Medtronic

Clinical Evidence Guide

Cuffed endotracheal tube (ETT) in pediatrics

Shiley™ endotracheal tube

A recent survey from a large geographical location shows cuffed endotracheal tubes (ETTs) are being used with increasing frequency in neonatal intensive care units (NICU) and in pediatric intensive care units (PICUs).[1]

Current study data from a large cohort indicates that use of cuffed ETT resulted in a decreased need for more than one laryngoscopy, and ETT size exchanges, without an increase in the incidence of post operative airway effects including post extubation stridor (PES).[2]

Cuffed ETTs continue to prove safe and may also decrease the risk of microaspiration/ventilator associated pneumonia (VAP).[3] Cuffed tubes are now recommended for term newborns and children.[3,4]

For use by clinical staff. The endotracheal tubes are sterile, single-use patient medical devices not intended to be reprocessed (cleaned, disinfected/sterilized) and used on another patient. Please refer to the product Instructions for Use (IFU) for detailed usage and troubleshooting instructions.

Cuffed ETT use in pediatrics

Current evidence supporting cuffed ETT use

Benefits	Evidence
Improved ventilation	• Thomas et al. 2016 ***
Fewer accidental extubations	• Dariya et al. 2022 ***
No association of cuffed ETTs with ventilator associated pneumonia (VAP) Less ventilator associated pneumonia/aspirations	• Jeria et al. 2021 ** • Thomas et al. 2016 ***
Less exposure of health care workers to aerosolized particles such as SARS-CoV-2; known as COVID-19	• Dariya et al. 2022 ***
Less gas leak around the ETT (less gas pollution in OR/atmosphere)	• Dariya et al. 2022 *** • Chand et al. 2018 ** • Thomas et al. 2016 ***
Cost effectiveness, less use of anesthetic and other gases	• Chand et al. 2018 ** • Eschertzhuber, et al. 2010 **
Fewer episodes of atelectasis	• Thomas et al. 2021 ***

Notes: These studies included:
* Neonatal population; ** pediatric population; *** Neonatal & pediatric populations.

Review the evidence of benefits associated with use of cuffed ETT in pediatrics.

Improved ventilation

- Thomas et al. 2016

Fewer accidental extubations

- Dariya et al. 2022

Less incidence of VAP

- Thomas et al. 2016
- Jeria et al. 2021

Less exposure of health care workers to aerosolized particles such as Covid 19

- Dariya et al. 2022

Less gas leak around the ETT (less gas pollution in OR/atmosphere)

- Dariya et al. 2022
- Chand et al. 2018
- Thomas et al. 2016

Cost effectiveness, less use of anesthetic and other gases

- Chand et al. 2018
- Eschertzhuber, et al. 2010

Less incidence of post extubation stridor (PES)

- Williams et al. 2022
- Jeria et al. 2021
- de Wit, et al. 2018

Less incidence of tube exchange/laryngoscopy

- Chand et al. 2018
- Williams et al. 2022

Fewer reintubations

- Dariya et al. 2022
- Williams et al. 2022
- Thomas et al. 2021

Less incidence of post extubation subglottic stenosis

- Bibl et al. 2022
- Dariya et al. 2022
- Greaney et al. 2018

Cuffed ETT use in pediatrics

Current evidence supporting cuffed ETT use

Benefits	Evidence
No association of cuffed ETT use and increase in post extubation stridor (PES)	• Williams et al. 2022 *** • Jeria et al. 2021 ** • de Wit, et al. 2018 ***
Less incidence of tube exchange/laryngoscopy	• Chand et al. 2018 ** • Williams et al. 2022 **
Fewer reintubations	• Dariya et al. 2022 *** • Williams et al. 2022 ** • Thomas et al. 2021 ***
No higher risk of post extubation subglottic stenosis	• Bibl et al. 2022 * • Dariya et al. 2022 *** • Greaney et al. 2018 **
Increased utilization of ETT	• Lee at al. 2019 ***

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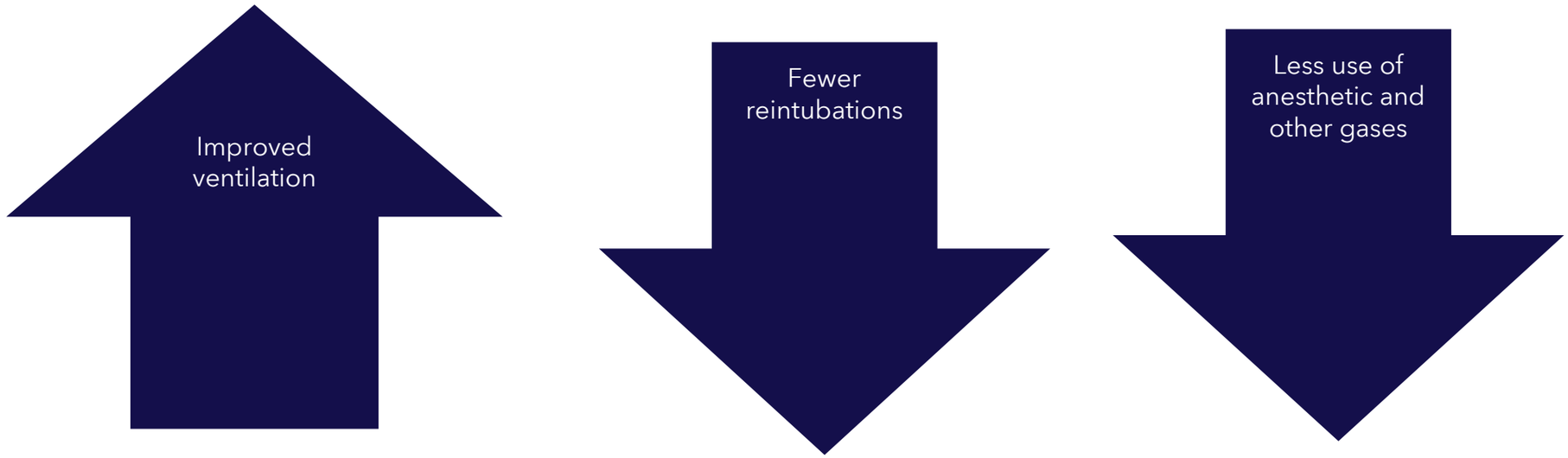
- Dariya et al. 2022
- Greaney et al. 2018

Thomas R, Rao S, Minutillo C.

Cuffed endotracheal tubes for neonates and young infants: a comprehensive review.

Arch Dis Child Fetal Neonatal Ed. 2016;101(2):F168-F174.[5]

Compared to uncuffed ETT, cuffed ETT offer the following advantages:



Study information	
Study design	Comprehensive review
Methods	7 studies and nine relevant reports abstracted from reference list.
Results	Cuffed ETT use was associated with: • Lower rate of ETT leak improving ventilation. • Less aspiration and ventilator associated pneumonia. • Less reintubations to find the correct ETT size. • A smaller ETT through the delicate cricoid. • Less airway damage. • Less gas leak, and use of anaesthetic and other gases.

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- Greaney et al. 2018

Dariya V, Moresco L, Bruschettini M.
Cuffed versus uncuffed endotracheal tubes for neonates.
Cochrane Database of Systematic Reviews. 2022;1(1):1-45.[6]

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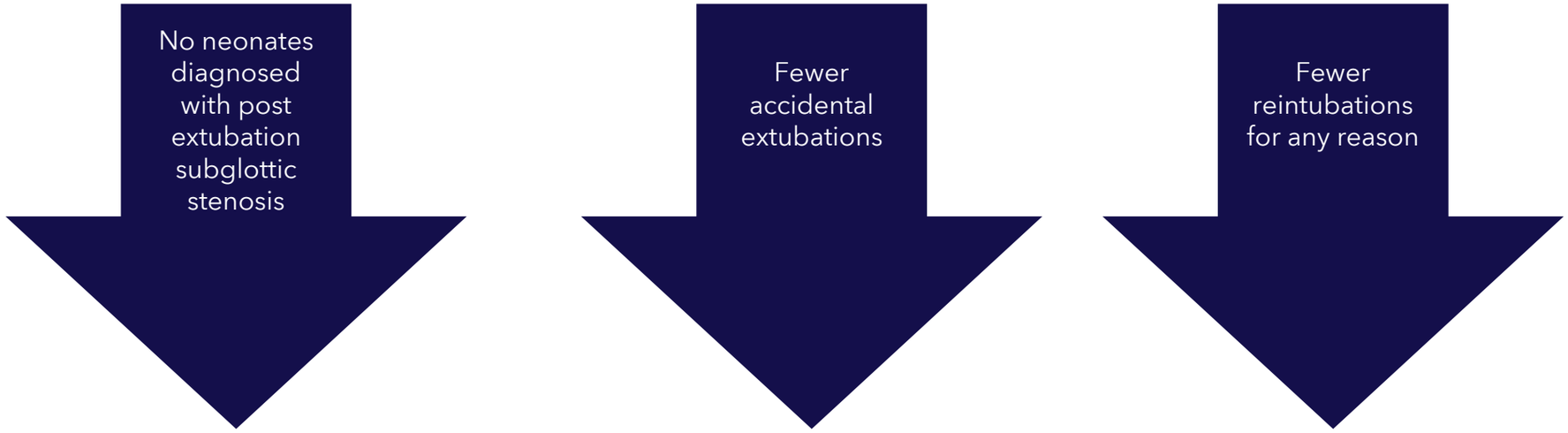

Study information

Study design	Systematic review
Methods	• Systematic review of randomized controlled trials (RCTs), quasi-RCTs, and cluster-randomized trials comparing cuffed (inflated and non-inflated) versus uncuffed ETTs in newborns. 1 study met the inclusion criteria (n=69).
Primary outcome	• Primary endpoints included postextubation airway complications: stridor, subglottic stenosis.
Results	Cuffed ETT use was associated with: • Fewer reintubations. • Fewer accidental extubations. • Less gas leak around the ETT. • Less exposure of HCW to: 1) inhaled anesthetics in operative setting and less wastage of expensive anesthetic agents. 2) Less exposure of HCW to aerosolized particles such as SARS-CoV-2; known as COVID-19. • No neonate diagnosed with postextubation subglottic stenosis.

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- Bibl et al. 2022
- Dariya et al. 2022
- Greaney et al. 2018

Jeria R, Sobarzo M, Lamatta, J.

Is tracheal tube cuff associated with post extubation stridor in pediatric subjects?

Ped Crit Care Med. 2021;22:3(Suppl): P0411.[7]

Study information	
Study design	Observational prospective study
Methods	• n= 81 intubated patients admitted to PICU at a University Hospital.
Primary outcome	• Primary endpoint included PES with cuffed ETT, and related factors connected with MV for more than 12 hours.
Results	• No association of cuffed ETT use and PES. • No association of cuffed ETT and extubation failure or VAP.

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- Bibl et al. 2022
- Dariya et al. 2022
- Greaney et al. 2018

Thomas R, Erickson S, Hullett B, et al.

Comparison of the efficacy and safety of cuffed versus uncuffed endotracheal tubes for infants in the intensive care setting: a pilot, unblinded RCT.

Arch Dis Child Fetal Neonatal Ed. 2021;0:F1–F7.[8]

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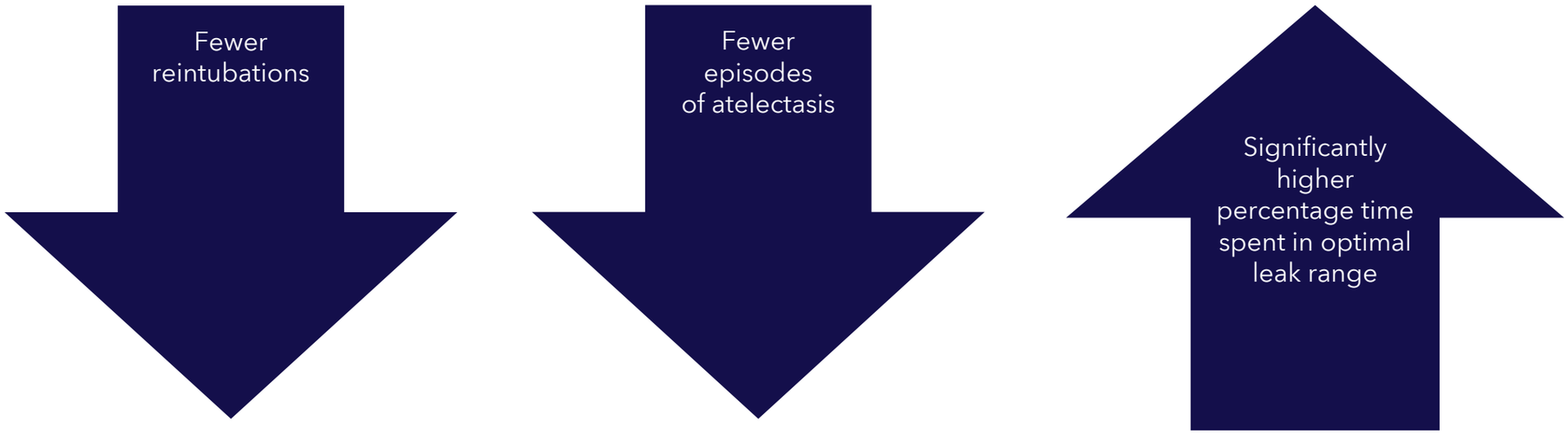

Study information	
Study design	Pilot, unblinded RCT
Methods	• n=76 infants ≥35 weeks gestation and infants <3 months of age, ≥3 kg.
Primary outcome	• Primary endpoint included achievement of optimal ETT leak in target range (10%–20%). • Secondary endpoints included reintubations, ventilatory parameters, ventilatory complications, postextubation complications and long-term follow-up.
Results	Cuffed ETT use was associated with: • Significantly higher percentage time spent in optimal leak range. • Fewer episodes of atelectasis. • Reduced reintubations to optimize ETT size. • No difference in immediate postextubation complications or evidence of airway pathology at long term follow up. • No patient diagnosed with subglottic stenosis at long-term follow-up. The mean age at follow up was 35 months in both groups.

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Williams Z, Kim S, Naguib A.

Use of cuffed endotracheal tubes in infants less than 5 kilograms: A retrospective cohort *study*. *J Pediatr Surg*.2022;57(3):375-381.[2]

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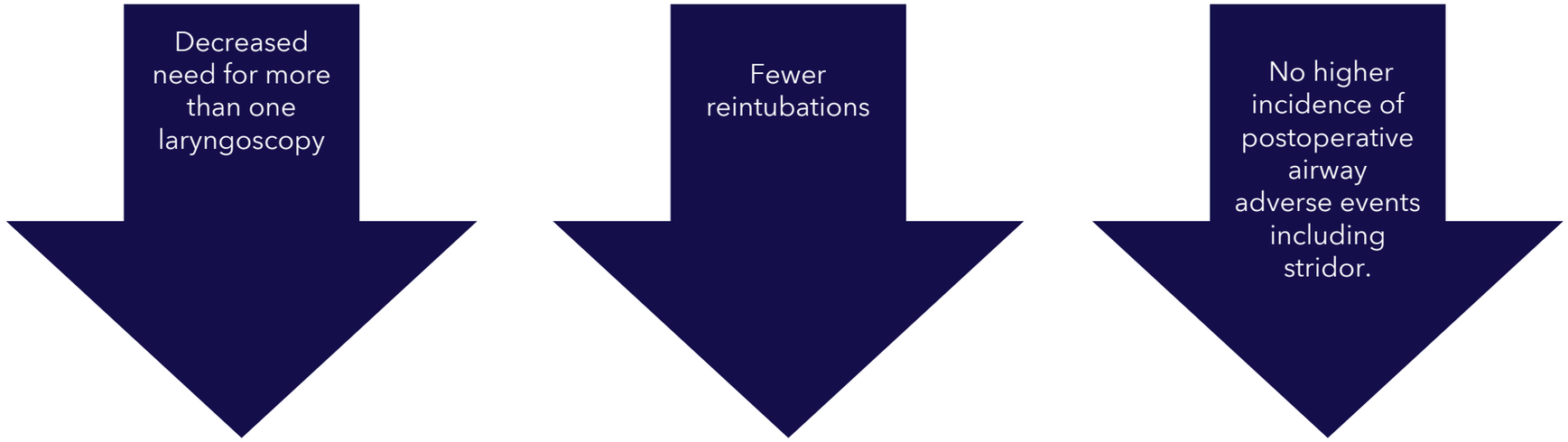

Study information	
Study design	Retrospective cohort
Methods	• 1162 total infants, 1086 intubated with a cuffed ETT and 76 with an uncuffed ETT; admitted to a tertiary care children's hospital involving a three-year period. • Infants divided into two groups for analysis: 2 to < 3 kg, and 3 to 5 kg.
Primary outcome	• Primary endpoints included anesthetic care, airway management, and postoperative course.
Results	Cuffed ETT use was associated with: • In both weight groups (2 to < 3 kg and 3 to 5 kg) cuffed ETTs use resulted in a decreased need for more than one laryngoscopy. • Fewer ETT changes to a smaller or larger size. • No increase in postoperative airway effects including stridor.

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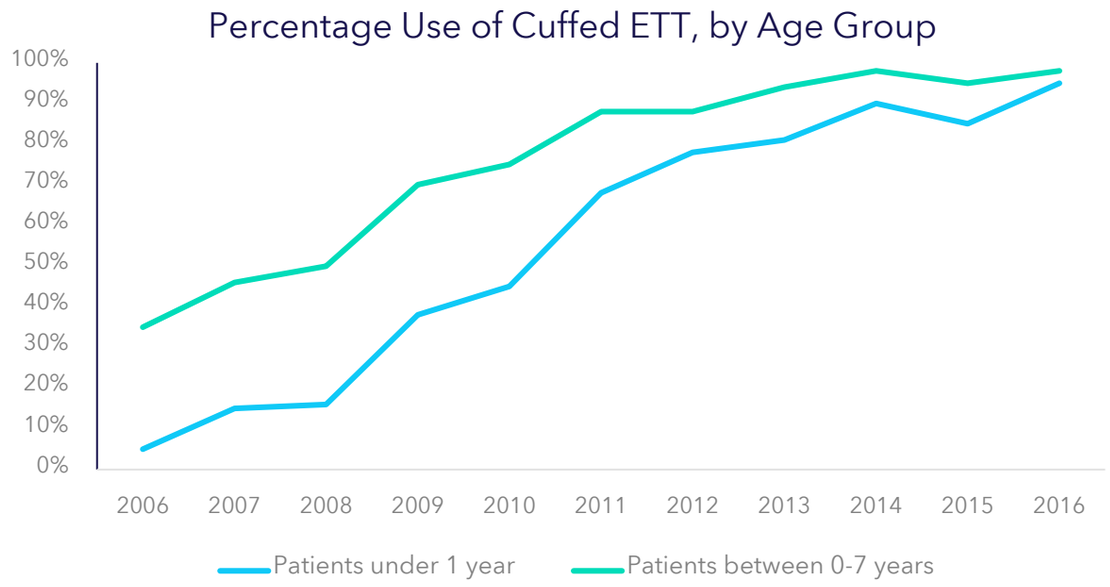
de Wit M, Peelen L, Wolfswinkel L.

The incidence of postoperative respiratory complications: a retrospective analysis of cuffed vs uncuffed tracheal tubes in children 0-7 years of age.

Paediatr Anaesth. 2018;28 (3):210-217.[9]



*Adapted from de Wit et al. (2018), Figure 2

Study information	
Study design	Retrospective analysis
Methods	• Data collected represents local data base of anesthesia information management system (AIM) Netherlands, of a pediatric tertiary university hospital.
Primary outcome	• 6796 total patients. n= 5247 used cuffed tube (77% cuffed ETT use); and 1427 (61.1%) in age <1 year subgroup. • Primary endpoint included acute postoperative respiratory complications.
Results	• Cuffed tube use was not associated with an increased incidence of acute respiratory complications, defined as the combination of the presence of one or more of these symptoms: stridor, dyspnea, wheezing, presence of oxygen desaturations requiring an intervention. • Data over a 10-year period suggests an increasing trend in cuffed ETT use in both age groups. • Desaturation events (≤90%) needing an intervention were found less often after cuffed ETT use. • No differences found in acute post operative respiratory complications between cuffed and uncuffed ETT use.

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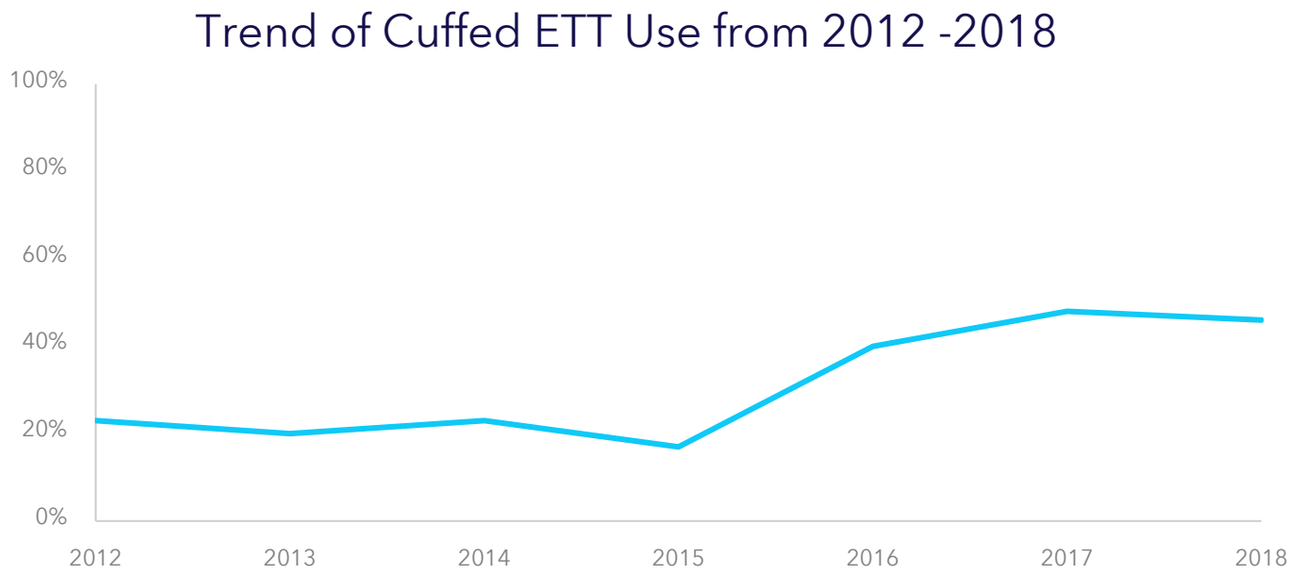
Bibl K, Pracher L, Kung E, et al.

Incidence of post-extubation stridor in infants with cuffed vs. uncuffed endotracheal tube: a retrospective cohort analysis.

Front. Pediatr. 2022;10:1-9.[10]



*Adapted from Bibl et al. (2022), Figure 2

Study information	
Study design	Retrospective cohort analysis
Methods	• 271 infants (bodyweight 2-6 kg) admitted to two NICUs of the Medical University of Vienna between 2012-2019. • n=92 intubated with a cuffed ETT; n=179 intubated with an uncuffed ETT.
Primary outcome	• Primary endpoint included post extubation stridor.
Results	Cuffed ETT use was associated with: • Shorter time of invasive ventilation as compared to uncuffed ETT group (1 day vs. 3 days; $p < 0.001$). • No difference in the incidence of post-extubation stridor between cuffed ETT and uncuffed ETT use. • Infants who developed subglottic stenosis were intubated with an uncuffed ETT.

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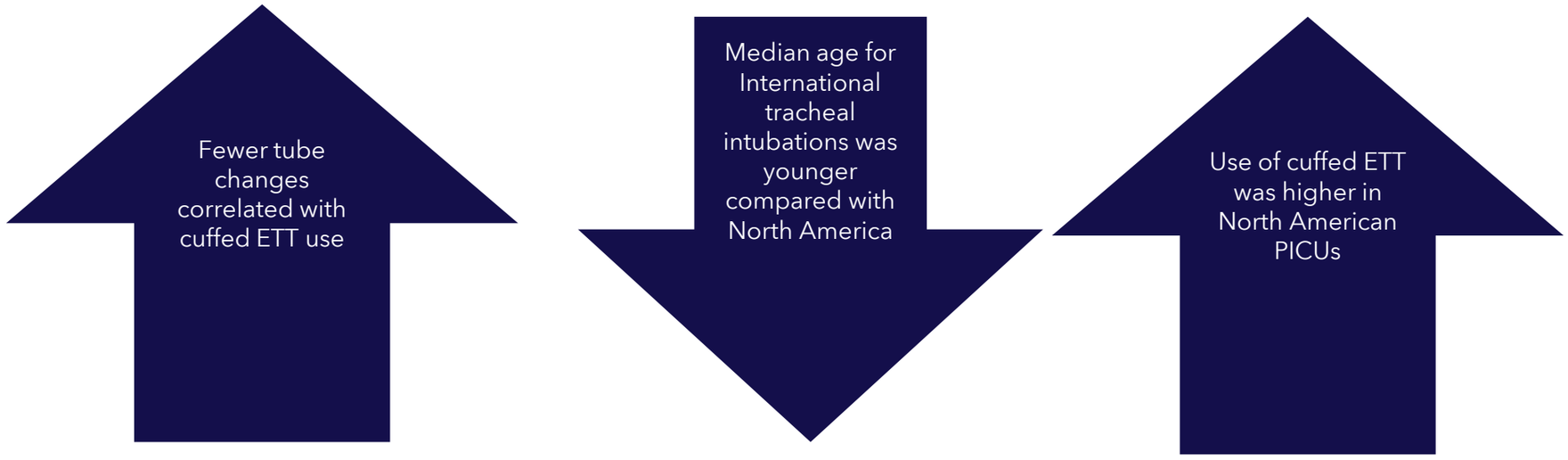
Lee JH, Nuthall, G, Ikeyama T. et al.

Tracheal Intubation Practice and Safety Across International PICUs: A Report From National Emergency Airway Registry for Children.

Ped Crit Care Med. 2019;20(1):1-8.[11]



Study information

Study design	Prospective multicenter pediatric tracheal intubation database,(National Emergency Airway Registry for Children).
Methods	• **Multicenter tracheal intubation (TI) project (NEAR4KIDS)** from six different geographical regions (New Zealand, Japan, Singapore, Germany, India, and North America). • n=(42 ICUs worldwide: six PICUs from non-North American (international) regions and 36 PICUs and cardiac ICUs from North America).
Primary outcome	• Primary endpoint was adverse tracheal intubation associated events and desaturation occurrence (oxygen saturation < 80%).
Results	• Proportion of cuffed ETT use per PICU was inversely correlated with the rate of tube change (r = –0.67; $p < 0.001$). • Cuffed ETT were used less often in International PICUs (51.7%) compared with North American PICUs (95.0%), $p < 0.001$. • Median age for International tracheal intubations was younger compared with North America (0 yr [interquartile range, 0–2 yr] vs 1 yr (0–7 yr); $p < 0.001$). • Occurrence of any adverse tracheal intubation–associated event was New Zealand 8%, Japan 17%, Singapore 9%, Germany 17%, India 6%; and International 11% versus North American 14%; $p = 0.003$.

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Greaney D, Russell J, Dawkins I.

A retrospective observational study of acquired subglottic stenosis using low-pressure, high-volume cuffed endotracheal tubes.

Paediatr Anaesth. 2018;28(12):1136-1141.[12]

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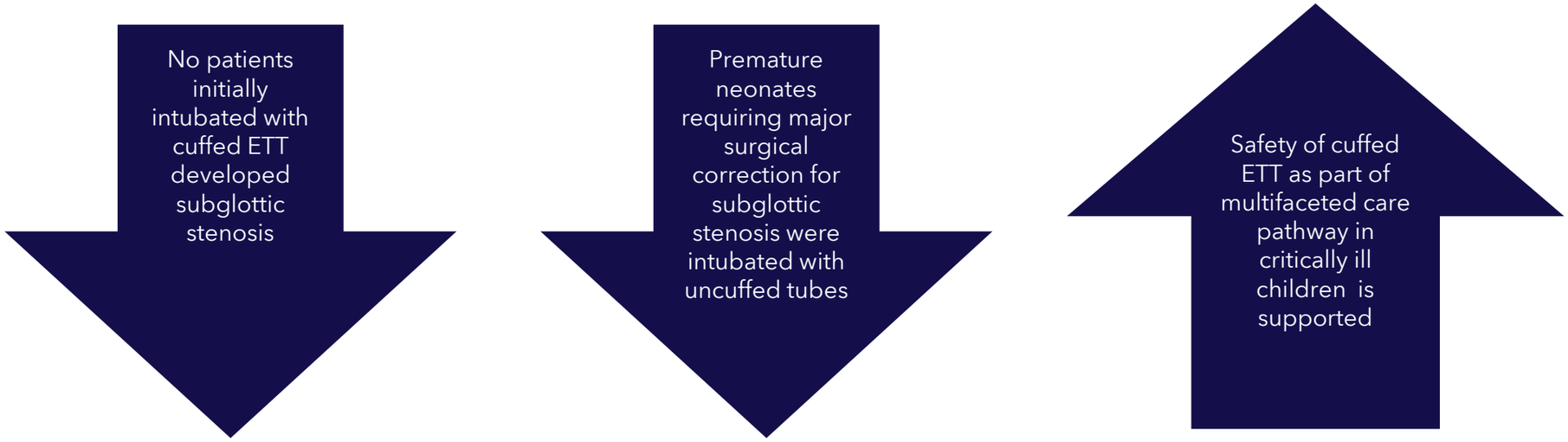

Study information	
Study design	Retrospective observational study, data sourced from the validated Pediatric Intensive Care Network (PICANet database).
Methods	• n=5039 patients admitted between 2012- 2017 to a tertiary pediatric critical care unit.
Primary outcome	• Primary endpoint included, subglottic stenosis on a micro laryngoscopy within six months of invasive ventilation.
Results	Cuffed ETT use was associated with: • Less incidence of developing subglottic stenosis requiring surgical correction, when initially intubated with a cuffed ETT. • All premature neonates requiring major surgical correction were ex-premature neonates (24-35 weeks gestation) initially intubated with uncuffed tubes in a neonatal intensive care unit (NICU).

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Chand R, Roy Chowdhury S, Rupert E.
Benefits of using high-volume–low-pressure tracheal tube in children undergoing congenital cardiac surgery: evidence from a prospective randomized study.
Seminars in Cardiothoracic and Vascular Anesthesia. 2018,22(3):300–305.[13]

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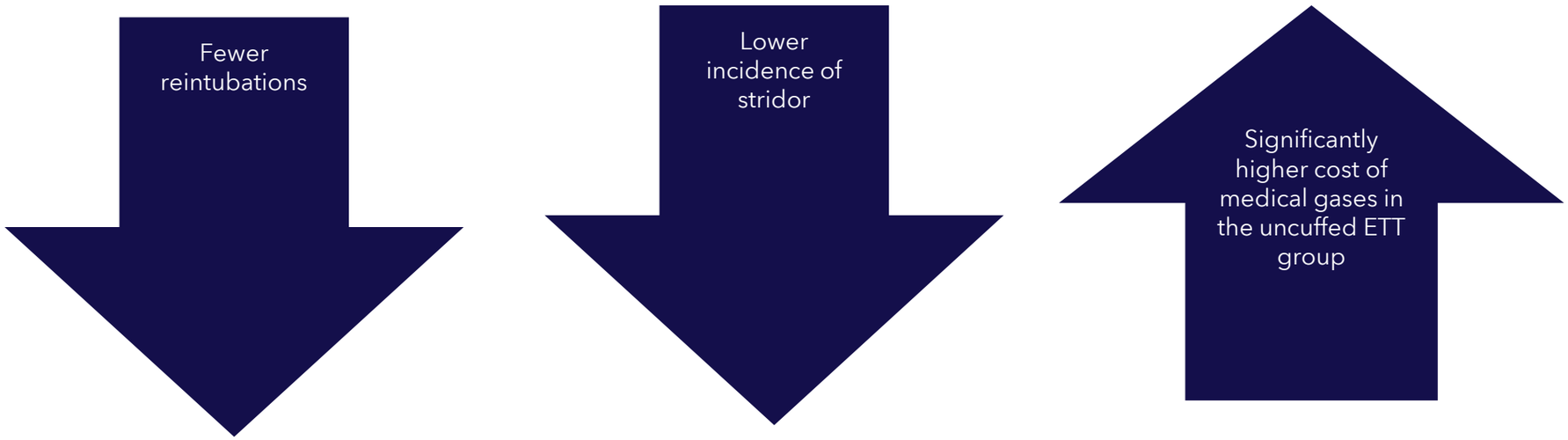

Study information

Study design	Prospective randomized controlled trial (RCT)
Methods	• n= 80 children less than five years age undergoing elective, congenital cardiac surgery.
Primary outcome	• Primary endpoint included post extubation stridor. • Secondary endpoints included reintubations, volume of anesthetic gases required and associated costs.
Results	Cuffed ETT use was associated with: • Significantly lower incidence of stridor, reintubations, less gas leak around ETT; and anesthetic gas requirements and costs. • The number of tube changes was significantly higher in the uncuffed group. There was a three-fold risk of stridor associated with tube changes. • Isoflurane, oxygen flow requirement s and the costs were significantly higher in the uncuffed group.

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Less incidence of VAP
- Thomas et al. 2016
- Jeria et al. 2021

Less exposure of health care workers to aerosolized particles such as Covid 19
- Dariya et al. 2022

Less gas leak around the ETT (less gas pollution in OR/atmosphere)
- Dariya et al. 2022
- Chand et al. 2018
- Thomas et al. 2016

Cost effectiveness, less use of anesthetic and other gases
- Chand et al. 2018
- Eschertzhuber, et al. 2010

Less incidence of post extubation stridor (PES)
- Williams et al. 2022
- Jeria et al. 2021
- de Wit, et al. 2018

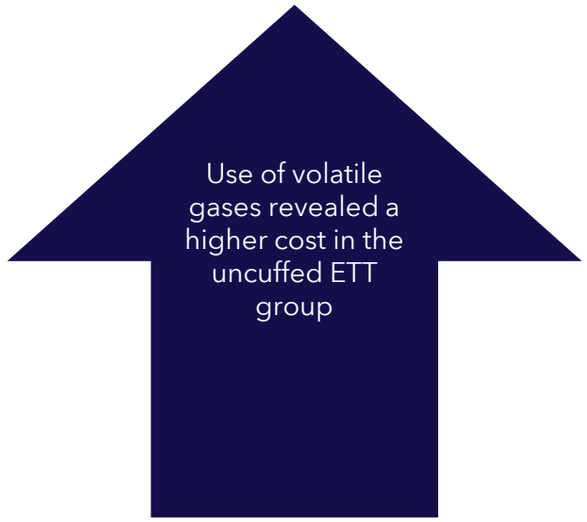
Less incidence of tube exchange/laryngoscopy
- Chand et al. 2018
- Williams et al. 2022

Fewer reintubations
- Dariya et al. 2022
- Williams et al. 2022
- Thomas et al. 2021

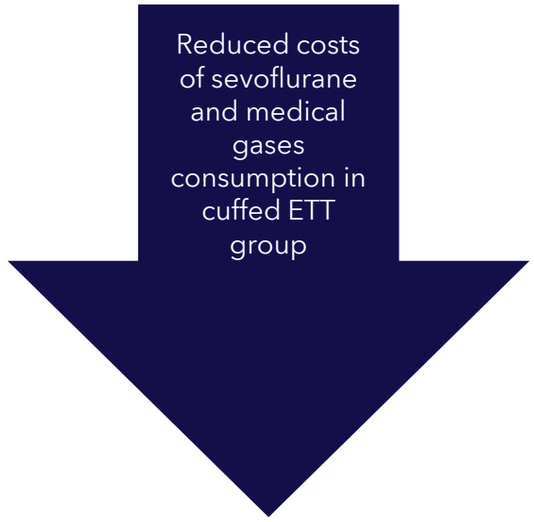
Less incidence of post extubation subglottic stenosis
- Bibl et al. 2022
- Dariya et al. 2022
- Greaney et al. 2018

Cost Savings of Anesthetic Gases and Cuffed ETT Use

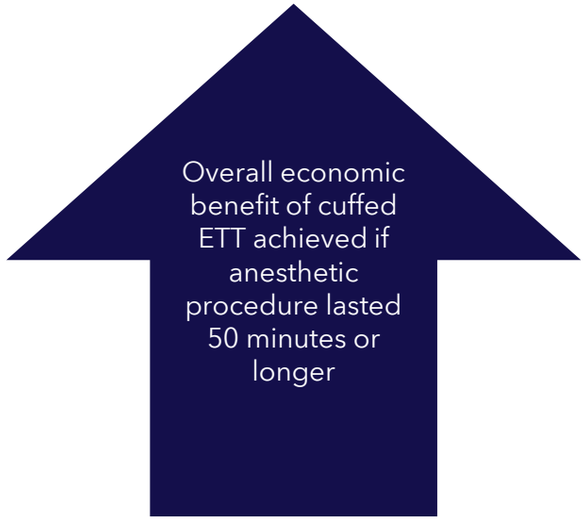
Chand, et al. 2018[13]



Eschertzhuber, et al. 2010[14]



Eschertzhuber, et al. 2010[14]



Cost savings and cuffed ETT

Chand et al. 2018[13]

- There was a significantly higher cost incurred in the conventional uncuffed ETT group vs. high-volume–low-pressure microcuff ETT ($p < .0001$) for volatile gas use.
- There was a significantly higher number of tube changes in the uncuffed group with 61 uncuffed tubes required as opposed to 42 in the microcuff group.
- The overall cost of a high-volume–low-pressure microcuff ETT was partially offset by a reduction in the number of tube changes and the reduction of volatile gas usage.

Eschertzhuber, et al. 2010[14]

- The median medical gas consumption was 129 liters in the uncuffed group vs 46 liters in the cuffed ETT group.
- The use of cuffed ETT in children significantly reduced the costs of sevoflurane and medical gas consumption during anaesthesia. Total cost of sevoflurane and medical gases were almost two and a half times higher per patient in the uncuffed ETT group compared to the cuffed ETT group.
- Higher costs of cuffed ETT compensated after first 50 minutes of anesthesia.

Review the evidence of benefits associated with use of cuffed ETT in pediatrics.

Improved ventilation

- Thomas et al. 2016

Fewer accidental extubations

- Dariya et al. 2022

Less incidence of VAP

- Thomas et al. 2016
- Jeria et al. 2021

Less exposure of health care workers to aerosolized particles such as Covid 19

- Dariya et al. 2022

Less gas leak around the ETT (less gas pollution in OR/atmosphere)

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- Dariya et al. 2022
- Williams et al. 2022
- Thomas et al. 2021

Less incidence of post extubation subglottic stenosis

- Bibl et al. 2022
- Dariya et al. 2022
- Greaney et al. 2018

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