Re-intubation frequency in paediatric surgical patients: a randomised controlled trial

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Background: Paediatric tracheal intubation represents a challenge to many anaesthesiologists and requires considerable expertise. We assessed re-intubation frequency and the time needed for intubation in children undergoing elective surgical operations.

Methods: A prospective randomised single blinded study was conducted in Mansoura University Children's Hospital, Egypt from April 2016 till April 2017. We enrolled 50 children scheduled for elective surgery not exceeding 90 minutes with general anaesthesia using an uncuffed endotracheal tube. They were randomly allocated into one of two groups (age-based group versus ultrasound-based group). Primary outcome variables were re-intubation frequency and the time taken for intubation. Secondary outcome variables were optimum tube selection and complications after extubation.

Results: In the ultrasound-based group, the frequency of re-intubation frequency was decreased due to an endotracheal tube which was too large (p = 0.047). The optimum tube selection was higher (p = 0.034) and the time taken for intubation was longer (p = 0.004). A significant correlation was found between the outer diameter of the endotracheal tube and the transverse diameter of the subglottic airway (r = 0.988, p < 0.001). No significant differences were detected between groups regarding complications after extubation (p > 0.05).

Conclusion: Ultrasonography was superior to the use of an age-based formula in reducing re-intubation frequency but intubation was slower.

Introduction

Paediatric tracheal intubation represents a challenge to many anaesthesiologists and requires considerable expertise. Anatomically the larynx of a paediatric patient has a funnel shape with its narrowest part at the cricoid ring level that cannot be seen during conventional laryngoscopy.

Choosing the correct endotracheal tube (ETT) size for paediatric patients is important because an inappropriately large ETT can lead to upper airway injuries such as local ischaemia, scar development and ulceration with subsequent subglottic stenosis. In contrast, too small ETT may cause inadequate ventilation, a high risk of aspiration, incorrect end-tidal gas monitoring and leak of anaesthetic vapour into the operating theatre. Also repeated intubations may cause post-extubation stridor, mucosal irritation, swelling and significant airway obstruction.

Detecting the ideal method for reducing repeated intubations using accurate ETT sizing could decrease these complications.

Ultrasound is a helpful tool for evaluation of subglottic transverse diameter being safe, simple, painless and non-invasive.

Although the use of ultrasonography in selecting the optimum tube size has previously been reported to be better than an age-based formula, limited trials have been conducted to evaluate its effectiveness in reducing re-intubation frequency and time needed for intubation.

We compared an ultrasound-guided technique with an age-based formula regarding re-intubation frequency and time for intubation in children undergoing elective surgical operations with general anaesthesia.

Patients and methods

Study design and participants

A prospective randomised single blinded study was conducted in Mansoura University Children’s Hospital, Egypt from April 2016 till April 2017. The study was accepted by the institutional research board of Faculty of Medicine, Mansoura, Egypt (Code Number MS/16.01.143) and registered with clinicaltrials.gov (Identifier: NCT03676387). Written informed consent was obtained from legal guardians of 50 children aged from one to six years of either sex scheduled for elective surgery not exceeding 90 minutes with general anaesthesia using an uncuffed ETT.

Patient exclusion criteria included anticipated difficult airway, head and neck surgery, respiratory diseases causing airway narrowing, pre-existing laryngeal or tracheal pathology and lesions causing airway deformity due to fibrosis or the presence of neck anatomical pathologies that could affect airway ultrasound evaluation.

Sample size calculation

The power of our study was calculated using MedCalc Version 18.11.6. Using re-intubation frequency as the primary variable (11.8% and 52.6% in Altun et al.) and assuming alpha error = 0.05 and beta error = 0.2, a total sample size of 40 patients was estimated (20 patients for each group). To account for drop-out of cases, we added seven patients to each group.

Patients were randomly allocated into one of two groups (27 patients in each group, Figure 1) using a computer-generated...
randomisation. In the age-based group (group A), ETT size was determined according to child age [ID (mm) = (age in years /4) + 4]. While in the ultrasound-based group (group U), the tube size was determined according to the subglottic transverse diameter estimated with ultrasonography. During follow-up, four patients were excluded due to surgical duration that exceeded 90 minutes (Figure 1).

In the operating room, pulse oximetry, ECG and non-invasive blood pressure (NIBP) were monitored, and baseline values were recorded. An intravenous cannula (24 gauge) was inserted and secured. Induction of general anaesthesia was done using sevoflurane 6% in 6 L/min of 100% oxygen. Atracurium (0.5 mg/kg) was administered and monitored by acceleromyography using stimulating electrodes placed on the wrist (the ulnar nerve landmark) and observation of the adductor muscle of thumb. The patients were ventilated via a facemask before intubation until the onset of muscle relaxation.

**Ultrasound-based technique**

The patients were placed in the sniffing position (head extended and lower neck flexed). Ultrasonography was performed by the same anaesthetist experienced in ultrasonography for each patient. A 10–13 MHz linear probe (Korean, Siemens, Acuson, x300) was placed in the anterior neck midline (Figure 2). Before patients were paralysed, the true vocal folds were visualised as paired hyperechoic linear structures that moved with swallowing and respiration. Then the probe was moved caudally until the cricoid arch appeared as an arched rounded hypoechoic structure (Figure 3). After patients were paralysed, the diameter of subglottic transverse air column was measured at the lower edge of the cricoid cartilage (Figure 4).

The measurements of the subglottic diameter were used to select ETT outer diameter using the equation [ETT outer diameter = 0.55 × (subglottic diameter) + 1.16 mm]. We used uncuffed Mallinckrodt ETTs with Murphy’s eyes. Laryngoscopic airway...
assessment was performed by the same senior anaesthesiologist and done when Train-of-Four was < 10% which was considered as the onset time of muscle relaxation. The position of the ETT was confirmed by capnography and the presence of bilaterally equal breath sounds.

**Determination of appropriateness of ETT size**

Another anaesthesiologist, who was blinded to the group allocation, carried out the air leak test in all patients. The air leak test was done after successful intubation of ETT. The ETT size was considered optimum when an audible air leak occurred around the tube at an inspiratory airway pressure of 10–30 cmH₂O, with the head and neck in the neutral position. The presence of air leak was detected by closing off the pop-off valve and allowing a slow rise of airway pressure. A stethoscope was used to detect the leak on the tube. If an airway pressure of 30 cmH₂O was achieved and there was no audible air leak, the tube was exchanged with another one 0.5 mm smaller. If the leak occurred when inflation pressure < 10 cmH₂O, the tube was exchanged for another one 0.5 mm larger.

After intubation, all patients were ventilated with volume-controlled ventilation with sevoflurane 2% with fresh gas flow 3 L/min of 50% oxygen and air. Tidal volume was adjusted at 7–10 ml/kg with a respiratory rate of 20 breaths/min and an inspiratory-expiratory ratio of 1:2 to maintain end-tidal CO₂ at 35–40 mmHg and pulse oximeter at 97–100%. After operation, patients were extubated and transferred to the recovery room to assess any post-extubation complications (oedema, laryngeal stenosis and stridor).

**Outcome variables**

Primary outcome variables were re-intubation frequency (frequency of tube exchange, either smaller or larger at induction) and the time needed for intubation starting from the onset time of muscle relaxant up to the confirmation of appropriate tube size. Secondary outcome variables were optimum tube selection and post-extubation complications.
Table I: Characteristics of the studied groups

|                      | Group U       | Group A       | P-value*    |
|----------------------|---------------|---------------|-------------|
| Age (years)*         | 2.1 ± 1.6     | 2.3 ± 1.7     |             |
| Sex (n, %)           |               |               |             |
| Females              | 7 (28%)       | 8 (32%)       |             |
| Males                | 18 (72%)      | 17 (68%)      |             |
| Weight (kilograms)*  | 12.6 ± 1.9    | 11.3 ± 3.1    |             |
| Duration of surgery (minutes)* | 82 ± 13       | 76 ± 13      |             |

Table II: Intraoperative variables in studied groups

|                      | Group U       | Group A       | P-value*    |
|----------------------|---------------|---------------|-------------|
| Pulse (beats/minute) | 97.5 ± 5.8    | 96.3 ± 3.5    | < 0.001     |
| Respiratory rate (cycles/minute) | 21.8 ± 2.8    | 20.3 ± 2.4    | 0.041       |
| Airway pressure (cmH2O) | 19.3 ± 1.1    | 20.2 ± 3.3    | 0.189       |
| End-tidal CO2 (mmHg) | 35.1 ± 1.1    | 35.2 ± 1      | 0.696       |
| SpO2 (%)             | 99.6 ± 0.6    | 99.5 ± 0.7    | 0.666       |

Table III: Outcome variables in the studied groups

|                      | Group U       | Group A       | P-value*    |
|----------------------|---------------|---------------|-------------|
| Optimum tube selection frequency* (n, %) | 23 (92%)      | 17 (68%)      | 0.034       |
| Re-intubation frequency† |             |               |             |
| Small tube (n, %)     | 2 (8%)        | 3 (12%)       | 0.637       |
| Large tube (n, %)     | 0             | 5 (20%)       | 0.047       |
| Time needed for intubation† (minutes) | 2.5 ± 0.5    | 2.2 ± 0.2     | 0.004       |

Table IV: Complications after extubation

| Complications       | Group U       | Group A       | P-value*    |
|---------------------|---------------|---------------|-------------|
| Öedema              | 1 (4%)        | 2 (8%)        | 0.551       |
| Laryngeal stenosis  | 0             | 1 (4%)        | 0.313       |
| Stridor             | 0             | 2 (4%)        | 0.149       |

Statistical analysis

Statistical analysis was done using SPSS version 20. Categorical data were expressed as numbers and percentages, and compared with chi-square and Fisher’s exact tests. Kolmogorov-Smirnov test was used initially to test the normality of continuous data. Normally distributed continuous data were described as mean and standard deviation (SD), and compared using Student’s t-test. The 95% confidence interval (CI) for the frequency of correct size of ETT was calculated. P-values ≤ 0.05 were considered statistically significant.

Results

Both groups were similar as regards age, sex, body weight, duration of surgery and types of operations (p > 0.05) (Table I). All patients were Cormack-Lehane grade 1 with easy intubation at laryngoscopy.

There was statistically significant difference as regards pulse and respiratory rate (p < 0.001 and 0.041, respectively) between groups. However, no significant differences were detected between both groups as regards airway pressure, capnography and SpO2 (p = 0.19, 0.70 and 0.67, respectively) (Table II).

With respect to the outcome variables, optimal tube selection was more frequent in group U while intubation was longer (increased time 2.5 ± 0.5 minutes) in comparison to group A (p = 0.03 and 0.004, respectively). In group A there was a higher re-intubation frequency due to an ETT which was too large in size than in group U (p = 0.047) (Table III).

There was no statistically significant difference between groups as regards post-extubation complications (p > 0.05) (Table IV).

There was a significant correlation between ETT OD and the transverse diameter of the subglottic airway in group U (r = 0.988, p < 0.001) (Figure 5).

Discussion

In paediatric anaesthesia, the correct selection of ETT size is a challenge. Several formulas based on age, height, weight and finger size have been postulated and used to predict optimal size. Recently, ultrasound has gained popularity in perioperative airway assessment. In the current study, we compared an ultrasonography-based technique with an age-based formula as regards re-intubation frequency using uncuffed ETT in paediatric patients.

In the current study, the lower incidence of re-intubation in the ultrasound group was assumed due to improved selection of an appropriate ETT size. This explanation is supported by Bae et al. who found that the incidence of appropriate uncuffed tube size was higher using the ultrasound method than an age-based method (60% and 31%, respectively). The incidence of correct tube size recorded by Gnanaprakasam and Selvaraj was 74.7% for ultrasound and 45.3% for age-based formula. This finding goes hand in hand with Schramm et al. who reported that ultrasonography reduced the re-intubation numbers compared...
to an age-related formula.\textsuperscript{13} Also, Altun et al. reported that 11.8% patients needed exchange of the tube in the ultrasound-based group in comparison to 52.6% in an age-based group. Seventy patients out of 152 (46%) in the age-based group were reintubated due to overestimation of ETT size.\textsuperscript{9}

With regard to time needed for intubation, use of ultrasonography took longer than intubation using the age-based formula. This can be explained by ultrasonography being an experience-based technique.\textsuperscript{14}

Our finding of a strong correlation between the subglottic diameter and the outer diameter of an optimal uncuffed ETT in the ultrasound-based group is supported by Shibasaki et al. who used the same ultrasound technique as we did and reported it superior for detecting optimal paediatric ETT size than patient age or height.\textsuperscript{11} Moreover, Lakhal et al. found that ultrasonography seems to be a reliable method for assessment of the subglottic diameter and offers a number of advantages compared to other competitive imaging modalities.\textsuperscript{14}

Gnanaprapakam and Selvaraj also reported a strong correlation between the outer diameter of an optimal uncuffed ETT and subglottic diameter measured with ultrasound in paediatric patients ($r = 0.827$, $p < 0.001$).\textsuperscript{6} In contrast to our results, Husein et al. reported that ultrasonography may underestimate ETT size and recommended invasive manoeuvres for measuring subglottic diameter.\textsuperscript{15}

In the current study, postoperative airway complications in the ultrasound group were lower than the age-based group but this difference did not reach statistical significance. The study was not powered to detect this outcome measure. The relatively lower post-intubation complications with ultrasound technique may usefully be explored with further studies.

An alternative to identifying an optimal size ETT in paediatric practice is the use of auffed tube. On reviewing the literature, despite the recent increasing usage of microcuff ETT in children, several obstacles limit its widespread application. Sathyamoorthy et al. reported post-intubation stridor after using microcuff ETT. They found that cuffed ETT limited the ID of the ETT leading to the very sensitive subglottic mucosa causing post-extubation stridor.\textsuperscript{15} The relatively high cost of microcuff paediatric ETT also limits its use.\textsuperscript{17} Moreover, the need for continuous pressure monitoring adds more obstacles to the microcuff ETT usage.\textsuperscript{18}

Limitations
A relatively small sample size with limited studied variables.

Conclusion
Ultrasonography was superior to an age-based formula in reducing re-intubation frequency at induction in children undergoing elective surgery not exceeding 90 minutes. Ultrasonography increased the time for intubation. We recommend further large scale randomised controlled trials including other types of surgeries, in particular to compare impact on post-extubation complications.

Conflict of interest
We declare that we have no financial or personal relationships which may have influenced us in writing this paper.

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