

## Safety and Efficacy of Cuffed and Uncuffed Endotracheal Tube in Paediatric Patients

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### Abstract

### Original Research Article

Uncuffed endotracheal tubes (UETTs) are traditionally used for intubation in all children under 8 years of age, irrespective of the indication and duration of intubation, which has its own pros and cons. The recently developed cuffed endotracheal tube is called the Microcuff<sup>®</sup>, which has been specifically designed for use in paediatric anaesthesia. We studied the clinical performance of paediatric Microcuff<sup>®</sup> ETT with uncuffed ETT. Sixty patients undergoing lower abdominal surgery of duration more than 1 hour, of ASA I and ASA II status with age between 1-5 years were divided into two groups. Group 1-Cuffed tubes and Group 2-Uncuffed tubes. Microcuff<sup>®</sup> ETT and Uncuffed ETT were inserted after anaesthesia and adequate muscle relaxation. The parameters like number of ETT exchanges, ventilatory efficacy, requirement of anaesthetic agent and post-operative adverse events were noted. The number of attempt did not differ significantly between two study groups. The mean FGF (O<sub>2</sub> and N<sub>2</sub>O) was found to be significantly higher in Uncuffed ETT (2.76 L) compared to Cuffed ETT (2.18 L) which was statistically significant. The mean EtCO<sub>2</sub> of Cuffed ETT was lower (33.80 mmHg) than that of Uncuffed ETT (37.60 mmHg). Mean total amount of sevoflurane used in Cuffed ETT was 9.43ml as opposed to 17.74ml in Uncuffed ETT, the difference was statistically significant. Advantages of the Microcuff<sup>®</sup> endotracheal tube in this population, therefore would be constant minute ventilation, precise respiratory monitoring and capnography, low fresh gas flow and lesser risk of pulmonary aspiration.

**Keywords:** Uncuffed ETT, Microcuff<sup>®</sup> ETT, HVLP Cuff, EtCO<sub>2</sub>, Sevoflurane.

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## INTRODUCTION

Uncuffed endotracheal tubes (UETTs) are traditionally used for intubation in all children under 8 years of age, irrespective of the indication and duration of intubation [1]. Disadvantages of uncuffed tubes include air leak, difficulties in effectively ventilating patients with lung disease, environmental contamination of anaesthetic gases, risk of aspiration and difficulty in accurate measurement of End Tidal carbon Dioxide (EtCO<sub>2</sub>) concentration [2].

For a long time, the Cuffed Endotracheal Tube (CETT) was not recommended by most paediatric anaesthetists for children younger than 5-8 years. Primarily because the diameter of a CETT had to be 1-2 sizes smaller than the uncuffed tube. Hence in spontaneously breathing children the flow resistance and the work of breathing would be drastically increased. The second reason was the earlier reports of airway morbidity caused by poor design and material of earlier CETT [3]. Recent studies using magnetic

resonance imaging (MRI) scans postulated that the CETTs with low pressure, high volume cuff will seal the airway at the upper trachea where the posterior membranous wall can stretch and produce a complete seal with low cuff pressure of <15 cm H<sub>2</sub>O without any increase in airway complications [1].

Recently developed cuffed endotracheal tube called the Microcuff<sup>®</sup> has been specifically designed for use in paediatric anaesthesia. This tube consists of an ultra-thin polyurethane cuff (10 µm), which does not form folds and channels between the cuff and the tracheal wall. The Murphy's eye has been eliminated, which has allowed the cuff to be moved more distally on the CETT shaft. The cuff is short and when inflated, it expands below the sub-glottis, providing a seal with cuff pressure less than 10 cm H<sub>2</sub>O [1].

It is a high volume-low pressure (HVLP) cuff which allows a more effective tracheal seal at pressures below those known to cause tracheal mucosal pressure

necrosis. This latter feature more reliably places the cuff below the non-distensible cricoid ring and theoretically reduces the chance of an accidental main bronchus intubation.

We compared the clinical performance of the Paediatric Microcuff<sup>®</sup> with uncuffed ETT in anaesthetized patients on controlled ventilation, undergoing elective surgical procedures with respect to; number of ETT exchanges, ventilatory efficacy, requirement of anaesthetic agent and post-operative adverse events like change in voice, change in cry, cough, laryngospasm, stridor etc.

## MATERIALS AND METHODS

After ethical committee approval, the study was conducted at the attached tertiary care teaching hospital from September 2016 till January 2018.

- Study design –The study was Prospective Randomized Comparative study.
- Consent- A written informed consent was taken from each parent, in the language he or she understands.
- Selection of patients
  - Sample Size: Our study included 60 patients belonging to ASA I/II.
  - Sampling Technique: They were randomly divided by chit method into 2 groups of 30 each. Namely Group 1 and Group 2.
    - Group 1 received cuffed tubes: 30 patients.
    - Group 2 received Uncuffed tubes: 30 patients.

### Inclusion criteria

All patients within age of 1 year to 5 years, ASA I/II grades, undergoing elective and emergency surgical interventions in supine position, requiring oro-tracheal intubation as a part of their anaesthetic care with controlled ventilation of 1 or >1 hour and planned extubation after the procedure in the operating theatre.

### Exclusion criteria

- Known airway anomalies
- Known or suspected difficult intubation
- Surgery of the larynx and/or of the trachea, neck, and/or upper oesophagus
- Planned postoperative ventilation in the ICU

### Methodology of study

- All patients were asked to fast atleast 4 hours prior to the surgery/procedure.
- Inj.Glycopyrrolate 0.004mg/kg IV, Inj.Midazolam 0.02mg/kg or Inj.Ketamine 1mg/kg were administered IV to the patient 20 minutes prior to surgery.
- Baseline parameters like Peripheral oxygen saturation (SPO<sub>2</sub>), ECG, heart rate, non-invasive blood pressure was noted.

- Standard Anaesthesia protocol was followed. Neuromuscular block was achieved with Inj. Vecuronium 0.08 mg/kg.
- Once adequate depth was achieved, in Group 1, Cuffed endotracheal tube and in Group 2, Uncuffed Endotracheal tube was inserted by an experienced Anaesthesiologist.
- Cuffed ETTs sizes were selected as follows. 3.5mm for 8 months to 2 years, 4mm for 2-<4 yrs, 4.5mm 4-<6 years. Uncuffed ETT sizes were selected as follows 3mm for 6months to 1 year, 3.5/4mm for 1-2years, 4/4.5mm for 2-4 years, 4.5/5mm for 4-6 years [4].
- Tracheal intubation was performed under direct laryngoscopy and ETT insertion depth was managed by following criteria, according to depth markings on cuffed ETT and for uncuffed; 8-10cm for 6 months to 1 year, 11cm for 1 year, 12cm for 2 years, 15 cm for 6 years. If there was resistance to passing a tube, a tube one size smaller was selected [5].
- Air leak pressure after intubation was tested with the patient supine and the head in the neutral position. An audible air leak at the patient's mouth had to be present at ≤10 cm H<sub>2</sub>O positive inflation pressure in uncuffed ETTs and in cuffed ETTs with the cuff fully deflated. If an audible leak is present at 10cm H<sub>2</sub>O pressure, both ETT will be exchanged with a one size bigger tube. Also the number of attempts of ETT exchange was noted.
- Cuff of Microcuff<sup>®</sup> ETT was inflated with air to 10 cm of H<sub>2</sub>O pressure and maintained at this pressure throughout anaesthesia using a cuff pressure monitor. Both the devices were fixed by taping the tube over the chin and was connected to ventilator (Mindray, Wato™ EX-30/Wato™ EX-55, Shenzhen Mindray Biomedical Electronics Co. Ltd., Germany).
- Maintenance was achieved by oxygen with nitrous oxide, sevoflurane and intermittent doses of intravenous Inj.Vecuronium. Intra operative heart rate, non-invasive blood pressure, oxygen saturation and end tidal carbon dioxide, inhalational agent concentration, cuff pressure by using cuff pressure monitor was recorded every 15 minutes throughout the procedure.
- Fresh Gas Flow (FGF) – after initial FGF of 3+3 Litres (O<sub>2</sub>+N<sub>2</sub>O) for 15 minutes, it was decreased to 1+1 Litres. Then it was adjusted / increased to keep EtCO<sub>2</sub> within acceptable range of 35-45 mm Hg.
- Requirement of inhalational agents was judged by haemodynamic parameters with the aim to maintain parameters within acceptable limits.
- The tidal volume was set at 10ml/kg body weight and Respiratory Rate was set to achieve the desired minute ventilation.
- All patients received caudal epidural block as standard anaesthesia care.

- At the end of surgical procedure anaesthesia was discontinued, neuromuscular blockade was reversed with Inj. Neostigmine 0.04 mg/kg and Inj. Glycopyrrolate 0.01mg/kg intravenously and the device was removed. Blood staining of the device, tongue, lip and dental trauma was recorded.
- Duration of intubation, occurrence of laryngospasm and post-extubation stridor was recorded.
- Post-extubation stridor is defined as any new high pitched inspiratory sound after 1 hour. Patients were assessed after regaining of full consciousness and again after 6 hours, 12 hours, 24 hours to assess pharyngo-laryngeal morbidity (Cough, change in cry, change in voice).
- The following formula was used for calculating the volume of liquid Sevoflourane [6].

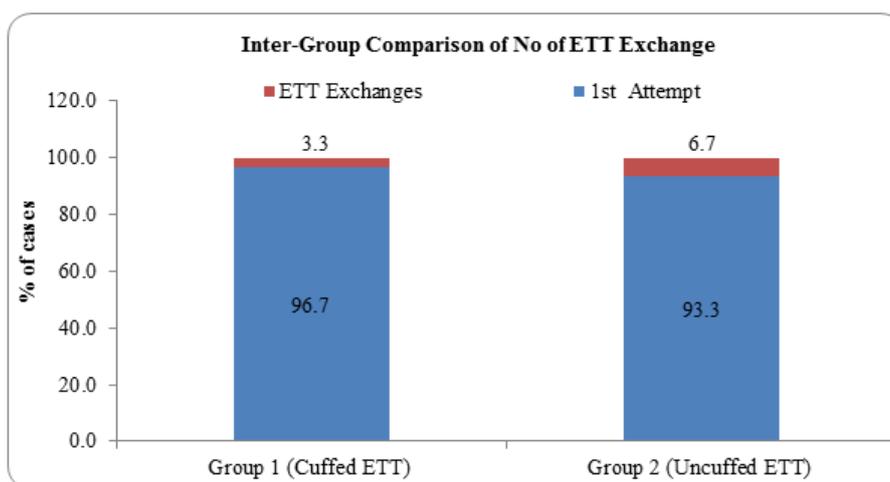
$$A=C \times FGF \times 60/20$$

- A-amount of liquid volatile used (ml/h)
- C- Concentration of volatile agent (%)
- FGF-Fresh gas flow (l/min)
- 60- Conversion factor for minutes to provide hourly consumption.
- 20-Conversion factor for approximation of vapour to liquid volume.
- The entire data is statistically analyzed using Statistical Package for Social Sciences (SPSS ver 21.0, IBM Corporation, USA) for MS Windows. The inter-group comparison of categorical variables is done using Chi-square test

### OBSERVATIONS & RESULTS

**Table-1: Demographic data**

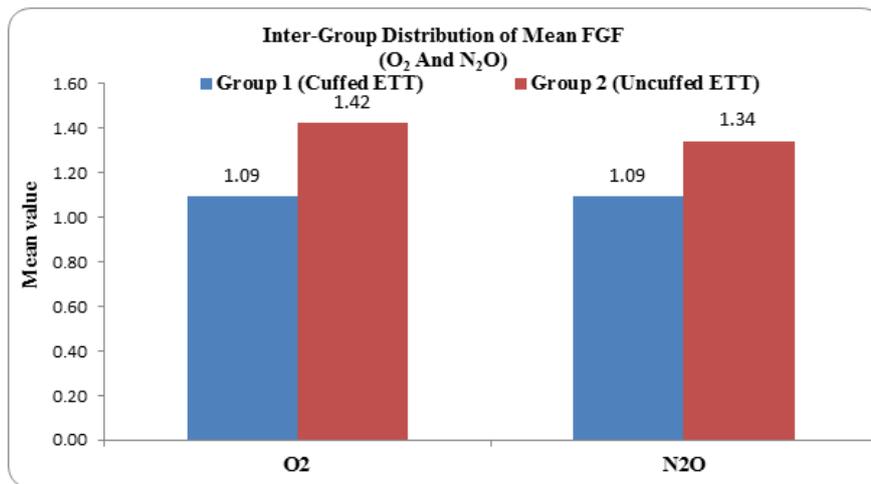
Mean variables	Group 1 (Cuffed ETT)	Group 2 (Uncuffed ETT)	p-value
Age (years)	2.48	2.80	0.284 <sup>NS</sup>
Weight (kg)	13.00	12.80	0.73 <sup>NS</sup>
Sex			
Male	27	29	0.612 <sup>NS</sup>
Female	3	1	



**Graph-2: Inter-group comparison of no. of ETT exchanges among the cases studied**

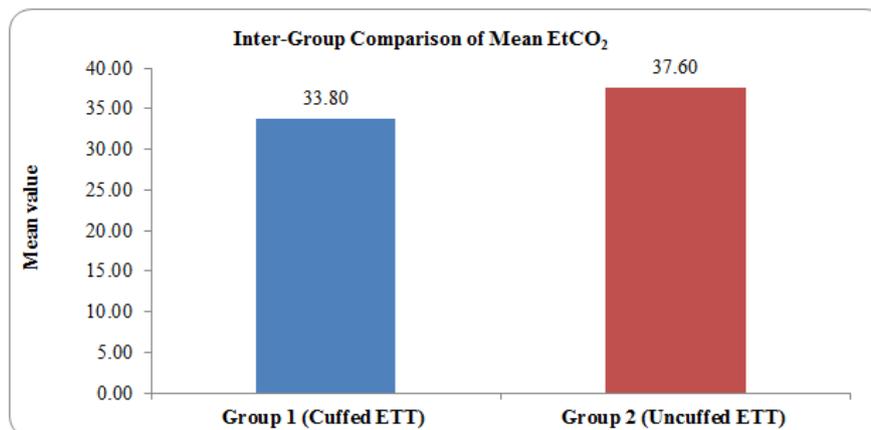
- Demographic data were comparable in both the groups

- The distribution of no. of attempt did not differ significantly between two study groups (P-value>0.05).



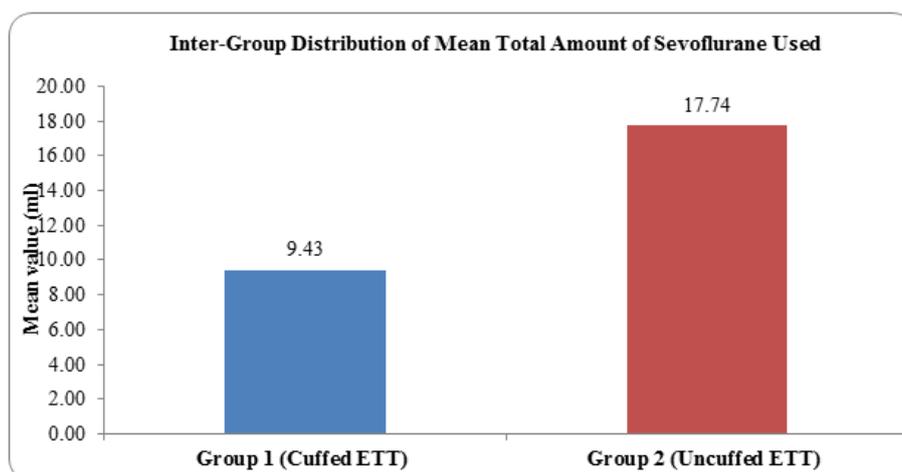
**Graph-3: Inter-group comparison of mean FGF (O<sub>2</sub> and N<sub>2</sub>O)**

- The mean ± SD of FGF (O<sub>2</sub>+N<sub>2</sub>O) in Group 1 and Group 2 cases was 2.18 ± 0.38 and 2.76 ± 0.41 respectively.
- The distribution of mean FGF (O<sub>2</sub>+N<sub>2</sub>O) is significantly higher in Group 2 (Uncuffed ETT) compared to Group 1 (Cuffed ETT) (P-value<0.001).



**Graph-4: Inter-group comparison of mean EtCO<sub>2</sub> of cases studied**

- The mean ± SD of EtCO<sub>2</sub> in Group 1 and Group 2 cases was 33.80 ± 1.90 and 37.60 ± 3.56 respectively.
- The distribution of mean EtCO<sub>2</sub> of cases studied is significantly higher in Group 2 (Uncuffed ETT) compared to Group 1 (Cuffed ETT) (P-value<0.001).



**Graph-5: Inter-group comparison of mean total amount of sevoflurane used**

- The mean  $\pm$  SD of total amount of sevoflurane used in Group 1 and Group 2 cases was  $9.43 \pm 3.46$  ml and  $17.74 \pm 7.16$  ml respectively.
- The distribution of mean total amount of sevoflurane used is significantly higher in Group 2 (Uncuffed ETT) compared to Group 1 (Cuffed ETT) (P-value<0.001).

## DISCUSSION

- The basic function of a tracheal tube is to provide a reliable connection between the patient's lung and the bag or ventilator. Microcuff<sup>®</sup> endotracheal tube is specifically designed for the paediatric airway anatomy. Intubation depth marks and short cylindrical cuff near tracheal tube tip allow adequate placement with a cuff-free subglottic zone, without the risk of endobronchial intubation [7].
- In our prospective randomized control study, sixty patients between the age of 1-5 years of ASA I and ASA II category were posted for elective and emergency surgeries under controlled ventilation in various surgeries like herniotomy, hypospadias repair, orchidopexy, pyeloplasty, cystoscopy, PSARP, circumcision etc.
- Sixty patients were divided into two groups, Cuffed ETT and Uncuffed ETT.
- We compared cuffed endotracheal tubes (Microcuff<sup>®</sup>) with uncuffed endotracheal tubes with respect to number of ETT exchanges, ventilatory efficacy, requirement of anaesthetic agent and post-operative adverse events like change in voice, change in cry, cough, laryngospasm, stridor etc. in children undergoing surgery of duration 1 hour and more.
- The number of attempt did not differ significantly between two study groups. Dullenkopf *et al.* found a very low rate of tube exchange (1.6%) as well as a very low rate of airway morbidity (croup requiring therapy, 0.4%) in patients intubated with Microcuff<sup>®</sup> endotracheal tubes [8].
- The mean FGF (O<sub>2</sub> and N<sub>2</sub>O) was found to be significantly higher in Uncuffed ETT (2.76 L) compared to Cuffed ETT (2.18 L) in our study in order to attain acceptable level of EtCO<sub>2</sub>. Similar study conducted by Khine *et al.* found that the lungs of patients with cuffed tubes were adequately ventilated with 2 l/min fresh gas flow, whereas 11% of those with uncuffed ETT needed greater FGF [9].
- Also, the mean total amount of sevoflurane used in Cuffed ETT was less (9.43ml) than in Uncuffed ETT (17.74ml). A similar study conducted by Schmitz A *et al.* were also comparable to our findings in which lowest possible fresh gas flow and Sevoflurane concentration were used in Microcuff<sup>®</sup> ETT [10]. Similarly Chand R *et al.* also found significant lower consumption of anaesthetic gases in their studies [11].
- The mean EtCO<sub>2</sub> of Cuffed ETT was lower (33.80 mmHg) than that of Uncuffed ETT (37.60 mmHg). For the purpose of our study, effective ventilation meant a square wave capnogram as found in patients with cuffed ETT, with EtCO<sub>2</sub> values in the clinically acceptable range of 35–45 mm Hg and ability to ventilate with low flow (<2 L/min). Our findings were comparable to the results of Rameshwar Mhamane *et al.* who also studied the appropriateness of ETT size selection, sealing pressure, ability to ventilate with low flow, quality of capnography and post-extubation laryngospasm or stridor in patients intubated with Microcuff<sup>®</sup> ETT [12].
- Advantages of the Microcuff<sup>®</sup> endotracheal tube in this population, therefore, would be constant minute ventilation, precise respiratory monitoring and capnography, low fresh gas flow and lesser risk of pulmonary aspiration.
- Selection of an appropriately-sized cuffed endotracheal tube is important to prevent airway mucosal injury.
- We were able to intubate the trachea without resistance in all patients, confirming the

appropriateness of the size selection recommendations.

- None of our patients had post-operative adverse effects due to ETT use. Larger study is required to see adverse effects.

### Limitations

- The study was conducted in small sample size and in surgeries of shorter duration.
- High cost of the Microcuff® ETT compared to uncuffed ETT. Though the cost of Microcuff tube was more than uncuffed ETT, this can be compensated with less use of anaesthetic gases and fresh gas flow.
- We could not assess the amount of operation room contaminant gases in our study due to unavailability of appropriate equipment.

### CONCLUSIONS

- Tracheal sealing with a cuffed tube is a much more logical way of obtaining a leak proof link between the anaesthesia machine and the patient.
- The gap between a deliberately smaller tube and the trachea is filled by a cuff inflated to a cuff pressure of 20 cm H<sub>2</sub>O.
- The new Microcuff® paediatric tube has been designed and tested to fit the dimensions of the paediatric airway, to seal at cuff pressures below 20 cm H<sub>2</sub>O and to allow precise positioning due to clear and correct depth markings.
- Acceptable EtCO<sub>2</sub> with low flow anaesthesia can be achieved with plateau type of graph with Microcuff® ETT.
- The requirement FGF and anaesthetic agent was found significantly less in Microcuff® tubes as compared to uncuffed endotracheal tubes.
- The increased cost of the cuffed tracheal tube can be compensated by a lower cost of sevoflurane consumption. In addition, there are further savings due to reduced consumption of oxygen and nitrous oxide as well as reduced indirect costs due to primary success of intubation.
- Reliable seal of airway and less environmental pollution by the use of cuffed tracheal tubes.
- With such an endotracheal tube paediatric anaesthesiologists can safely switch to cuffed tubes in infants and small children.

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