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A clinical comparative study of Microcuff Paediatric Tracheal tube v/s Uncuffed Endotracheal tubes in Paediatric patients undergoing Abdominal surgeries.

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ABSTRACT:
Introduction: The use of cuffed versus uncuffed endotracheal tubes in pediatric anesthesia is debated. Microcuff tubes are designed to provide an effective seal with minimal cuff pressure. This study compares the performance and safety of microcuff versus uncuffed tubes in children undergoing abdominal surgeries.

Methods: In a randomized trial, 70 children aged 1-8 years were assigned to receive either a microcuff (Group M, n=35) or an uncuffed (Group U, n=35) endotracheal tube. Primary outcomes included ease of intubation, tidal volume leaks, and post-operative complications. Secondary outcomes included ventilation parameters and cuff pressure monitoring.
Results: Intubation ease was similar between groups. Group M had significantly fewer tube exchanges (0% vs. 11.4%, p=0.114) and throat pack requirements (0% vs. 22.9%, p=0.005). Air leaks were higher in Group U (p=0.01). No significant differences were found in oxygenation, ventilation, or post-operative complications.
Conclusion: Microcuff tubes demonstrated advantages over uncuffed tubes, including fewer air leaks and reduced throat pack usage, without compromising safety or ventilation. Microcuff tubes are a safe and effective alternative for pediatric abdominal surgeries, though further research is needed.

INTRODUCTION:-

Endotracheal intubation and mechanical ventilation are essential components of general anaesthesia for various surgical procedures in the paediatric population. Ensuring a secure airway and adequate ventilation is crucial for maintaining patient safety and optimizing surgical outcomes.[1] However, the use of endotracheal tubes (ETTs) in paediatric patients poses unique challenges due to the anatomical and physiological differences compared to adults.[2]

Traditionally, uncuffed ETTs have been the preferred choice for paediatric airway management, as they were believed to minimize the risk of airway complications, such as post-extubation stridor, subglottic stenosis, and mucosal injury.[3][4] The absence of a cuff in these tubes is thought to reduce the potential for excessive pressure on the delicate tracheal mucosa, thereby reducing the risk of ischemic injury. However, uncuffed ETTs have their own limitations, including the potential for air leaks, difficulty in maintaining adequate ventilation, and the risk of aspiration.[5]

In recent years, the introduction of microcuff paediatric ETTs (Cuffed endotracheal tubes- CETT) has offered an alternative approach to paediatric airway management.[6] These tubes feature a thin, high-volume, low-pressure (HVLP) cuff designed to seal the airway at lower pressures, potentially reducing the risk of mucosal injury while maintaining adequate ventilation and preventing aspiration.[7] Several studies have investigated the efficacy and safety of microcuff paediatric ETTs, with some suggesting potential advantages over uncuffed tubes in terms of improved ventilation and reduced air leaks.[8][9] To ensure proper placement in the subglottic zone without the risk of endobronchial intubation, intubation depth markings and a small, cylindrical cuff near the tracheal tube tip is helpful.[10]

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Despite the increasing adoption of microcuff paediatric ETTs in clinical practice, there remains a paucity of high-quality, comparative studies evaluating their performance against traditional uncuffed ETTs in specific surgical settings. Abdominal surgeries in paediatric patients often involve long duration, changes in patient positioning, and the potential for increased abdominal pressure, which may impact airway management and ventilation requirements.[11]

We aimed to conduct a clinical comparative study to evaluate the performance of microcuff paediatric ETTs versus uncuffed ETTs in paediatric patients undergoing abdominal surgeries. By assessing key outcomes such as ventilation parameters, airway complications, and postoperative complications, this research endeavours to provide valuable insights into the relative merits and potential drawbacks of each tube type in this specific surgical context.

MATERIAL AND METHODOLOGY:-

This prospective, randomized, comparative study was conducted at the Department of Anaesthesiology, Dr. D. Y. Patil Medical College, Pune, from August 1, 2022, to July 31, 2024, after obtaining ethical committee clearance I.E.S.C./403/2022.

Seventy pediatric patients undergoing elective abdominal surgeries under general anesthesia were randomized into two groups: one using microcuff endotracheal tubes (Group M) and the other using uncuffed endotracheal tubes (Group U).

Inclusion criteria included ASA grade I or II fit patients, ages between 1 to 8 years of either sex, patients undergoing elective pediatric abdominal surgeries, acceptance of study and signing informed consent from the parent.

Exclusion criteria included patients with ASA physical status III or more, patients posted for emergency procedures, patients with increased risk of aspiration GERD/ hiatus hernia/previous gastric surgery, patients with history of lung disease neck pathology, facial anomalies or URI, children with known/predicted difficult airway.

Mean (standard deviation) cuff pressure was found to be 11.2 (1.9) in WinPepi software taking the acceptable difference of 0.7 at 95% confidence level, sample size comes to 35. Similar number of participants were taken for other group. So total number comes to 70 [12].

PLAN OF STUDY:

Institutional ethics committee approval was taken prior to the commencement of the study. 70 patients undergoing elective paediatric surgeries were selected randomly after applying already mentioned stringent inclusion and exclusion criteria.

Group M – Microcuff ETT was used.
Group U – Uncuffed ETT was used.
Formula for calculating ETT:

UNCUFFED ETT-

Age < 6 years - $\frac{age}{3} + 3.5$

Age > 6 years - $\frac{age}{4} + 4.5$

CUFFED ETT-

Khine formula– $\frac{age}{4} + 3$

Motoyama formula– $\frac{age}{4} + 3.5$

In newborns to infants <1 year, ID 3.0 mm CETT and in children from 1-2 years, ID 3.5 mm CETT was used.

METHODOLOGY:

All patients were thoroughly evaluated pre-operatively. The entire necessary and relevant laboratory and other investigations were carried out. In the pre-operative room, the patient's pulse, blood pressure, SpO2 and heart rate were taken, with the patient lying comfortably in supine position.

During pre-anaesthetic assessment, a detailed history and examination of each patient was carried out to optimize them prior to surgery. An informed written consent was taken from the parents. All the patients were kept fasting for 6 hours. In the operating room, all monitors were attached to patients such as pulse oximeter, ECG and non-invasive blood pressure cuff. A wide bore 22 or 24 G intravenous line was established. Intra–operatively end tidal carbon dioxide ($ETCO_2$) was monitored.

The patients were pre-medicated with intravenous Glycopyrrolate 0.004 mg/kg, Ondansetron 0.1 mg/kg, and Midazolam 0.02 mg/kg, fentanyl 2 mcg/kg and were pre-oxygenated with 100%oxygen . General anaesthesia was induced with Propofol 2 mg/kg and Atracurium 0.5 mg/kg. After induction, appropriate size of Microcuff tube was used in M group and appropriate size uncuffed ETT was used in U group. Same anaesthesiologist inserted Microcuff or Uncuffed ETT in all the 70 cases. Ease of insertion of tube was graded. Anaesthesia was maintained with sevoflurane (0.6 - 1) in 60% N_2O / 40% O_2 mixture. Controlled mechanical ventilation was applied to maintain end tidal CO_2 between 30-40 mm of Hg.

All ventilatory parameters such as inspiratory TV, expiratory TV, leak and ETCO2 graph were monitored. We took into consideration the cuff pressure, ease of passage of tube, requirement of throat pack, tube exchange rates etc. For patients who had tidal volume leak more than 10 but less than 20, throat pack was done and with patients who tidal volume leak more than 20, tube exchange was done. After procedure, reversal was done by using Inj. Neostigmine 0.05 mg/kg and Inj. Glycopyrrolate 0.008 mg/kg. Post-operative complications such as stridor, cough, change in voice, pitch were watched for.

CLINICAL PARAMETERS MONITORED

Monitoring was done for following parameters:

1. Ease of passage of tube, graded as
   - Easy to pass -1
   - Difficult to pass - 2
2. Ventilatory parameters: ETCO2, Peak airway pressure. Tidal volume leak
3. Tube exchange rates
4. Throat pack requirement
5. Cuff pressure
6. Perioperative complications
   - Cough
   - Laryngospasm
   - Bronchospasm
   - Blood on device
   - Aspiration
   - Hoarseness/sore throat

STATISTICAL ANALYSIS

The presentation of the Categorical variables was done in the form of number and percentage (%). On the other hand, the quantitative data were presented as the means ± SD and as median with 25th and 75th percentiles (interquartile range). The data normality was checked by using Shapiro-Wilk test. The following statistical tests were applied for the results:

1. The comparison of the variables which were quantitative in nature were analysed using Independent t test.

2. The comparison of the variables which were qualitative in nature were analysed using Chi-Square test. If any cell had an expected value of less than 5 then Fisher's exact test was used.

The data entry was done in the Microsoft EXCEL spreadsheet and the final analysis was done with the use of Statistical Package for Social Sciences (SPSS) software, IBM manufacturer, Chicago, USA, ver 25.0. For statistical significance, p value of less than 0.05 was considered statistically significant.

RESULTS:-

70 patients who had undergone elective pediatric abdominal surgeries were included in the study and were randomly divided into two groups:-

- Group M:- Microcuff ETT was used
- Group U:- Uncuffed endotracheal tube was used

1. Age, Gender, and Weight: No significant differences between Group M (Microcuff) and Group U (uncuffed) in terms of mean age ($p = 0.255$), gender distribution ($p = 0.811$), or weight ($p = 0.961$).

2. ASA Grade and Ease of Passage: Comparable between groups, with no significant differences in ASA grade ($p = 0.232$) or ease of passage ($p = 0.71$).

3. Tube Exchange and Throat Pack:
   - Tube Exchange: Significantly lower in Group M (0%) compared to Group U (17.14%) ($p = 0.025$).

Table no.1 Comparison of tube exchange between group M and U.

Tube exchange	Group M(n=35)	Group U(n=35)	Total	P value
No	35 (100%)	29 (82.86%)	64 (91.43%)	0.025*
Yes	0 (0%)	6 (17.14%)	6 (8.57%)	
Total	35 (100%)	35 (100%)	70 (100%)	

* **Fisher's exact test**

- Throat Pack: Significantly lower in Group M (0%) compared to Group U (22.86%) (p = 0.005).

Table no 2- comparison of throat pack between group M and group U

Throat pack requirement	Group M(n=35)	Group U(n=35)	Total	P value
No	35 (100%)	27 (77.14%)	62 (88.57%)	0.005*
Yes	0 (0%)	8 (22.86%)	8 (11.43%)	
Total	35 (100%)	35 (100%)	70 (100%)	

* **Fisher's exact test**

4. SpO_2 and $EtCO_2$: No significant differences at baseline, 5 minutes, or 10 minutes.

5. Tidal Volumes:

- Leak Volume: Significantly higher in Group U at baseline (p = 0.01), but no significant differences at 5 or 10 minutes. For the uncuffed group, the patients who had leak more than 10 but less than 20, throat packing was done and the patients who had leak more than 20, exchange of tube was done.

Table no 3- Comparison of tidal volume(Leak) mL between group M and U.

Tidal volume(Leak) Ml	Group M(n=35)	Group U(n=35)	Total	P value
At baseline				
Mean ± SD	7.91 ± 1.46	11.51 ± 7.71	9.71 ± 5.8	0.01‡
Median(25th-75th percentile)	8(7-9)	8(6-16)	8(7-9)	
Range	4-10	4-32	4-32	
At 5 minutes				
Mean ± SD	6.34 ± 1.68	6.17 ± 1.36	6.26 ± 1.52	0.64‡
Median(25th-75th percentile)	7(5-8)	6(5-7)	6(5-7)	
Range	4-9	4-9	4-9	
At 10 minutes				
Mean ± SD	5.71 ± 1.49	5.77 ± 1.42	5.74 ± 1.44	0.87‡
Median(25th-75th percentile)	6(4.5-7)	6(5-7)	6(5-7)	
Range	3-8	3-9	3-9	

‡ **Independent t test**

- Inspiratory and Expiratory Volumes: No significant differences between groups at any time point.

Table no 4- Descriptive statistics of cuff pressure(mmHg) in group M.

Variable	Mean ± SD	Median(25th-75th percentile)	Range
Cuff pressure(mm Hg) in group M	9.06 ± 0.8	9(8.5-10)	8-11

6. Peak Airway Pressure and Cuff Pressure: No significant differences at baseline, 5 minutes, or 10 minutes.

7. Post-Operative Complications:

- Early Complications: No significant differences in laryngospasm, bronchospasm, aspiration, or hoarseness.
- Late Complications: No significant differences in cough, sore throat, or hoarseness at 6 and 12 hours; none at 24 hours.

Overall, Group M showed fewer tube exchanges and throat pack needs, with similar safety profiles and post-operative outcomes compared to Group U.

DISCUSSION:-

Endotracheal intubation and mechanical ventilation play a critical role in administering general anesthesia for various pediatric surgeries. Maintaining a secure airway and adequate ventilation is vital for patient safety and enhancing surgical outcomes.[1] However, using endotracheal tubes (ETTs) in pediatric patients presents distinct challenges due to their anatomical and physiological differences from adults.[2]

This study aimed to compare the clinical performance and safety of microcuff paediatric endotracheal tubes versus conventional uncuffed endotracheal tubes in children undergoing abdominal surgeries. The use of cuffed endotracheal tubes in paediatric anaesthesia has been a topic of debate, with concerns over potential complications such as airway injury, mucosal damage, and post-operative respiratory issues. However, recent advances in technology have led to the development of microcuff tubes, which are designed to provide an effective seal while minimizing cuff pressure and associated risks.

Our study evaluated various parameters including ease of intubation, ventilation parameters, tidal volume leaks, and post-operative complications, to assess the relative advantages and disadvantages of microcuff and uncuffed tubes in the paediatric population. The findings of this study contribute to the growing body of evidence on the use of cuffed endotracheal tubes in paediatric anaesthesia practice and provide valuable insights for clinicians in selecting the most appropriate airway management strategy.

A. DEMOGRAPHIC PROFILE:

In each group 35 patients were selected after considering inclusion and exclusion criteria.The patient in both groups did not show any statistically significant differences in demography with respect to their age, sex, weight, ASA grading (p value >0.05). Similarly, the study by Kutemate et al. (2019) does not indicate that the differences in age, sex, weight, and ASA grade between the Microcuff and uncuffed endotracheal tube groups were statistically significant.[12]

B. EASE OF TUBE PASSAGE, REQUIREMENT OF THROAT PACK AND TUBE EXCHANGE:

The ease of passage was similar in both groups, with a majority of patients graded as Grade I, indicating smooth intubation. The proportion of patients who required tube exchange was significantly lower in group M compared to group U (0% vs. 17.14%, respectively) (P value = 0.025). The tube exchange in the uncuffed group due to air leaks was found to be 26% (P value < 0.0003) in the Pooja MN et al.[13] We chose uncuffed tube from a single company in order to get around this. Our study's low rate of Microcuff paediatric tracheal tube exchange (0%), which is statistically significant when compared to uncuffed ETT (p<0.0003).

Our study found a significantly higher requirement for throat packs in the uncuffed group (22.86%) compared to the microcuff group (0%) (p = 0.005).
As a result, the microcuff paediatric tracheal tube was a superior option than the uncuffed ETT, which decreased the frequency of tube exchanges, requirement of throat pack, the need for repeated laryngoscopy attempts, the need for intubation, and the trauma involved.

The primary cause of the uncuffed group's tube exchange is the difficulty in choosing an appropriate sized uncuffed tube from several manufacturers with various outside diameters for the same internal diameter, which can lead to difficulties for paediatric children after extubation. We chose uncuffed tube from a single company in order to get around this.
As a result, the microcuff paediatric tracheal tube was a superior option than the uncuffed ETT, which decreased the frequency of tube exchanges, the need for repeated laryngoscopy attempts, the need for intubation, and the trauma involved.

C. ADEQUACY OF VENTILATION:

The adequacy of ventilation was assessed by five parameters:

1. SPO_2
2. $ETCO_2$
3. Tidal volume leak percentage
4. Peak airway pressure
5. Cuff pressure

1.SPO_2 : OXYGEN SATURATION :
No significant difference was seen in SpO_2(%) at baseline (p value=0.367), at 5 minutes(p value=0.648), at 10 minutes(p value=1) between group M and U.
2.ETCO2:
The ETCO2 levels were comparable between the two groups, at baseline (p value = 0.071), 5minutes(p value=

0.851), 10 minutes (p value= 0.935) suggesting similar ventilation efficacy.

3.TIDAL VOLUME LEAK PERCENTAGE:
Our study found no significant differences in inspiratory (p value= 0.01) and expiratory tidal volumes(baseline p value= 0.67, 5minutes p value=0.83, 10minutes p value= 0.36) between the two groups. However, the tidal volume leak was significantly higher in the uncuffed group, at baseline (p value = 0.01) whereas the p value of leak at 5 minutes and 10 minutes were 0.64 and 0.87 respectively. For the uncuffed group, the patients who had leak more than 10 but less than 20, throat packing was done and the patients who had leak more than 20, exchange of tube was done. Therefore after which the tidal volume leak was comparable between two groups (M and U) at 5 minutes and 10 minutes. This is consistent with the findings of study done by pooja et al,[13] where there was excessive air leak found in 11 patients of the uncuffed group. Similarly the difference in tidal volume leaks between the microcuff and uncuffed groups was statistically significant (P value < 0.01) in the study done by Kutemate PR et al.[12]

4.PEAK AIRWAY PRESSURE:
The peak airway pressures were similar in both groups p value at baseline, 5minutes and 10 minutes being 0.90, 0.19 and 0.78 respectively, which is in agreement with the findings of Weiss et al.[14] who reported no significant differences in peak airway pressures between cuffed and uncuffed tubes.

5. CUFF PRESSURE:
The mean value of cuff pressure (mmHg) in group M was 9.06 ± 0.8, with a median of 9 (8.5-10). In the study done by pooja et al[13] the mean cuff pressure in microcuff ETT group was 9.26 which is in line with our study, whereas in the study done by Nandini et al the mean cuff pressure was 11.72.[15] In 2004, M Weiss, A Dullenkopf, C Gysin, C.M. Dillier, A.C Gerber studied the shortcomings of cuffed paediatric tracheal tubes. They concluded that A better design of cuffed tubes with a short high-volume, low-pressure cuff, cuff-free subglottic space and adequately placed depth markings are urgently needed.[16]

In 2009 December, Weiss M, Dullenkopf A, Fischer JE, Keller C, Gerber concluded that the use of cuffed TTs in small children provided a reliably sealed airway at cuff pressure of < or = 20cm H_2O, reduces the need for TT exchanges.[17]

D. POST OPERATIVE COMPLICATIONS:
The incidence of early post-operative complications, such as blood on the device and cough, was comparable between the two groups . There was blood on device in 2 patients (5.71%) of group M and 3 patients (8.57%) of group U. Cough was found in 2 patients (5.71%) each of group M and U. There was no incidence of laryngospasm, bronchospasm and stridor in both groups. Late post-operative complications such as cough, sore throat, and hoarseness were observed in 2 patients (5.71%) each of group M and U. This could be attributed to the short follow-up period of 24 hours. Post-extubation stridor was observed in 4.4% of patients with cuffed TTs and 4.7% with uncuffed TTs (P=0.543) according to Weiss, M. Dullenkopf, et al.[4] They came to the conclusion that, as compared to uncuffed endotracheal tubes, the use of cuffed ETT in young children did not raise the risk for post-extubation stridor. According to Shi, Fenmei Xiao, et al.[18] in 2016, patients undergoing cuffed tube intubation had a lower TT exchange rate (p<0.00001) and the incidence of post-extubation stridor was not significantly increased by the use of cuffed ETTs. In terms of airway issues, multiple studies have established the safety of the cuffed endotracheal tube—as long as the correct size is used and the cuff pressure is closely maintained.[3,19] Duracher et al. found six cases of problems (dysphonia, hoarse cough, and laryngeal dyspnea) in a trial involving 204 patients, and they linked those cases to the use of an erroneously anticipated bigger tube size.[20] In the Weiss et al. research, the incidence of stridor using a Microcuff® tube was 4.4%.[4]

In 1994 July, Deakers TW, Reynolds G, Stretton M, Newth CJ, studied on cuffed endotracheal tubes in paediatric intensive care. They studied during a 7 month period to compare cuffed and uncuffed ETT utilization and outcome. They concluded that cuffed endotracheal tube intubation is not associated with an increased risk of post extubation stridor and significant long term sequal.[21]

The findings of this study could have significant implications for optimizing paediatric airway management during abdominal surgeries, ultimately contributing to enhanced patient safety, improved surgical outcomes, and potentially reduced healthcare costs associated with airway-related complications. Therefore, we conducted a clinical comparative study of microcuff paediatric tracheal tube v/s uncuffed endotracheal tube in paediatric patients undergoing abdominal surgeries.

CONCLUSION
The study highlights the potential benefits of using microcuff pediatric endotracheal tubes over conventional

uncuffed tubes in children undergoing abdominal surgeries. Microcuff tubes showed lower incidence of air leaks, reduced need for throat packs, and no tube exchanges, suggesting enhanced ventilation efficiency and airway management ease. Differences in oxygenation, ventilation parameters, and early post-operative complications were minimal between groups. Both groups exhibited few late post-operative complications (e.g., cough, sore throat, hoarseness) during the 24-hour follow-up. However, longer-term studies with larger samples are needed to fully assess risks and benefits of microcuff tubes.

Overall, the study supports microcuff tubes as a safe and effective alternative to uncuffed tubes in this context, emphasizing improved airway seal and reduced leaks. Proper cuff pressure monitoring and management protocols are crucial. Optimal tube selection should consider patient factors, surgical needs, and anesthesia team expertise.

LIMITATIONS

In the study, several limitations were noted:

1. Operative Period Only: The study focused exclusively on the operative period and did not include patients who were mechanically ventilated postoperatively.
2. Comparison with Cuffed Endotracheal Tube: The study did not compare Microcuff endotracheal tubes with conventional cuffed endotracheal tubes.
3. Cost Effectiveness: Microcuff endotracheal tubes were found to be not cost-effective.
4. Sample Size: The relatively small sample size limited the ability to draw definitive conclusions regarding postoperative complications.

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