WORKSHEET for Evidence-Based Review of Science for Emergency Cardiac Care

Worksheet author(s)

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Resubmission after initial review: 13 November 2009
Revision: 3 February 2010

Clinical question.

In children requiring emergent intubation (pre-hospital, in-hospital) (P), does the use of cuffed ETTs (I) compared with uncuffed ETTs (C) improve therapeutic endpoints (eg, oxygenation and ventilation) or reduce morbidity or risk of complications (eg, need for tube change, airway injury, aspiration) (O)?

Is this question addressing an intervention/therapy, prognosis or diagnosis? Intervention

State if this is a proposed new topic or revision of existing worksheet: Revision

Conflict of interest specific to this question

Do any of the authors listed above have conflict of interest disclosures relevant to this worksheet? None at all

Search strategy (including electronic databases searched).

PubMed “intubation, intratracheal” as MESH (headings) AND “Cuffed” textword in abstract AND “Children” textword in abstract LIMITED TO 2004 – 2009 (As this is an update on worksheet last completed in Jan 2005)

EMBASE search using “intubation” text words (all fields) AND “Children” AND “Cuffed” LIMITED TO PERIOD 2004 -2009 (As this is an update on worksheet last completed in Jan 2005)

AHA EndNote Master library (No new articles retrieved)

Cochrane database for systematic reviews, Central Register of Controlled Trials, - “Intubation, Intratracheal” AND “Children”

Review of references from articles.

• State inclusion and exclusion criteria

Major inclusion criteria was CHILDREN. No specific exclusion criteria was used. The search was NOT limited to English language only references. The search period was limited to 2004-2009.

Studies reported in the literature in abstract form only were not included in the evidence evaluation. There were none in the period 2004 – 2009, as opposed to the first review of this worksheet when there were 4.

• Number of articles/sources meeting criteria for further review:

17 new articles were retrieved for further review in the period 2004 -2009, however only 3 of these – 1 LOE 4 and 2 LOE 5s were considered relevant enough to the PICO question to be included on the evidence evaluation grid to the previous 11 articles.

Note 1 article (Habib, 2002) on the old worksheet that was a LOE 6 (old scoring) and of fair quality, was reevaluated and I considered this to be too weak to remain on the grid with the revised evaluation schema.

The updated grids now have 15 references, however two references refer to the same data (one in English, the other in French) – see Devys 2003, 2004 under the Neutral category, and two other references have results that necessitate placement in both the Supporting as well as the Neutral categories – see Felten 2003.

Update February 2010

3 new key relevant article added to the grid (Publication Oct 2009, Nov 2009, Jan 2010)
### Summary of evidence

**Evidence Supporting Clinical Question**  
In the OR and PICU Settings

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**Italics = Animal studies**

- E1 - Decrease or low rate of re-intubation
- E2 – Decrease or low amount of fresh gas flow (FGF)
- E3 – Decrease or low Nitrous oxide pollution
- E4 – Decrease or low rate of post-extubation complications like stridor (croup) (CET Vs UET)
- E5 – Decrease aspiration
- E6 – Decrease or low rate of subglottic stenosis

# Weiss M, 2009 – study looked at a very specific and novel paediatric cuffed tube (Microcuff PET) as the only cuffed tube in the study possibly limiting wider interpretation of it’s beneficial results.
# Evidence Neutral to Clinical question

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E6 – Cuff pressure constancy  
E7 – Cuff compliance/pressure

# Evidence Opposing Clinical Question

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E8 – Margin of safety (anatomical position)  
E9 - Consistency of design of CETs
Background information

The presence of a cuff on an endotracheal tube used routinely for intubation in adults and older children (>8 years of age), is premised on the need to reduce the risk of aspiration into the lungs as well as to provide adequate ventilation. This rationale and practice has not been extended to young children (<8 years of age), due to the anatomical differences between the adult and paediatric airway. The narrowest portion of the paediatric airway is below the vocal cords at the cricoid ring. It has long been held that not only does a tracheal tube that is 'snug' just below the vocal cords provide adequate protection against aspiration but also ensures adequate ventilation without excessive airleak. Conventional wisdom has thus dictated the use of uncuffed tubes in younger children i.e < 8-10years, teaching that not only is the use of a cuff unnecessary but also potentially harmful. The latter concern appears to be based on the extensive reporting of acquired tracheal stenosis following intubation. The causative factors that have been identified for this complication have been an oversized tube, movement of the tube and duration of intubation. The argument thus advanced against the use of a cuffed tube is that this would effectively behave as an oversized tube with the resultant excessive pressure on the mucosal surface of the trachea, particularly at the cricoid ring with the consequent development of subglottic stenosis.

To avoid undue pressure on the tracheal mucosa by the uncuffed tube, it is common practice to ensure a small airleak at an airway pressure of about 20 cmH2O. It is not known precisely what tracheal mucosal capillary pressure is in small children, but it is probably 20-25 cm H2O.

An oversized tube has long been recognised as a pivotal cause for the development of tracheal stenosis. From the very earliest reports of the successful use of prolonged tracheal intubation, tracheal complications were seen resulting from the use of too large a tube. Hardcastle in 1966 stated 'leaving a tube in the layrnx for more than a few hours, especially if it is a large tube to obtain an airtight fit for ventilation purposes, is asking for trouble'. Stocks in 1966, declared that 'The selection of an appropriate size of tracheal tube is fundamental to the success of the technique of prolonged nasotracheal intubation in children. Too small a tube will ... make intermittent positive pressure ventilation difficult because of the leakage of gases through the the layrnx. Too large a tube will make the development of subglottic stenosis a possibility'. He goes on to report that it was now his practice to use a tube 'which allows a slight leak of gases from the layrnx when the lungs are inflated through it. In this way, one can be certain that the tube is not too large, whilst the gas leak is so small that it is insufficient to interfere with the use of a respirator'. This practice has remained the norm for most paediatric anaesthetists and intensivists to this day. However there has been sporadic reporting in the literature of the use of cuffed tubes in younger children in the last decade including two studies one of which was randomized, indicating support for it's use. Whilst there appears to be an increasing swing towards this practice, the extent of this change is currently unknown. Two large registries contacted about the use of cuffed endotracheal tubes in children under 8 years, unfortunately do not capture such data (NRCPR and POCA).

Arguments put forward AGAINST Cuffed tubes

1. Cuff unnecessary, given the anatomical narrowing of the paediatric airway below the vocal cords effectively providing this cuff.
2. A cuff would be harmful as this would impinge on the mucosa of the trachea, particularly at the cricoid ring resulting in tracheal stenosis.
3. The use of a cuff would require very close monitoring to limit excessive pressure exerted on the tracheal wall.
4. With the use of nitrous oxide there is an increase in cuff pressure that results.
5. The correct placement of the tube is more difficult when using a cuffed tube. The margin of safety is reduced.
6. Use of a cuffed tube requires the selection of a sightly smaller tube for age (0.5-1.0mm), which increases the airway resistance and hence increases the effort with spontaneous breathing.
7. High cost of tube material.

Arguments put forward FOR the use of cuffed tubes

1. An airleak may lead to severe management difficulties in many cases where for example there is poor lung compliance.
2. A cuffed tube ensures against aspiration.
3. Modern ventilators are able to monitor lung fuction, which is more reliable with a cuffed tube in place.
4. End-tidal monitoring of CO2 and inhalational gas concentration measured more accurately.
5. Minimal contamination of environment with anaesthetic gases like Nitrous Oxide.
6. Tube exchange rarely necessary (when using age based formulae).

THE EVIDENCE

Evidence AGAINST (use of CETTs)

1. (Ho, Aun et al. 2002)

Reviewer's Comments - This analytical (mechanical) model provided a useful insight into the practical issue of tube positionig and raised the concern of the reduced margin of safety when using cuffed tubes. It appears difficult to argue against such theoretical considerations however whilst alerting us to the risk of using a cuffed tube, it remains to be tested in the clinical setting where
perhaps the use of a cuffed tube already does elicit more close attention to position amongst other considerations such as pressure of the cuff. This concern would therefore argue against the use of cuffed tubes, and particularly in the out-of-hospital setting in which less than ideal circumstances prevail.


**Reviewer's Comments** - An excellent study of the commonly available cuffed endotracheal tubes, with respect to their design and suitability for the paediatric airway taking into account the anatomical considerations. The authors compared 15 series of cuffed (11) and uncuffed (4) tracheal tubes of various sizes (ID 2.5 - 7.0) from four different manufacturers. This investigation very clearly demonstrated the variability between the different makes of tracheal tubes, with respect to a number of features (outer diameter, position and diameter of cuff, position of depth markings) and pointed out the potential risks for their usage. The authors did indicate a “Declaration of interest” that they involved in the design of a new cuffed paediatric tracheal tube. Whilst the authors did not go as far as stating that cuffed tracheal tubes should be avoided in the younger child, their recommendations intact are for a better designed cuffed tracheal tube. This data has been placed in the ‘evidence against’ group based on the assumption that at present given these apparent design shortcomings in the currently available paediatric cuffed tracheal tubes there exists the theoretical potential to cause harm.

A paper by Dillier et al, 2004 (in citation index), tends to lend credence to the above stated concerns. In their paper, a 13-month-old child developed a laryngeal web post intubation with a cuffed tube whose size and position was purportedly to blame. The authors conclusion seems to be fair given the findings and discussion in this paper – “Most cuffed paediatric tracheal tubes are poorly designed, in particular the smaller sizes. 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”

**Evidence NEUTRAL (advocating caution when using CETTs)**


**Reviewer's Comments** – A very well designed study with significant findings of relevance to this debate. The authors found that cuff pressure to be unpredictable after free air inflation and that numerous gas removals were required to maintain P(cuff) less than 25 cm H(2)O during N(2)O anesthesia in children. They went onto indicate that free inflation of the tracheal tube cuff, controlled only by the palpation of the pilot balloon, is not reliable and results in extremely variable (and sometimes very high) initial cuff pressures in children. In addition, nitrous oxide anesthesia may result in cuff hyperinflation requiring numerous gas removals. The authors themselves do not argue against the use of cuffed tracheal tubes in young children and indeed found some of the proposed advantages of cuffed tracheal tubes, such as a low rate of tube replacement (5.6% versus the often reported rate of 18-30% according to the authors), airway leak was reduced from 17% (14-20%) to 7.5% (6.0-9.0%), and OR pollution significantly reduced during anaesthesia with low fresh gas flow”

Again the inclusion of this data amongst the studies either opposed or against a revision to the current guidelines on cuffed tracheal tubes is based on the premise that any data available that shows potential for compromised safety of its use, requires a cautious approach. This means that a caveat to the more widespread use of this equipment would need to be made about the precautions and level of close monitoring of cuff pressure required in certain situations as described above with Nitrous Oxide anaesthesia.


**Reviewer's Comments** – A mechanical model looking at the relationship between cuff volume and pressure and hence cuff compliance. It was designed to test the assertion that modern cuffs are indeed high-volume-low pressure cuffs. A similar article by the same group with the same study data and conclusions published in a French journal appeared in 2003 (see citation table). This was a mechanical model that questioned the claim by manufacturers that the present cuffs are high volume low pressured (HVLP) cuffs thereby allowing for safety in use in children. Whilst the relevance of this study remains to be seen in the clinical setting, the authors raise an important safety flag in the use of these cuffed tubes, and recommend close monitoring of cuff pressure. This study therefore does not argue against the use of cuffed tubes but does caution against the accepted notion of “High Volume Low Pressure” cuffs as claimed by the manufacturers. The study is being placed in the evidence against, as this does tend to support the contention that there needs to be more closer attention to safety with its use as there is potentially a risk with their use, which for the moment may make their widespread use injudicious.


**Reviewer's Comments** - A relevant study despite being a mechanical model with acknowledged limitations in terms of simulating the actual anatomical/physiological reality. Similar to the study by Devys et al, this group looked at the compliance of the cuff in a model that actually measured the pressure in the simulated tracheal wall. They found that tracheal wall pressure was similar to the cuff pressure as long as the resulting cuff diameter was sufficiently large freely to drape the inner tracheal wall. However they did find that regardless of whether a higher or lower compliant tube cuff was used, cuff hyperinflation uniformly resulted in potentially compromised tracheal mucosal blood flow and concluded that cuff pressure monitoring using cuff pressure limitation is therefore strongly recommended. This study makes the case for using pressure monitoring and particularly by precise and continuous pressure measurements during use of cuffed ETTs to avoid compromise of tracheal blood flow.
Evidence IN SUPPORT (of CETTs)

1. (Browning, Graves 1983)
Reviewer's Comments - Browning et al, compared the incidence of aspiration of dye in a controlled study of intubated children with or without a cuffed tube. The study prospectively enrolled children admitted to a paediatric intensive care unit who were ventilated. A total of 22 children were included, 11 with cuffed and 13 with uncuffed tubes. Limitations of the study were the very small numbers, the unequal (not-age controlled) groups, and not randomized. However, despite the fact that the uncuffed group consisted of mainly the younger children, this study demonstrates the ineffectiveness of the 'anatomical cuff' in preventing aspiration around the sides of an uncuffed tube in young children. Although the clinical significance of this 'silent aspiration' has yet to be determined, it does provide support for the use of cuffed ETTs where there was a significantly decreased incidence of this phenomenon. Interestingly, the investigators of the study did not propose further research into using cuffed tubes in children as a possible solution. It should be pointed out that at the time, even though not mentioned in the paper, the type of cuffed tubes in use were of the low-volume high pressure cuffs latex compared to the modern high-volume low pressure cuffs made of PVC (polyvinyl chloride).

2. (Deakers, Reynolds et al. 1994)
Reviewer's Comments - A prospective non-randomized controlled study of cuffed versus uncuffed in the PICU setting to look at the incidence of post-extubation stridor. Good design and medium-term follow up on 282 consecutive tracheal intubations (243 patients). However, there was a significant difference in the age groups between the children with cuffed tubes (older) and those without (younger). This absence of age-matched controls, makes comparison less useful. The authors did analyse for complications controlling for age and hence attempted to avoid this problem. No indication of any newborns included. There was no significant difference in the incidence of stridor when controlling for intubation route, accidental extubations, or presence of airleak before extubation.

3. (Khine, Corddry et al. 1997)
Reviewer's Comments - A well-designed, randomized controlled trial in the Operating Room (OR) setting. Probably the best study done in this area, trying to answer not only the question of safety of cuffed tubes but also its efficacy and advantages over uncuffed tubes. It found statistically significant differences in favour of cuffed tubes with regards to the following: number of reintubations required, amount of fresh gas flow and Nitrous oxide pollution of the OR. There was no difference in the incidence of stridor between the two groups (cuffed versus uncuffed). The number of patients in each group (cuffed 251 Vs uncuffed 237) was large enough to demonstrate statistical differences and the results were thus compelling. Limitations - no long-term follow up of children particularly those who had symptoms of croup. Small number of these patients and perhaps a larger sample size would have been required to detect differences between the two groups. The number of newborns was not indicated.

4. (Mhanna, Zamel et al 2002)
Reviewer's Comments - The study investigators looked at the independent risk posed by the presence of a cuffed endotracheal tube for postextubation stridor. There findings were that in young patients (<7 years old), the incidence of postextubation stridor was not different among patients with or without a cuffed ET (7 of 16(43%) vs. 26 of 48(54%), respectively; p=0.46). The authors of this paper state that "this further supports the the recommendations of Deakers et al. who showed the safety of cuffed ETs in young children."

5. (Bordet, F.B. Allaouchiche, et al. 2002)
Reviewer's Comments - A large prospective study (1996 children - 6.45 +/- 2.9 years) in the OR setting looking at the device user, the duration of anaesthesia and the type of airway device used as well as adverse respiratory events during the perioperative and postoperative periods comparing LMA, face mask and ETs. Overall there were 75.6% of children that had a cuffed tube. Cuffed tubes were used in 30% of children under the age of 6 years and in 98% of those 6 years and above. The study found that cuffed tracheal tubes were NOT associated with an increase risk of perioperative airway complications. With univariate analysis for cuffed tubes the risk of complications was not significant p=0.85 Odds ratio = 1.05 (95% CI 0.58-1.92).

Reviewer's Comments - A large prospective study that had a well-defined population of children requiring intensive care management. A significant number of children under 8 years received cuffed tubes making a reasonably good comparison to the uncuffed group. Study end-points were defined, such as the need for racemic adrenaline post-extubation and the rate of successful extubation, were assessed and showed no significant differences between the groups. The longer term sequelae such as the need for tracheostomy was observed over this 12 month period and no differences noted, which arguably may be too short a period. Two potential points of criticism of this study are (a) the physicians assessing the need for post-extubation racemic epinephrine were not blinded to the type of ETT used and (b) a compounding factor to the outcome of extubation would be the indication and nature of pathology in the child, and this did not seem to be controlled for, for instance what proportion of each group had upper airways
pathology. The fact that there was a significant difference in the length of mechanical ventilation and duration of intubation (for those 24 months and under) in the two groups points to either different disease processes and/or severity. It would have also been useful to know how many children were excluded from the analysis of the cuffed group based on choice of tube size noted in keeping with the criteria above i.e one-half size less than that determined by the modified Coles formula.

7. (Engelhardt T et al, 2006)
**Reviewer’s Comments** – Small study, good design, correct population and randomization present. However the study was not designed to look at therapeutic endpoints or reduction in morbidity or complications and so not quite within PICO question. Nevertheless it did provide evidence for the use of CET over UET with the advantage of having less airleak and hence need for lower fresh gas flow (FGF) with CET. This advantage of CET has been cited as one of the rationale’s for a move towards CETs.

8. (Duracher C et al, 2008)
**Reviewer’s Comments** – Good paper, very relevant to this worksheet question, a non-randomized prospective study looking at correct sizing of CETTs. One of few papers reporting on outcomes of use of cuffed ETTs in children. Whilst the actual purpose of this study was to look at correct sizing of CET, and not necessarily the outcomes, this was reported in the paper and the rate was low, providing further degree of reassurance with the use of CET under optimal conditions (pressure monitoring). The number of children involved were high (204) but there was no control group (i.e uncuffed) as this was not in the design of the study. Range of children good 1 day – 15 years. Limitations on study were that the complications reported were fairly subjective i.e the anaesthetist performing the intubation reported whether this was traumatic or not and that the complications were also based only on signs and symptoms i.e croup, cough, sore throat etc. I think whilst this is a low level of evidence (LOE 4) paper given that the design was not to examine the outcomes of use of CET, this does add to the evidence for it’s use and more importantly it provides evidence on the appropriate prediction of size of CET required which would assist in it’s safer use.

9. (Weiss M et al, 2009)
**Reviewer’s Comments** – Relevant paper looking at Cuffed Vs Uncuffed TT usage in young children (0-5 years) in a multicentre (24 European Paeds Anaesthetic centres) randomized fashion. Although investigators had initially planned and powered study to include just under 4000 individuals, and the study prematurely ended (reasons not provided), they included 2246 children across all these centres and study design was truly randomized with concealing of allocation numbers. The study outcomes were to look specifically at post-extubation stridor rates between the two groups (CETT and UETT) as well as compare the tube exchange rate between the groups. This is a LOE 1 study which I regard as good in methodology and analysis. However this study’s main limitation as indicated by the authors is the fact that they used a specialized cuffed TT called the Microcuff PET, that whilst commercially available is not yet in widespread use. The beneficial findings of the cuff therefore pertain to this specifically designed type of cuffed tube and may not necessarily apply to all types of cuffed tubes in common usage. Whilst the PICO question does not exclude this type of cuffed tube it was designed to look at all cuffed tubes in current usage, and therefore I feel this study should be included in the evidence evaluation grid which a qualification as to it’s relevance. This is important too as the Microcuff PET may become popular as a result of it’s unique design. The authors have disclosed the financial support for the study was from Microcuff GmbH, Weinheim, Germany who provided the CETTs, cuff manometers and release valves. It also received funding from a study grant (from the Swiss Society for Anaesthesia and Resuscitation).

10. (Mossad E et al, 2009)
**Reviewer’s Comments** – This was a retrospective chart review of children with Congenital Heart Defects (CHD) that underwent an operation and documented the incidence of post-operative subglottic stenosis (SGS) in this population. Whilst the authors pointed out the increased risk of other congenital abnormalities including subglottic stenosis, the review looked at this as a post-operative complication and noted the various risk factors associated with the development of SGS. This is a relevant paper as the development of SGS has been a feared outcome of the use of CETT and this study looked at the use of CETT Vs UETTs. The data was from one centre over a period of 4-years (Jan 2002 – Dec 2005) and included 1572 children ( < 18 years). SGS was noted in 17 cases representing an incidence of 1.08 in all children. These 17 cases were all under 2 years and this represented an incidence of 2.1% (17/809) in all children under 2 years who were in the study. These 17 cases were all born at full term and had no airway abnormalities preoperatively according to the paper. Of these 17 patients only two had a cuffed tube. The authors pointed out the change in practice over recent years with more frequent use of cuffed tubes and in this population 783 out of 809 (97%) of the children less than 2 years of age had a CETT. It was interesting that 15 of the 26 children who received uncuffed tubes developed SGS possibly as the authors indicate related to their cardiac condition, health status and duration of postoperative intubation. They noted that other contributing factors to the development of acquired SGS in children with CHD include (from previous experience and references provided) infection and bacterial colonization of ETT, autoimmune reaction, and the presence of gastroesophageal reflux disease.
They concluded that that the development of SGS is multifactorial, although some factors as age < 2 years and prolonged intubation are shown (in this study) to increase the risk of SGS postoperatively. Contrary to prior opinions, the use of CETTs, even in very small children, in the current era does not appear to increase the risk of SGS postoperatively. Careful ETT selection, limited airway instrumentation and protocols for early extubation, especially in the very small child, may decrease the incidence of SGS.

11. (Dorsey D et al, 2010)
Reviewers comments – A retrospective review of paediatric patients with burns 0-10 years over a 10 year period who required intubation at a single centre with a view to looking specifically at CETTS versus UETTs in relation to the clinical airway outcomes such as significant tidal volume loss and/or need for reintubation. The incidence of post-extubation stridor across the two groups was also looked at. Clinical airway outcomes were compared using multivariable logistic regression, controlling for relevant patient and injury characteristics. Compared to those receiving CETTs, children receiving UETTs were significantly more likely to demonstrate clinically significant loss of tidal volume (OR 10.6 95% CI – 2.2 -50.5) and require immediate reintubation to change tube size/type (OR 5.54, 95% CI-2.1-13.6). No significant differences were noted for rates of post-extubation stridor (7.2% for CETTs vs. 3.4% UETTs), or for failed extubation (1.8% CETTs vs. 3.4% UETTs) or for self-extubation (0.9% in both groups).

**Final Comments**

1. It is well known that intubation has the potential to result in complications particularly subglottic stenosis.
2. The causative factors are the use of an oversized tube, movement of the tube and duration of intubation. Young age also appears to be a risk factor.
3. It has thus been the practice to have a small airleak around the sides of an uncuffed tube to ensure no undue compression of the mucosa of the trachea.
4. This practice of ensuring a leak effectively excluded/contraindicated the use of a cuffed tube in children under the age of 8 years. There have been exceptions to this rule, whenever for instance optimal ventilation in a situation of poor lung compliance exists. In these cases cuffed tubes have been used.
5. No controlled studies however reflected this theoretical concern
6. It has not been until fairly recently that the long held view that a cuffed tube would cause more complications (specifically subglottic necrosis and then stenosis) than an uncuffed tube, has been challenged.
7. There are no studies that have compared the use of cuffed to uncuffed endotracheal tubes in children of any age during resuscitation.
8. There is no data on the use of cuffed endotracheal tubes in the pre-hospital setting.
9. The recommendations being made are therefore based upon the experiences from the paediatric general anaesthesia and intensive care settings.
10. It has been shown that children intubated with cuffed tubes for a short-time under general anesthesia, have no increased risk of postextubation stridor than those with uncuffed tubes.
11. Probably more significantly studies of more longer-term usage of cuffed tubes in young children such as in the intensive care setting, has also not shown any short-term or long-term complications.
12. It has also been shown that cuffed tubes result in less likelihood of aspiration, less contamination of the operating environment with nitrous oxide, more efficient use of fresh gas for anaesthesia and required less tube changes than with uncuffed tubes.
14. More recent data has indicated the need to develop better designed cuffed tubes in children as the currently available tubes may be unsuitable in as far as cuff design and position is concerned.
15. Despite the apparent safety and advantages of cuffed tubes, there are some important caveats.
   - The correct position of the cuff has to be ensured. (the margin of safety has been shown to be reduced)
   - The cuff pressure has to be closely and continuously monitored. The intracuff pressure during anaesthesia with nitrous oxide (N₂O) is particularly unpredictable and variable.
   - The correct size of tube must be selected.(smaller tubes – 0.5 – 1.0 mm less than that calculated for an uncuffed tube is what has been used)
   - The smaller the size required the greater the relative increased airway resistance.( a concern that should be borne in mind with neonates).
   - the evidence presented were based on low-pressure high volume cuffs(the cuffs presently utilized).
16. It has been suggested that tracheal mucosal perfusion may be lowered during periods of haemodynamic instability and we may therefore conclude that cuff pressure monitoring is especially important in these situations which frequently pertains in the resuscitation scenario, in order to avoid any tracheal injury.
17. There is concern about the smaller sized tubes (< 4.0 ID) being cuffed, in as far as it may increase the work of breathing and make tracheal suctioning difficult. Cuffed tubes have nevertheless been used in neonates in the studies with no reported adverse outcomes.
The table below shows the cuff pressures and leak pressure thresholds used and described in their papers. In the case of Dorsey, this was a personal communication of the institutions routine practice.

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<th>Study</th>
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<td>Khine 1997</td>
<td>25 cm H₂O</td>
<td>20 – 30 cm H₂O</td>
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<td>Newth 2004</td>
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<td>25 cm H₂O</td>
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<td>Weiss 2009</td>
<td>20 cm H₂O</td>
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<td>Dorsey 2010</td>
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</table>

**Acknowledgements**: My wife Feroza, daughter Aalia and son Fuaad for patiently putting up with me in completing this work. Serah van Vuuren for assisting me with the printing of references and Biziwe Tembe our wonderful librarian who has been an absolute lifesaver.
### Citation List

<table>
<thead>
<tr>
<th>Citation Marker</th>
<th>Full Citation*</th>
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<tbody>
<tr>
<td></td>
<td>- LOE – 5, Quality – Poor, Evidence Neutral</td>
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<tr>
<td></td>
<td>- A very good and relevant study despite being a mechanical model with acknowledged limitations in terms of simulating the actual anatomical/physiological reality. These investigators looked at the compliance of the cuff in a model that actually measured the pressure in the simulated tracheal wall.</td>
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<td></td>
<td>- Financial disclosure - The tracheal tubes studied were ordered from the local distributors. No financial support was obtained from the manufacturers for the presented study. PD Dr Weiss is involved in designing paediatric tracheal tube cuffs made from polyurethane in co-operation with Microcuff GmbH, Weinheim, Germany, and TYCO Health Care, R &amp; D Athlone, Ireland. No agreements or financial benefits arise from these co-operations.</td>
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<td>- LOE – 5, Quality – Poor, Evidence - Supportive</td>
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<td>- A large prospective study (1996 children -6.45 +/- 2.9 years) in the OR setting looking at the device user, the duration of anaesthesia and the type of airway device used as well as adverse respiratory events during the perioperative and postoperative periods comparing LMA, face mask and ETTS. Overall there were 75.6% of children that had a cuffed tube. Cuffed tubes were used in 30% of children under the age of 6 years and in 98% of those 6 years and above. The study found that cuffed tracheal tubes were NOT associated with an increase risk of perioperative airway complications. With univariate analysis for cuffed tubes the risk of complications was not significant p=0.85 Odds ratio = 1.05 (95% CI 0.58-1.92).</td>
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<td>- No comment about industry funding</td>
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<td>- LOE, -5, Quality – Poor, Evidence - Supportive</td>
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<td>- They compared the incidence of aspiration of dye in a controlled study of intubated children with or without a cuffed tube. The study prospectively enrolled children admitted to a paediatric intensive care unit who were ventilated. A total of 22 children were included, 11 with cuffed and 13 with uncuffed tubes. Limitations of the study were the very small numbers, the unequal (not-age controlled) groups, and not randomized</td>
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<td>- LOE – 5, Quality – Good, Evidence - Supportive</td>
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<td>- A prospective non-randomized controlled study of cuffed versus uncuffed in the PICU setting looking at the incidence of post-extubation stridor. Good design and medium-term follow up on 282 consecutive tracheal intubations (243 patients). However there was a significant difference in the age groups between the children with cuffed tubes (older) and those without (younger). This absence of age-matched controls, makes comparison less useful. The authors did analyse for complications controlling for age and hence attempted to avoid this problem. No indication of any newborns included. There was no significant difference in the incidence of stridor when controlling for intubation route, accidental extubations, or presence of airleak before extubation.</td>
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<td>- No comment about industry funding</td>
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</tbody>
</table>
- LOE - 5, Quality – Poor, Evidence – Neutral  
- See comments in related citation below  
- No comment about industry funding |
- LOE - 5, Quality – Poor, Evidence - Neutral  
- A mechanical model looking at the relationship between cuff volume and pressure and hence cuff compliance. A similar article by the same group with the same study data and conclusions published in a French journal appeared in 2003 (see citation above). This was a mechanical model that questioned the claim by manufacturers that the present cuffs are high volume low pressured (HVLP) cuffs thereby allowing for safety in use in children. The authors raise an important safety flag in the use of these cuffed tubes, and recommend close monitoring of cuff pressure. This study therefore does not argue against the use of cuffed tubes but does caution against the accepted notion of “High Volume Low Pressure” cuffs as claimed by the manufacturers.  
- No comment about industry funding |
Not on evidence grid – background information only |
Article In Press (at time of inclusion in worksheet 30 Jan 2010)  
- LOE - 5, Quality – Fair, Evidence – Supportive  
- This was considered a fair quality paper and although represented a specific population (paediatric burns), it was considered important as it was in children that required intubation for a variety of reasons not all of whom had smoke inhalation or obstructive airways as a result. Also this study was designed specifically to look at the comparative outcomes (positive and negative) of cuffed versus uncuffed tubes. It included children from 0-10 years and spanned a 10 year period during which time the authors noted an interesting phenomenon of a switch in ETT type preference in the first five years (1998-2002) and the next five years (2003-2007) towards cuffed ET Ts (29.5% in the first half to 70.6% in the second period).  
- It could be argued that this population comes the closest to the emergent intubation population that the PICO question is addressing as intubation may have been required in a non-elective fashion, where anatomical challenges may have been present and extensive fluid resuscitation could be a compromising factor in terms of airway anatomy.  
- The authors of the manuscript have no conflicts of interest with respect to the report  
- This study was funded, in part, by the Alpha Omega Alpha Honor Society’s Carolyn L. Kuckein Student Research Fellowship, the Foundation for Anesthesia Education and Research Medical Student Anesthesia Research Fellowship, the David and Nancy Auth-Washington Research Foundation Endowment, and the National Center for Research Resources (NCRR, 1KL2RR025015-01). Sponsors had no role in the study design, in the collection, analysis and interpretation of data; in the writing of the manuscript; or in the decision to submit the manuscript for publication. |
8.  
- **LOE - 5, Quality – Fair, Evidence – Supportive**  
  Good paper, very relevant to this worksheet question, a non-randomized prospective study looking at correct sizing of CETTs. One of few papers reporting on outcomes of use of cuffed ETTs in children. Whilst the actual purpose of this study was to look at correct sizing of CET, and not necessarily the outcomes, this was reported in the paper and the rate was low, providing further degree of reassurance with the use of CET under optimal conditions (pressure monitoring). The number of children involved were high (204) but there was no control group (i.e uncuffed) as this was not in the design of the study. Range of children good 1 day – 15 years. Limitations on study were that the complications reported were fairly subjective i.e the anaesthetist performing the intubation reported whether this was traumatic or not and that the complications were also based only on signs and symptoms i.e croup, cough, sore throat etc.  
- **No comment about industry funding**

**Engelhardt, 2006**  
- **LOE - 5, Quality – Good, Evidence - Supportive**  
  Small study, good design, correct population and randomization present. However the study was not designed to look at therapeutic endpoints or reduction in morbidity or complications and so not quite within PICO question. Nevertheless it did provide evidence for the use of CET over UET with the advantage of having less air leak and hence need for lower fresh gas flow (FGF) with CET. This advantage of CET has been cited as one of the rationale’s for a move towards CETs  
- **No comment about industry funding**

**Felten, 2003**  
- **LOE - 5, Quality – Fair, Evidence - Supportive and Neutral**  
  A very well designed study with significant findings of relevance to this debate. The authors found that cuff pressure to be unpredictable after free air inflation and that numerous gas removals were required to maintain P(cuff) less than 25 cm H(2)O during N(2)O anesthesia in children. They went onto indicate that free inflation of the tracheal tube cuff, controlled only by the palpation of the pilot balloon, is not reliable and results in extremely variable (and sometimes very high) initial cuff pressures in children. In addition, nitrous oxide anesthesia may result in cuff hyperinflation requiring numerous gas removals.  
  The authors themselves do not argue against the use of cuffed tracheal tubes in young children and indeed found some of the proposed advantages of cuffed tracheal tubes, “such as a low rate of tube replacement (5.6% versus the often reported rate of 18-30% according to the authors), airway leak was reduced from 17% (14-20%) to 7.5% (6.0-9.0%), and OR pollution significantly reduced during anaesthesia with low fresh gas flow” (hence inclusion in supporting grid)  
  The inclusion of this data in the neutral grid is based on the premise that any data available that shows potential for compromised safety of it’s use, requires a cautious approach. This means that a caveat to the more widespread use of this equipment would need to be made about the precautions and level of close monitoring of cuff pressure required in certain situations as described above with Nitrous Oxide anaesthesia  
- **No comment about industry funding**

**Hardcastle, 1966**  
Not on evidence grid – background information only

**Ho, 2002**  
<table>
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<th>Study Title and Details</th>
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| Paediatric tracheal tubes." *Anaesthesia* 57(2): 173-5. | **LOE - 5, Quality – Poor, Evidence - Opposing**
| | • This analytical (mechanical) model provided a useful insight into the practical issue of tube positioning and raised the concern of the reduced margin of safety when using cuffed tubes. It appears difficult to argue against such theoretical considerations however whilst alerting us to the risk of using a cuffed tube, it remains to be tested in the clinical setting where perhaps the use of a cuffed tube already does elicit more close attention to position amongst other considerations such as pressure of the cuff. This concern would therefore argue against the use of cuffed tubes, and particularly in the out-of-hospital setting in which less than ideal circumstances pertain. |
| Khine, 1997 | **LOE - 5, Quality, good, Evidence - Supportive**
| Khine, H. H., D. H. Corddry, et al. (1997). "Comparison of cuffed and uncuffed endotracheal tubes in young children during general anesthesia." *Anaesthesiology* 86(3): 627-31; discussion 27A. | • A well designed, randomized controlled trial in the Operating Room (OR) setting. The best study so far in this area, trying to answer not only the question of safety of cuffed tubes but also it's efficacy and advantages over uncuffed tubes. It found statistically significant differences in favour of cuffed tubes with regards to the following: number of reintubations required, amount of fresh gas flow and Nitrous oxide pollution of the OR. There was no difference in the incidence of croup between the two groups (cuffed versus uncuffed). The number of patients in each group (cuffed 251 Vs uncuffed 237) was large enough to demonstrate statistical differences and the results were thus compelling. Limitations - no longterm follow up of children particularly those who had symptoms of croup. Small number of these patients and perhaps a larger sample size would have been required to detect differences between the two groups. The number of newborns was not indicated. |
| Mhanna, 2002 | **LOE - 5, Quality – Poor, Evidence – Supportive**
| Mhanna, M. J., Y. B. Zamel, et al. (2002). "The "air leak" test around the endotracheal tube, as a predictor of postextubation stridor, is age dependent in children." *Crit Care Med* 30(12): 2639-43. | • The study investigators looked at the independent risk posed by the presence of a cuffed endotracheal tube for postextubation stridor. There findings were that in young patients (<7 years old), the incidence of postextubation stridor was not different among patients with or without a cuffed ET {7 of 16(43%) vs. 26 of 48(54%), respectively: p=0.46}. |
| Mossad, 2009 | **LOE - 5, Quality- Fair, Evidence – Supportive**
| Newth, 2004 | **LOE - 5, Quality- Fair, Evidence – Supportive**
| Newth, C.J., et al., *The use of cuffed versus uncuffed endotracheal tubes in pediatric intensive care.* *J Pediatr*, 2004. 144(3): p. 333-7. | • A large prospective study that had a well-defined population of children requiring intensive care management. A significant number of children under 8 years received cuffed tubes making a reasonably good comparison to the uncuffed group. Study end- |
points were defined, such as the need for racemic adrenaline post extubation and the rate of successful extubation, were assessed and showed no significant differences between the groups. The longer term sequelae such as the need for tracheostomy was observed over this 12 month period and no differences noted, which arguably may be too short a period. Two potential points of criticism of this study are (a) the physicians assessing the need for post extubation racemic epinephrine were not blinded to the type of ETT used and (b) a compounding factor to the outcome of extubation would be the indication and nature of pathology in the child, and this did not seem to be controlled for, for instance what proportion of each group had upper airways pathology. The fact that there was a significant difference in the length of mechanical ventilation and duration of intubation (for those 24 months and under) in the two groups points to either different disease processes and/or severity. It would have also been useful to know how many children were excluded from the analysis of the cuffed group based on choice of tube size noted in keeping with the criteria above i.e one-half size less than that determined by the modified Coles formula.

- No comment about industry funding

Weiss, 2009


- LOE - 5, Quality – Good, Evidence – Supporting
- A good multi-centre prospective randomized study that looked specifically at the use of cuffed ETT compared to uncuffed ETTs. Had large number of participants. The study design was truly randomized but not blinded. The study outcomes were well defined and described. There was similar Baseline characteristics for both groups and one of few studies using very small infants (i.e from birth). The major limitation of this study is that it used only Microcuff PET as the cuffed TTs and so the results obtained from this study needs to be interpreted as such when attempting to apply the implications of cuffed tubes. It needs to be noted that the Microcuff PET cuffed TT, whilst not in widespread use are commerically available.
- The authors have disclosed the financial support for the study was from Microcuff GmbH, Weinheim, Germany who provided the CETTs, cuff manometers and release valves. It also received funding from a study grant (from the Swiss Society for Anaesthesia and Resuscitation).

Weiss, 2004


- LOE - 5, Quality – Poor, Evidence – Opposing
- An excellent study of the commonly available cuffed endotracheal tubes, with respect to their design and suitability for the paediatric airway taking into account the anatomical considerations. The authors compared 15 series of cuffed (11) and uncuffed (4) tracheal tubes of various sizes (ID:2.5 -7.0) from four different manufacturers. This investigation very clearly demonstrated the variability between the different makes of tracheal tubes, with respect to a number of features (outer diameter, position and diameter of cuff, position of depth markings) and pointed out the potential risks for their usage.
- Declaration of interest. The investigated paediatric cuffed tracheal tubes were ordered from local distributors and partially provided without charges. No financial support was obtained for the presented work. Dr Weiss and Dr Gerber are actually involved in designing a new cuffed paediatric tracheal tube in co-operation with Microcuff GmbH, Weinheim, Germany.

Stocks, 1966

Stocks JG. Prolonged intubation and subglottic stenosis. BMJ 1966; 2: 1199±1200

Not on evidence grid – background information only