COMPARATIVE STUDY OF CLINICAL EFFECT OF CUFFED VS UNCUFFED ENDOTRACHEAL TUBE IN NEONATES UNDERGOING SURGERY UNDER GENERAL ANAESTHESIA

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ABSTRACT

BACKGROUND

The use of cuffed Endotracheal Tube (ET tube) in neonates is not much popular, because of the fear of airway complications. But this traditional thinking is now changing with cuffed tube becoming more acceptable and popular.

This study was conducted to compare postoperative airway complications and tube exchange rate in neonates intubated with cuffed or uncuffed endotracheal tube.

MATERIALS AND METHODS

Fifty neonates who were undergoing surgery under general anaesthesia with endotracheal intubation were included in this randomised active-controlled single-blinded study. They were randomly allocated into two groups to receive intubation with either cuffed ET tube (Group C, n= 25) or uncuffed ET tube (Group U, n= 25). Data from 23 neonates in each group was available for analysis with the relaxation of study protocol. The tube exchange rate and incidences of postoperative airway adverse events such as hoarse cry, laryngospasm and apnoeic spell were noted in both the groups.

RESULTS

Mean ages of neonates in both groups were comparable (13.5 days and 12.7 days, respectively). The tube exchange rate was considerably less in cuffed tube group compared with uncuffed tube group (4.3% versus 65%, respectively, p= 0.000002). Incidence of postoperative airway adverse events was also found to be significantly less in cuffed tube group compared with uncuffed group (4% versus 43%, respectively, p= 0.00009).

CONCLUSION

The use of cuffed ET tube in neonates reduces the need for tube exchange and reduces postoperative adverse events, such as hoarse cry and apnoeic spell compared with the use of uncuffed ET tube.

KEY WORDS

Neonate, Endotracheal Tube, Intubation, Morbidity, Postoperative Period.

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BACKGROUND

Majority of neonatal and infant surgical procedures are being carried out under general anaesthesia with endotracheal intubation to provide safety and to allow adequate ventilation. Two articles were published as early as in 1965 in the British Journal of Anaesthesia regarding the use of endotracheal intubation in paediatric patients for prolonged ventilation.^[1,2] It reported about the incidence of severe subglottic narrowing in a 2-year-old child ventilated for prolonged period.

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In the very next year (1966), in a seminal article in British Medical Journal, Stocks JG^[3] pointed out the importance of selecting appropriate size of tracheal tube as fundamental to the success of prolonged nasal intubation in children. Later, Battersby et al^[4] concluded that there was no subglottic stenosis from proper use of endotracheal tubes (ET tube) for long-term intubation. Black et al^[5] confirmed this in a study as early as in 1990. Hence, it is very important to choose proper sized ET tube in children requiring mechanical ventilation to reduce post-intubation adverse events.

The loose areolar tissue covering the anterior surface of epiglottis and cricoid is very prone to develop oedema. Any compression to this mucosa by an oversized ET tube may cause mucosal oedema, subsequently fibrosis leading to stenosis. Few of the studies also demonstrated that an oversized ET tube use was associated with development of ductal cysts and scars bridging the vocal cords.^[6] Therefore, uncuffed ET tubes have been used for many years to minimise tracheal and laryngeal injury. However uncuffed tubes have many additional disadvantages, i.e. requirement of multiple

changes to make a complete seal to avoid air leak.^[7] Chance of displacement is also high. Use of throat pack is related to hoarse cry and delayed oral feeding. In addition to this, monitoring of ventilator parameters and exhaled volumes become difficult.^[8] Therefore, a great debate has developed while choosing between cuffed and uncuffed ET tube.

Cuffed tube has not been very popular because of the fear that the cuff would cause airway mucosal injury, leading to subglottic stenosis.^[9-11] Contrary to the previous practice, UK practice has changed now with cuffed tube becoming more acceptable for use in children.^[7] Although, the cuffed ET tube has several advantages, the necessity of costly microcuff, frequent cuff pressure monitoring etc., remain to be prerequisite for ensuring its benefits. Hence, the efficacy of cuffed ET tube in neonatal setting still remains to be a controversial issue. Therefore, this study was conducted to compare the tube exchange rate (Primary outcome), incidence of post-extubation morbidities (Secondary outcome) in neonates, undergoing surgery under general anaesthesia with tracheal intubation with either cuffed or uncuffed ET tube.

MATERIALS AND METHODS

The present randomised active-controlled single-blinded study was designed to compare the ET tube exchange rate between neonates undergoing surgery under general anaesthesia using either cuffed ET tube or uncuffed ET tube. Weiss et al⁸ observed that tube exchange rate was 30.8% with uncuffed tubes, whereas it was only 2.1% using cuffed tubes. Consultation with other literature reveals that the reported incidence of tube exchange rate varies from 25%^[12] to 37.6%^[13] in the uncuffed tubes and 1.97%^[14] to 2.1%^[8] in the cuffed group. Setting the power of study at 80%, Confidence Interval (CI) at 95% and allowing type 1 error of 5%, the estimated sample size was found to be 22.7 for each group using the following formula ($n = 2(Z\alpha + Z\beta)^2 \times [p_1(1-p_1) + p_2(1-p_2)] / (p_1 - p_2)^2$). Considering the possible dropout, we recruited 25 neonates for each group.

Neonates who underwent surgery under general anaesthesia with American Society of Anesthesiologists (ASA) physical status I-II were included in the present study. Both male and female neonates were included. Neonates conforming to ASA physical status more than II with known airway anomalies, known or suspected difficult intubation were excluded from the study. Neonates, who required postoperative ventilation in ICU were also excluded from this study.

The study was initiated after obtaining approval from Institute's Ethics Committee. The study protocol was explained to the legally acceptable guardians to obtain their consent. After getting written consent from guardians, neonates were randomly allocated into two groups for intubation with either cuffed ET tube (Group C, n= 25) or uncuffed ET tube (Group U, n= 25) according to the computer-generated codes (Random numbers). Allocation concealment was achieved by placing the randomisation sequence for each technique (Random numbers) in sequentially numbered sealed opaque envelopes. Each time before the start of anaesthesia, one envelope is opened to get the random number indicating the group.

Standard protocol of induction of general anaesthesia in neonates was followed with inhalation of 6 - 8% sevoflurane

in 100% oxygen. Intravenous access was secured. Precordial stethoscope was used in every case to monitor the ventilation and heart rate. Monitoring of vital parameters such as systolic and diastolic blood pressure (SBP, DBP), heart rate, oxygen saturation, ECG, capnogram and core temperature was performed.

After induction of hypnosis, face mask ventilation was confirmed and thereafter muscle paralysis was achieved with injection atracurium (0.5 mg/kg). Then tracheal intubation was performed under direct laryngoscopy by oral route. All intubations were done by expert paediatric anaesthesiologist.

For premature neonates cuffed ET tubes with internal diameter of 2.5 mm and for mature neonates (more than 2.5 kg body weight), cuffed ET tubes with internal diameter of 3 mm were used. Then the cuff was inflated with the use of cuff pressure manometer (Portex). Cuff pressure was limited to 15 mmHg with the help of pressure release valve. During steady state ventilation, the cuff pressure was gradually reduced until there was an audible leak at the mouth of the neonate. Then the cuff pressure was increased till the disappearance of that leak. The cuff pressure at this moment is called the 'minimal sealing pressure,' which was maintained. This minimal cuff pressure which was required to seal the airway was recorded. Throat packs were given to prevent air leak when uncuffed ET tubes were selected as per study protocol. Lungs were checked for bilateral equal breath sounds and position of the ET tube was confirmed by bilateral equal breath sounds and capnography. Once it is confirmed that a proper sized ET tube has been used in either groups, adequacy of sealing was tested by mechanical ventilation. The tube was secured with adhesive tape. General anaesthesia was maintained according to standard protocol using N₂O:O₂ = 2: 1, sevoflurane (1 - 2%), injection atracurium.

An intraoperative analgesia was provided with injection fentanyl (2 microgram/ kg), paracetamol suppository (15 mg/kg). During intraoperative period, all the vital parameters were assessed. Any need for tube exchange was recorded (Primary outcome).

On completion of surgery, extubation was done after giving antagonist of residual neuromuscular block (Injection neostigmine- 0.05 mg/kg and Injection glycopyrrolate- 0.01mg/kg). Supplementary oxygen was provided in the postoperative period. All neonates were sent to neonatal care unit after extubation. The incidence of hoarse cry, laryngospasm, apnoeic spell, number of episodes of vomiting, time for first oral intake and any other complications in first 24 hours were recorded by an anaesthesiologist who was blinded to group allocation. Incidences of these morbidities were calculated for each group.

Tube exchange rate was taken as primary outcome and incidence of postoperative morbidities such as hoarse cry, laryngospasm and apnoeic spell were considered as secondary outcome measures. In the present study 'cuffed' ET tube (Newer method or Test) has been compared with 'uncuffed' ET tube (Control). As uncuffed ET tube is also a mode of therapy, it is acting as active control. Only the patients (Neonates) were unaware of therapy they received. Owing to the specific design of cuffed or uncuffed ET tube, it was not possible to make the primary investigator blind.

Data were charted on the Excel Workbook (Microsoft Office Home and Student 2007, Microsoft Corporation, One

Microsoft Way in Redmond, WA 98052, USA) and analysed using Statistical Package for the Social Sciences (SPSS) for Windows (version 12.0, SPSS Inc., Chicago, IL, USA). Independent sample t-test (Unpaired t-test) was used to analyse numerical data such as age, weight, duration of surgery and duration of anaesthesia. Fisher's exact test was utilised to analyse categorical data such as tube exchange rate (number of tube exchange required) and incidence of postoperative morbidity such as hoarse cry, apnoeic spell, etc. All statistical tests were two-sided and were performed at a significance level of $p = 0.05$. Hence, a $p < 0.05$ was taken to be of statistical significance.

RESULTS

The study spanned over approximately eight months (From May 2017 to December 2017). Two neonates in cuffed tube group developed laryngospasm immediately after induction with sevoflurane. This stormy induction was managed accordingly with relaxation of study protocol. In the uncuffed group, one neonate had upper respiratory tract infection in the morning of operation day and another was excluded for having diarrhoea on the day of surgery. Data from those four neonates were not taken into consideration for analysis as there was violation of the study protocol. Hence, data from 23 neonates from each group were available for analysis. The two groups were comparable in respect to demographic data such as age, weight as well as duration of surgery and duration of anaesthesia [Table 1]. There was no significant difference in type of surgery performed in both the groups [Figure 1].

The primary outcome of the study, i.e. the tube exchange rate was higher with the use of uncuffed ET tube (65%) in comparison to the use of cuffed ET tube (4.3%). The difference was statistically significant ($p < 0.05$) [Table 2]. The incidence of postoperative hoarse cry was 39% (9 out of 23) in neonates intubated with uncuffed ET tube compared with no such occurrence with the use of cuffed ET tube. It was also observed that one neonate of each group showed apnoeic spell. Though apnoeic spell was taken as a postoperative respiratory complication, it cannot be concluded that this complication was directly related to the type of tube (cuffed or uncuffed) used for intubation. But the overall incidence of postoperative morbidity was significantly higher in uncuffed tube (43%) in comparison to the cuffed tube (4%) [Table 3].

Figure 1. Type of Surgery

Parameters	Uncuffed (n=23)	Cuffed (n=23)	P-value
Age (days)	12.7 ± 4.05 (0.84)	13.5 ± 4.01 (0.84)	0.472
Weight (kg)	2.71 ± 0.23 (0.047)	2.66 ± 0.22 (0.046)	0.151
Duration of Surgery (min)	36.08 ± 12.96 (2.7)	32.95 ± 14.44 (3.01)	0.972
Duration of Anaesthesia (min)	46.95 ± 12.5 (2.6)	42.39 ± 14.5 (3.03)	0.77
Data is expressed as Mean ± Standard Deviation (Standard Error of Mean). Unpaired t-test is used to compare the data. P less than 0.05 is considered to be significant.			
Table 1. Demographic Data			

Tube Exchange Rate	Uncuffed	Cuffed	Statistical Test	P value	Statistical Significance
Once	10	1	Fishers' Exact Test	0.0000002	Highly Significant
Twice	5	0			
Total	15	1			
Percentage of Occurrence	65%	4.3%			
Table 2. Tube Exchange Rate					

Post-operative Morbidity (Count)	Uncuffed	Cuffed	Statistical Test	P value	Statistical Significance
Hoarse Cry	9	0	Fishers' Exact Test	0.000009	Highly Significant
Apnoeic Spell	1	1			
Total	10	1			
Percentage of Occurrence	43%	4%			
Table 3. Postoperative Morbidity					

DISCUSSION

In the present study, the ET tube exchange rate was found to be 4.3% in cuffed tube group and 65% in the group receiving uncuffed ET tube. Khine et al^[7] also found a lower tube exchange rate in groups receiving cuffed ET tube compared with uncuffed ET tube (1.2% versus 23%, respectively). Khine et al^[7] also found that rate of reintubation required was 18% in cuffed tube versus 30% in uncuffed tube in children younger than 2 years. Similar type of observation was reported by Weiss et al^[8] where tube exchange rate was 2.1% in cuffed tube and 30.8% in uncuffed tube. Thus, it appears that the result of this study is consistent with the findings of the other previously reported studies. To prevent air leak in uncuffed tube, many a times throat pack is used to seal the leak. This technique results in a high incidence of delayed oral feeding and postoperative hoarse cry. The use of cuffed tubes reduces such problems as no additional throat pack is required to seal the airway.

In paediatric population, most of the surgeries are being carried out under general anaesthesia with endotracheal intubation. Previously uncuffed tubes were considered safe and were recommended in paediatric patients. But considering the problems associated with uncuffed ET tube,

cuffed ET tube is now becoming acceptable also in the paediatric population. A few of the newer study revealed that in paediatric group, cricoid lumen is not at all circular, but elliptical.^[15] When a round uncuffed ET tube is used there is considerable pressure over posterolateral wall of cricoids known as 'cricoid sealing.' If a proper size cuffed tube is used, the airway is sealed at the trachea known as 'tracheal sealing.'^[16] There is limited study comparing 'cricoid sealing' with the 'tracheal sealing.'

Tracheal capillary mucosal perfusion pressure in adult age group is in the range of 25 - 30 mmHg. If the cuff pressure is maintained at 25 mmHg or less, it ensures adequate seal to prevent aspiration as well as maintains mucosal perfusion. But in case of neonates and infants, this cuff pressure should be kept less than 20 mmHg to prevent mucosal damage.^[17-19] Hence, in the present study, the cuff pressure of ET tube was limited to 15 mmHg using a cuff pressure manometer.

One of the most important considerations for an anaesthesiologist is to choose appropriately sized endotracheal tube that provides controlled ventilation without considerable airway injury. As the trachea of neonate is very short in length, a little movement of the uncuffed tube inside the trachea may cause dislodgement and repositioning of the ET tube leading to high tube exchange rate. Many a times, uncuffed ET tube may not fit properly causing air leak around the tube. An excessive air leak around the tube may lead to unreliable monitoring of ventilator parameters, exhaled volumes, end expiratory gases which may be utmost important in the critically ill neonates or child requiring ventilatory support.^[20] The risk of aspiration is also high in case of excessive leak.^[21,22]

In the present study, it was found that higher incidence of postoperative hoarse cry in neonates intubated with uncuffed ET tube (39%) compared with no such occurrence with the use of cuffed ET tube. However, one neonate in both the groups showed apnoeic spell. So the incidence of postoperative morbidity was considerably higher in uncuffed ET tube group compared with cuffed ET tube group (43% vs 4%, respectively). This observation is in line with that of the previously stated studies.^{7,8} In the recent past, several studies have compared the effect of using cuffed and uncuffed tubes in children regarding the incidence of postoperative airway complications.^[23-27] Holzki et al^[10] reported that the incidence of laryngeal injury is higher in case of cuffed ET tube and they also stated that oversized cuffed ET tube was responsible for airway trauma. However, no study has demonstrated that proper sized cuffed ET tube has caused airway injury. Khine et al^[7] did not find any increased incidence of croup in children intubated with cuffed ET tube. Newth et al^[23] demonstrated no significance incidence of airway complications in cuffed ET tube. Risk of airway damage in cuffed tube is associated with oversized outer tube diameters, poorly designed cuffs, wrong placement of the tube and over-inflation of the cuff resulting in postoperative stridor. But proper size of the cuff, appropriate cuff inflation pressure and careful length adjustment may combat any postoperative airway morbidity. Furthermore uncuffed tubes may cause postoperative airway complication like hoarse cry, laryngospasm as throat pack is often used with uncuffed ET tube. In 2001, Murat et al^[24] and James et al^[25] reported no incidence of any postoperative airway complication among 15,000 paediatric patients intubated with cuffed ET tube.

Most of the previous studies showed significant results in favour of cuffed ET tube. A recent Cochrane review^[27] analysed three trials comparing cuffed with uncuffed ET tubes. It found no difference in post-extubation stridor between the two groups in two trials involving 2734 children. Another trial involving 70 children revealed that the use of cuffed ET tube reduced the amount of anaesthetic gas consumption owing to overall less gas flow. However, the review pointed out that caution to be exercised while interpreting studies comparing the use of cuffed and uncuffed ET tubes owing to the variability in the designs among several studies. Evidence is accumulating regarding the use of newly designed, sophisticated microcuff ET tube.^[28,29] Large, well-designed trials involving different geographical areas is warranted to clarify factors such as the ability of these cuffed ET tubes to curtail anaesthetic cost, respiratory adverse events, etc.

CONCLUSION

A proper sized cuffed ET tube provides better laryngeal seal with less tube exchange rate and also favourable adverse event profile compared with uncuffed ET tube.

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