive leak or no permissible leak, which depicts the difficulty in estimating and achieving an optimal tube size with uncuffed tubes.

Similarly, a significantly lower rate of tube exchanges in the cuffed ETT group as compared to the uncuffed ETT group has been reported in literature [7-8]. Tube exchanges, when performed multiple times, can lead to trauma to the airway mucosa, airway edema, and heightened chances of post-extubation stridor.

The increased likelihood of incorrect tube sizing associated with group U resulted in a higher incidence of tube exchange, airway manipulation, and repeated intubations, which in turn contributed to the higher rate of desaturation, post-extubation stridor, and the need for CPAP in this group.

On the other hand, in group M, 60% of patients required cuff inflation, whereas 32% did not require cuff inflation, as adequate ventilation was achieved with the deflated cuff itself; hence, highlighting the flexibility and adaptability of the microcuff ETT in achieving optimal ventilation and limiting tube exchanges. This reduced

need for tube exchanges in group M contributed to fewer airway-related complications.

This observation highlights the ability of microcuff ETTs to provide a better fit and seal, hence reducing tube readjustments. Microcuff ETTs may also help in reducing the time and resources spent on reintubation or tube size adjustments.

This could be particularly beneficial in settings where time-sensitive interventions are required, such as in neonates with unstable respiratory conditions.

Post-extubation stridor is a well-known complication of intubation, particularly in neonates and young infants, where the airway is more prone to trauma from the ETT cuff or the tube itself. We found a statistically significant difference in the incidence of post-extubation stridor between GpU and GpM ( $p = 0.02, < 0.05$ ).

Microcuff ETTs have softer polyurethane cuffs and lower inflation pressures (typically around 11 cm H<sub>2</sub>O), are designed to minimize airway trauma, and their cylindrical shape better conforms to the larynx [1]. This contrasts with the uncuffed ETT, which may cause more localized pressure and mucosal damage, especially when the tube size is suboptimal.

Also, the cuff of the microcuff ETT can be inflated to optimize ventilation without doing repeated laryngoscopies and airway manipulation. Studies comparing microcuff and uncuffed ETTs for post-extubation stridor have found similar rates in both groups [6,8].

However, these studies included pediatric patients of a wider age range hence, the stridor rates associated with the two types of tubes were similar to each other. Our study focused specifically on children  $\leq 3$  months, who are more prone to airway trauma from repeated airway manipulation and laryngoscopy hence, the incidence of post-extubation stridor is not similar in the two groups. It is worthwhile to mention here that all the patients in group U who developed stridor had more intubation attempts and had to undergo tube exchange to a 0.5 size smaller. Interestingly, one study reported a higher incidence of post-extubation stridor (17.2%) in the microcuff ETT group [5].

However, this study focused on neonates with prolonged ventilation in the neonatal ICU, suggesting that prolonged intubation, rather than the type of tube, may have contributed to a higher incidence of stridor in their study. Our study included children who required short-term intubations for administering general anesthesia and did not require postoperative ventilation.

There was no statistically significant difference in desaturation between both the groups. This could be due to unique pediatric respiratory physiology and increased oxygen consumption; there can be inadvertent

desaturation during extubation, and it does not depend on the type of ETT used [1].

Desaturation after extubation can also occur due to several factors, including airway obstruction, inadequate plane of anesthesia, poor mask seal, or insufficient oxygen delivery [6]. The mean weight of infants was  $2.86 \pm 0.67$  kg in Group U and  $2.79 \pm 0.53$  kg in Group M. It is worthwhile to mention that 12 patients in Group M had weights between 2 and 2.5 kg, out of which only one patient required tube exchange. So, microcuff ETTs can be safely used even in children below 3 kg, consistent with a retrospective audit [9].

The other PRAEs, including laryngospasm, bronchospasm, coughing, and soft tissue airway obstruction, were not encountered in any of the patients of the two groups. It could be due to the fact that the sample size of our study was too small, and studies with larger sample sizes may be needed for the same. Several limitations that must be considered: Firstly, it was a single-center study with a relatively small sample size.

The findings, though statistically significant, may not be generalizable to all institutions or populations. Further multi-center randomized controlled trials (RCTs) with larger sample sizes should be done to confirm these results.

Secondly, infants who required postoperative ventilation, underwent airway surgeries in the prone position, were syndromic children, or underwent airway surgeries and TEF repair were not included in this study.

Thirdly, long-term airway outcomes, such as the potential for tracheal stenosis or vocal cord injury, could not be evaluated. Thirdly, although randomization was done, there may have been the possibility of bias in clinical decision-making regarding tube selection. Fourthly, patients with post-conceptual age of more than 37 weeks were included; further studies may be required to confirm its efficacy in preterm neonates.

## Conclusion

Microcuff ETTs are associated with a lower incidence of tube exchanges and post-extubation stridor as compared to uncuffed ETTs in children up to three months of age. These findings highlight the potential

advantages of using microcuff ETTs for neonatal and infant airway management, particularly in terms of reducing airway injury and optimization of intubation.

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