

Cuffed versus uncuffed endotracheal tubes in children: a meta-analysis

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Abstract

Purpose Cuffed endotracheal tubes (ETTs) have increasingly been used in small children. However, the use of cuffed ETTs in small children is still controversial. The goal of this meta-analysis is to assess the current evidence regarding the postextubation morbidity and tracheal tube (TT) exchange rate of cuffed ETTs compared to uncuffed ETTs in children.

Methods A systematic literature search in PubMed, Web of Science, Embase, and Cochrane Central Register of Controlled Trials up to November 2014 was conducted to identify randomized controlled trials (RCTs) and prospective cohort studies that compared the use of cuffed and uncuffed ETTs in children. The primary outcome was the incidence of postextubation stridor and the second outcomes were the TT exchange rate, need for re-intubation, and duration of tracheal intubation. All pooled data were estimated using random effects meta-analysis.

Results Two RCTs and two prospective cohort studies including 3782 patients, in which 1979 patients for cuffed tubes and 1803 patients for uncuffed tubes, were included in our analysis. We found that the use of cuffed ETTs did not significantly increase the incidence of postextubation stridor (RR = 0.88; 95 % CI 0.67–1.16, $p = 0.36$), and the TT exchange rate was lower in patients receiving cuffed tubes intubation (RR, 0.07; 95 % CI 0.05–0.10, $p < 0.00001$). The

need for re-intubation following planned extubations and duration of tracheal intubation did not differ significantly between the cuffed tube group and the uncuffed tube group.

Conclusions Our study demonstrates that cuffed ETTs reduce the need for TT exchanges and do not increase the risk for postextubation stridor compared with uncuffed ETTs.

Keywords Cuffed endotracheal tubes · Stridor · Meta-analysis · Children

Introduction

Endotracheal intubation is a routinely performed technique in the anesthesia and critical care management in children. For more than 50 years, uncuffed tracheal tubes have been commonly used for intubation in children under 8 years of age [1] because of the anatomy of the pediatric larynx and the fear that the cuff will cause airway mucosal injury, leading to subglottic stenosis [2, 3]. However, there are shortcomings of uncuffed tracheal tubes, such as having a ventilation leak around the tube, which includes unreliable end-tidal carbon dioxide monitoring, wasting, and increasing costs of inhaled anesthetics, increasing pollution of the environment [4], and an increased risk of aspiration [5].

Recently, some clinical studies have shown that cuffed tracheal tubes may be safely used in pediatric airway management. The benefits are that cuffed tubes with more reliable sealing characteristics as well as evidence that cuffed tubes present no increased risk of airway morbidity [6, 7].

Therefore, it is necessary to assess the relative merits of cuffed and uncuffed endotracheal tubes in children. We conducted a meta-analysis to determine whether cuffed or uncuffed endotracheal tubes (ETTs) in children would be

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associated with postextubation airway morbidity, measured as postextubation stridor in children.

Methods

Literature search strategy

In accordance with recommendations of the Preferred Reporting Items for Systematic Review and Meta-analyses (PRISMA) statement and *Cochrane Handbook for Systematic Reviews of Interventions Version 5.1* [8, 9], we searched databases of PubMed, Web of Science, Embase, and Cochrane Central Register of Controlled Trials up to November 2014 without restriction to publication types or languages. Keywords searched were as follows: cuffed/uncuffed/non-cuffed, endotracheal tube/tubes or tracheal tube/tube neonate/newborn/infant/child*/pediatric. The reference lists of all retrieved studies, relevant review articles were also examined. We contacted the authors for additional unpublished data when necessary.

Inclusion and exclusion criteria

Randomized controlled trials (RCTs) and prospective cohort studies were included, if they compared outcomes in children receiving either cuffed or uncuffed ETTs. No restrictions on scenario (operating room or intensive care unit) were applied. Studies that met one of the following criteria were excluded: repeated publication, retrospective study, absence of important data, editorials, letters to the editor, case reports, review articles, animal experimental, or studies not written in English.

Data extraction and outcomes of interest

Two independent authors extracted and summarized data from the included studies. All discrepancies were resolved by discussion among authors, with the involvement of the corresponding author if necessary. The following variables were collected from each included study: first author, publication year, study design, patient characteristics, control group, intervention group, cuffed or uncuffed ETT size and insertion depth, cuffed tube type and cuff pressure, the incidence of postextubation stridor, tracheal tubes (TT) exchange rate, need for re-intubation following planned extubations and duration of tracheal intubation.

Quality assessment and statistical analysis

We rated studies for the level of evidence according to the criteria provided by the Centre for Evidence-Based Medicine in Oxford, UK [10].

Two authors independently performed the quality assessment. RCTs were assessed by the Cochrane risk of bias tool [11]. Prospective cohort studies were assessed by the modified Newcastle-Ottawa scale [12, 13], which included three factors: patient selection, comparability of the study groups, and assessment of outcome. After discussions to resolve disagreements, a consensus score was arrived for each factor of quality in each article. A full score allocated to each study except RCTs was 9 stars. RCTs and prospective cohort studies achieving a score ≥ 6 stars were considered to be high quality.

We employed Review Manager 5.2 (Cochrane Collaboration, Oxford, UK) to combine outcomes among studies. For dichotomous variables, we used risk ratio (RR) with 95 % confidence intervals (CIs). For continuous variables, we calculated the weighted mean difference (WMD) with 95 % confidence intervals (CIs). The technique described by Hozo et al. [14] was used to calculate the standard deviations, if studies that showed continuous data as means and range values.

Heterogeneity was assessed using the Chi-square test with significance set at $p < 0.10$ [15] and I^2 statistic [16], which is significant being set at $I^2 > 50$ % according to the Cochrane Reviewer's Handbook. The random-effects model was used for statistical analysis according to DerSimonian and Laird methodology [17] because of wide clinical and methodological variability among the trials. Heterogeneity between studies was evaluated according to the study design (RCT or cohort study). Sensitivity analyses were conducted for high-quality studies. We planned to evaluate potential publication bias with funnel plots. All statistical tests were two-sided.

Results

Evidence synthesis

Our initial search yielded 423 studies (264 from PubMed, 35 from Web of Science, and 33 from Cochrane Central Register of Controlled Trials, 91 from Embase). After removing 122 duplicate studies, we evaluated the abstracts of 301 studies. After evaluating the abstract of each study, we excluded 276 studies because 204 studies were irrelevant, 17 were editorials or reviews or surveys, ten were letters, 15 studies were about animals, and 30 studies were case reports. Then we carefully read the full text of the remaining 25 studies and excluded 21 for the following reasons: without a control group in five studies, no interested results in four studies, no full-text available in two studies, non-English in eight studies, about adults in one study and a retrospective study in one study. Four studies including 3782 cases (1979 cases for cuffed tubes and 1803 cases

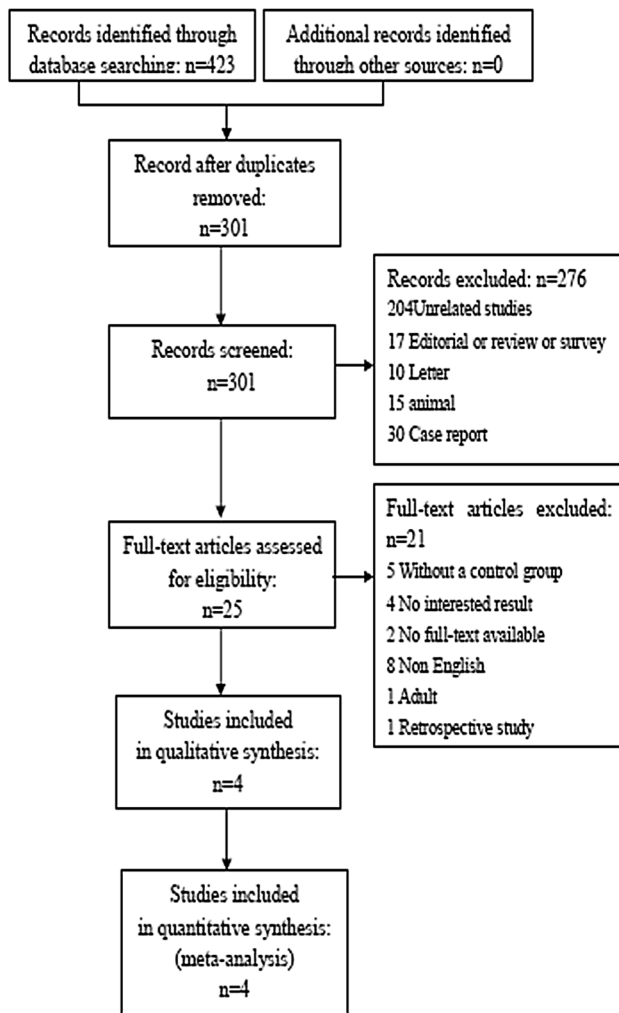


Fig. 1 Flow diagram of studies identified, included, and excluded

for uncuffed tubes) matched with the inclusion criteria and were included in our analysis (Fig. 1).

Characteristics of eligible studies

The characteristics of included studies are shown in Table 1. In the included studies, there were two RCTs (level of evidence: 2b) [18, 19]; One prospective cohort study compared contemporary series of patients (level of evidence: 2b) [20]; One cohort study failed to carry out a sufficiently long and complete follow-up of patients (level of evidence: 4) [21]. As for scenario, two studies were performed in pediatric intensive care units and two studies were performed in operating rooms.

Methodological quality of included studies

The quality of included studies is shown in Tables 2 and 3. There were only two RCTs using true randomization. The

information about allocation concealment was described in just one of the trials [18]. The information about the blinding method of the studies could not be found. Matching criteria were variable between the groups. Only one study [20] described the length of follow-up. The information about handling missing data was only described in two studies [19, 20].

Primary outcomes

Postextubation stridor rate

Ninety-four of 1979 patients (4.75 %) assigned to cuffed ETT intubation and 99 of 1803 patients (5.49 %) assigned to uncuffed ETT intubation developed stridor after extubation and showed no significant difference between the two groups (RR = 0.88; 95 % CI 0.67–1.16, $p = 0.36$) (Table 4). The result of the overall test for heterogeneity was not statistically significant, and the I^2 was 0 % (no significance of heterogeneity) (Fig. 2a). When stratified by scenario between the 2 groups, the RR for postextubation stridor rate decreased from 0.93 (95 % CI 0.65–1.33, $p = 0.70$) in the group in the operating room to 0.81 (95 % CI 0.53–1.24, $p = 0.33$) in the group in the pediatric intensive care unit, but there was still no significant difference between groups.

Secondary outcomes

Tracheal tubes (TT) exchange

Two studies [18, 19] performed in the operating room reported tracheal tubes (TT) exchange events for 2734 included patients. The TT exchange rate was 1.97 % (27 of 1370 patients) in the cuffed tube group and 29.40 % (401 of 1364 patients) in the uncuffed tube group. Reasons for TT exchanges were resistance to pass the tube (12.38 % of TT exchange cases), no air leak at 20 cm H₂O (38.08 %), excessive air leak at IPPV (49.07 %) and others (0.47 %). The TT exchange rate was lower in patients receiving cuffed tube intubation (RR = 0.07; 95 % CI 0.05–0.10, $p < 0.00001$) (Fig. 2b).

Need for re-intubation following planned extubations

Two studies [19, 20] reported the need for re-intubation rate (0.31 % in the cuffed tube group and 0.44 % in the uncuffed tube group) following planned extubations. Based on the data of the 2434 patients from two studies, the rate of need for re-intubation following planned extubations in the cuffed tube group was not significantly higher than the uncuffed tube group (RR = 0.76; 95 % CI 0.19–3.02; $p = 0.7$) (Fig. 3a).

Table 1 Characteristics of included studies

References	Deakers et al. [20]	Khine et al. [18]	Newth et al. [21]	Weiss et al. [19]
Level of evidence	2b	2b	4	2b
Design/setting	CS/PICU	RCT/OR	CS/PICU	RCT/OR
Cuffed				
Age (year) (mean \pm SD)	8.08 \pm 0.59	3.3 \pm 2.4	1.5 \pm 1.083	1.94 \pm 0.83
No.	93	251	438	1197
Tube type	HVLP tube (Mallinckrodt)	Mallinckrodt lo-po, oral RAE, or Sheridan low-pressure cuffed tube	Mallinckrodt	HVLP tube (Microcuff [®] PET)
Cuff pressure	A minimal air leak at current peak inspiratory pressure	Limited to 25 cm H ₂ O	25 cm H ₂ O	Limited to 20 cm H ₂ O, minimal cuff pressure 10.6 \pm 4.3 cm H ₂ O
Uncuffed				
Age (year) (mean \pm SD)	2.53 \pm 0.35	2.9 \pm 2.2	1.5 \pm 1.083	1.85 \pm 0.83
No.	95	237	422	1049
Effectiveness [RR (95 % CI)]	NA	0.05 (0.02, 0.17)	NA	0.07 (0.05, 0.10)
Matching	1, 3, 4, 5, 7, 8	1, 4	1, 2, 4, 6, 8, 10	1, 2, 5, 6, 8, 10
Follow-up (months)	18	NA	NA	NA
Quality score	★★★★★★	RCT	★★★★★	RCT

Comparability variables: 1, age; 2, gender; 3, weight; 4, trauma during intubation; 5, duration of intubation; 6, route of intubation; 7, actual or recent respiratory tract infection (<4 weeks); 8, accidental extubations; 9, presence of air leak before extubation; 10, changing patient's position while intubated. If all characteristics were comparable, two stars; if two or three characteristics were comparable, one star; otherwise, no star
 CS cohort study, NA data not available, PICU pediatric intensive care unit, OR operating room, mon month, HVLP high volume–low pressure

Table 2 Risk of bias in the prospective randomized controlled studies

References	Adequate random sequence generation	Allocation concealment	Blinding of participants and personnel	Adequate assessment of each outcome	Selective outcome reporting avoided	Handling of missing data
Khine et al. [18]	No	No	No	Unclear	Yes	Unclear
Weiss et al. [19]	Yes	Yes	Unclear	Yes	Yes	Yes

Table 3 Risk of bias in cohort studies using modified Newcastle-Ottawa scale

References	Selection			Comparability		Outcome		Outcome score
	Assignment for treatment	Representative treatment group	Representative reference group	Comparable for 1, 2, 3, 4, 5	Comparable for 6, 7, 8, 9, 10	Assessment of outcome	Adequate follow-up	
Deakers et al. [20]	No	Yes	Yes	1, 3, 4, 5	7, 8	Yes	Yes	★★★★★★
Newth et al. [21]	No	Yes	Yes	1, 4	NA	Yes	NA	★★★★

Comparability variables: 1, age, 2, weight; 3, trauma during intubation; 4, duration of intubation; 5, route of intubation; 6, actual or recent respiratory tract infection (<4 weeks); 7, accidental extubations; 8, presence of air leak before extubation; 9, changing patient's position while intubated; 10, type of procedure. If all characteristics were comparable, two stars; if two or three characteristics were comparable, one star; otherwise, no star

NA data not available

Table 4 Results of meta-analysis comparison of cuffed tube group and uncuffed tube group

Outcome of interest	Study no.	Cuffed patients, <i>n</i>	Uncuffed patients, <i>n</i>	WMD/RR (95 % CI)	<i>p</i> value*	Study heterogeneity			
						χ^2	<i>df</i>	<i>I</i> ² , %	<i>p</i> value
Primary outcome									
Postextubation stridor	4	1979	1803	0.88 (0.67, 1.16)	0.36	1.05	3	0	0.79
RCTs	2	1448	1286	0.93 (0.65, 1.33)	0.70	0.07	1	0	0.79
PCSs	2	531	517	0.81 (0.53, 1.24)	0.33	0.73	1	0	0.39
Secondary outcome									
TT exchange	2	1370	1364	0.07 (0.05, 0.10)	<0.00001	0.21	1	0	0.65
RCTs	2	1370	1364	0.07 (0.05, 0.10)	<0.00001	0.21	1	0	0.65
PCSs	0	0	0	NA	NA	NA	NA	NA	NA
Re-intubation	2	1290	1144	0.76 (0.19, 3.02)	0.70	0.68	1	0	0.41
RCTs	1	1197	1049	1.75 (0.16, 19.30)	0.65	NA	NA	NA	NA
PCSs	1	93	95	0.51 (0.10, 2.72)	0.43	NA	NA	NA	NA
Duration of intubation, h	3	1758	1591	3.31 (−9.86, 16.49) [§]	0.62	6.04	2	67	0.05
RCTs	1	1197	1049	0.14 (0.03, 0.25) [§]	0.009	NA	NA	NA	NA
PCSs	2	561	542	22.90 (−34.37, 80.16) [§]	0.43	5.96	1	83	0.01

TT tracheal tubes, WMD/RR weighted mean difference/risk ratio, *df* degrees of freedom, CI confidence interval, *h* hour, PCSs prospect cohort studies

* Statistically significant results are shown in **bold**

§ WMD

Duration of tracheal intubation

Duration of tracheal intubation was found in three studies [19–21]. We found the duration of tracheal intubation showed no significant difference between the cuffed tube group and the uncuffed tube group (WMD = 3.31 h, 95 % CI −9.86 to 16.49, *p* = 0.62) (Fig. 3b).

Subgroup analysis

Subgroup analysis of RCTs

Two RCTs contributed to the analysis [18, 19]. As for the postextubation stridor rate, there was no significant difference between the two groups (4.07 % compared with 4.35 %; RR = 0.93; 95 % CI 0.65–1.33; *p* = 0.70) (Fig. 2a). As for the need for re-intubation rate (0.17 % compared with 0.10 %; RR = 1.75; 95 % CI 0.16–19.30; *p* = 0.65) (Fig. 3a), there was also no significant difference between the two groups, except for two studies that showed that TT exchange rate was lower in cuffed tube group than in the uncuffed tube group (1.97 % compared with 29.40 %; RR = 0.07; 95 % CI 0.05–0.10, *p* < 0.00001) (Fig. 2b). One study including 2246 patients showed that the duration of tracheal intubation was longer in the cuffed tube group than in the uncuffed tube group (WMD = 0.14 h, 95 % CI 0.03–0.25, *p* = 0.009) (Fig. 3b).

Subgroup analysis of prospective cohort studies

Two prospective cohort studies were included in this subgroup analysis. There was no significant difference in this subgroup analysis in the postextubation stridor rate (6.59 % compared with 8.32 %; RR = 0.81; 95 % CI 0.53–1.24; *p* = 0.33) (Fig. 2a), need for re-intubation rate (2.15 % compared with 4.21 %; RR = 0.51; 95 % CI 0.10–2.72; *p* = 0.43) (Fig. 3a), or duration of tracheal intubation (WMD = 22.90 h, 95 % CI −34.37 to 80.16, *p* = 0.43) (Fig. 3b) between the two groups.

Sensitivity analysis and publication bias

The sensitivity analysis included two RCTs [18, 19] and one prospective cohort study [20, 21], which scored seven stars on the modified Newcastle-Ottawa scale. The outcomes were no change in the significance (Table 5). The degree of between-study heterogeneity was also no change. There were only four studies included in this meta-analysis, so tests for funnel plot asymmetry were not used for the reason that test power was usually too low to distinguish chance from real asymmetry [11].

Discussion

This meta-analysis of two RCTs and two prospective cohort studies including 3782 children comparing cuffed

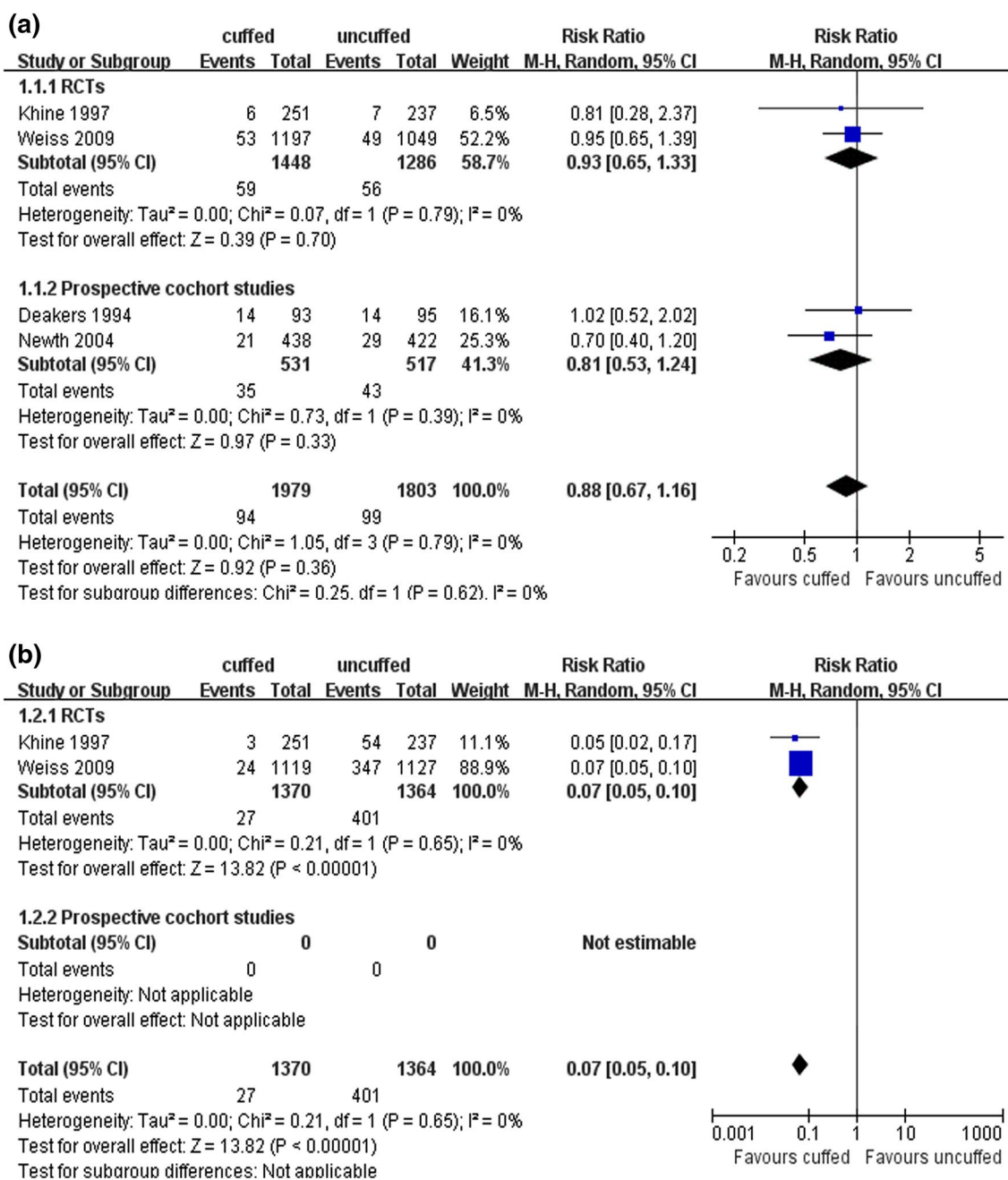


Fig. 2 Forest plot and meta-analysis of **a** the postextubation stridor rate between cuffed and uncuffed tubes group and **b** the tracheal tubes (TT) exchange rate between cuffed and uncuffed tubes group. *CI* confidence interval, *PICU* pediatric intensive care unit

and uncuffed endotracheal tubes (ETTs) showed that cuffed ETTs may be safely used in children, since no significant difference in the incidence of postextubation stridor was found. Furthermore, cuffed ETTs were associated with lower tube exchange rate and a reliable sealed airway. We found no significant difference in re-intubation rate and duration of tracheal intubation between those patients with cuffed ETTs compared with those with uncuffed ETTs.

The safety of children is always important in ETTs selection. The pooled data of postextubation stridor rate indicated that cuffed ETTs might be safe for children if size was appropriately selected and cuffed pressure was well controlled. There was no significant difference in postextubation stridor rate among patients using cuffed and uncuffed tubes. These findings may represent that the strict selection of an anatomically designed cuffed tube with controlled, tube sizes according to size recommendations and a

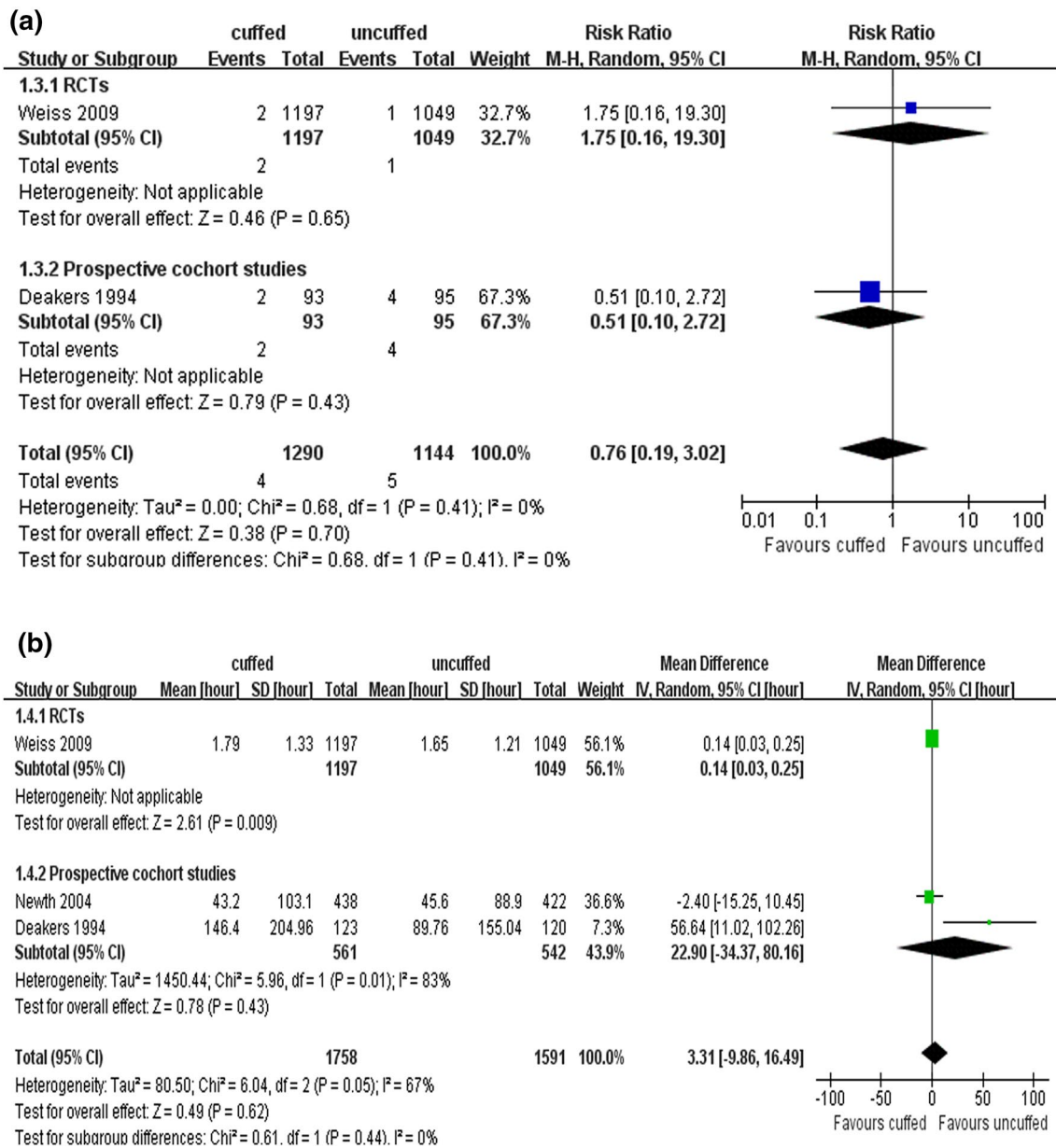


Fig. 3 Forest plot and meta-analysis of **a** the need for re-intubation rate following planned extubations between cuffed and uncuffed tubes group and **b** the duration of tracheal intubation between cuffed and uncuffed tubes group. *CI* confidence interval, *PICU* pediatric intensive care unit

limited cuff pressure was used in the cuffed tube group [7, 18–21]. The outcome of postextubation stridor rate in both groups was found to be in line with the finding of Ashtekar et al. [22] and would alleviate the fear of many pediatric anesthetists that cuffed ETTs might increase postextubation stridor rates in children [23]. It also showed us that postextubation stridor could occur after tracheal intubation with any type of ETT [24]. The pooled data of need for reintubation following planned extubations and duration of intubation showed no significant difference between the two groups. It demonstrated that cuffed ETTs did not increase the rate of reintubation compared to the uncuffed ETTs and

might be safely used for prolonged periods of time without causing postextubation stridor. However, it is important to know that cuffed ETTs with oversized outer tube diameters, not adequately designed cuffs, and without cuff pressure control can increase the risk of airway injury [3, 25].

The tracheal tube (TT) exchange rate was significantly higher in the cuffed ETT group than the uncuffed ETT group [18, 19]. The chance to find the appropriate ETT at the first attempt was higher for cuffed ETTs than uncuffed ETTs, because cuffed ETTs were selected with a smaller size and the cuffs were inflated as required to fill the gap between the tube and the tracheal wall. Furthermore, it is

Table 5 Sensitivity analysis comparison of cuffed tube group and uncuffed tube group

Outcome of interest	Studies, <i>n</i>	Cuffed patients, <i>n</i>	Uncuffed patients, <i>n</i>	WMD/RR (95 % CI)	<i>p</i> value*	Study heterogeneity			
						χ^2	<i>df</i>	<i>I</i> ² , %	<i>p</i> value
Primary outcome									
Postextubation stridor	3	1541	1381	0.95 (0.69,1.30)	0.75	0.13	2	0	0.94
Secondary outcome									
TT exchange	2	1370	1364	0.07 (0.05, 0.10)	<0.00001	0.21	1	0	0.65
Re-intubation	2	1290	1144	0.76 (0.19, 3.02)	0.70	0.68	1	0	0.41
Duration of tracheal intubation, h	2	1320	1169	23.59 (−30.97, 78.16) [§]	0.40	5.89	1	83	0.02

TT tracheal tubes, WMD/RR weighted mean difference/risk ratio, *df* degrees of freedom, CI confidence interval, *h* hour

* Statistically significant results are shown in *bold*

§ WMD

often difficult to determine the correct size of ETTs [26]. The recommendation for tube size [27] in children is various and the incorrect selection of tube size will result in a high TT exchange rate. The survey of Flynn et al. [28] reported that repeated tube exchanges could cause airway injury, which was associated with the tube tip and up-and-down movement of the tube within the larynx during ventilation [2]. However, although the uncuffed ETT group required more intubation attempts, we did not find more postextubation stridor events in patients using uncuffed ETTs. The different findings may be attributed to the limited number of articles in this paper, which only included two RCTs and two prospective cohort studies. The pooled data indicated that cuffed tubes could have a much higher chance of fitting at first attempt than uncuffed tubes when using appropriately designed cuffed ETTs with a clear concept for cuff pressure control and tube size selection.

Subgroup analysis based on the study design (RCTs or prospective cohort studies) was performed. The results showed that most outcomes were consistent with studies of different designs. A sensitivity analysis was conducted including only high-quality studies. The results were consistent with the finding of the analysis except for the duration of intubation, which was longer in the cuffed ETT group than the uncuffed ETT group. However, there was significant heterogeneity among studies. Because of ethical concerns and placing ETT in different locations, randomized trials on the use of cuffed versus uncuffed ETTs in critically ill children are very difficult to conduct. So it is difficult to reach any definitive conclusion for the limited number of RCTs.

It was significant for the duration of intubation between-study heterogeneity. The significant between-study heterogeneity might be due to the wide clinical and methodological variability among the studies. Although we used a random-effects model to combine the data, the effect of heterogeneity might be reduced but not be abolished.

Our study has strengths because we undertook multiple strategies to identify studies, using predefined criteria to evaluate the methodological quality of the studies. We also applied subgroup and sensitivity analysis to minimize heterogeneity. However, our meta-analysis has several limitations that are worthy of comment. First, the number of the included studies is limited. Only four studies were involved in this analysis including two RCTs and two prospective cohort studies. Random sequence generation and blinding were not adequate, which might increase the risk of bias. Second, as with all meta-analytical techniques, the pooled data were combined from different studies. Clinical heterogeneity may also exist because each included study had its own protocol and definitions. The recommendation for choosing ETTs and depth of intubation were different from hospitals and that could influence the outcomes. Third, evidence of the clinical efficacy of cuffed ETTs in the neonatal setting is still absent, so we could not evaluate the efficacy and safety of cuffed and uncuffed ETTs in neonates. Further studies should be directed toward optimizing ETT standards in the neonatal unit, where the greatest incidence of airway damage may occur. What's more, some data could not be found directly from articles and we got the data from statistical transformation, which might limit the quality of our conclusion. Additionally, the follow-up period of the studies was short, so we could not evaluate the long-term outcomes of using ETTs. Finally, there were no sufficient studies to detect asymmetry in a funnel plot, so we could not fully exclude publication bias.

In conclusion, according to this meta-analysis, we find that cuffed ETTs may be associated with a lower TT exchange rate. Two kinds of ETTs appear to be equivalent in terms of the postextubation stridor rate, the need for re-intubation following planned extubations and the duration of tracheal intubation.

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