Original article

A comparative study of paediatric endotracheal tubes available in the Indian market – a bench study

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Abstract

Introduction: A variety of paediatric endotracheal tubes (ETT) are available in India. **Aim:** Comparison of paediatric cuffed and uncuffed ETT with respect to dimensions, depth markings, cuff characteristics and cost. **Methods:** 65 cuffed and 38 uncuffed paediatric ETT (3.0-7.0 mm ID) from 12 different manufacturers were evaluated. The outer diameter, position of depth markings, length and position of cuff, largest diameter of cuff inflated at 20 cm H_2O of the ETTs were measured and compared with dimensions of trachea. **Results:** Outer diameters of similar ID ETTs varied between manufacturers and between cuffed and uncuffed ETTs from the same manufacturer. 26 tubes studied did not have a depth marking. In many tubes the distances from depth marking to tube tip were greater than half the age-related minimum tracheal length. If the tube tips were placed in midtrachea, many cuffs were placed within the larynx. If cuffs were placed 0.5 cm below cricoid level, many tube tips lay too close to the carina. Diameters and cross-sectional area of the cuff at 20 cm H_2O pressure mostly covered maximal internal age related tracheal diameters and cross sectional areas. **Conclusion:** Most paediatric ETTs are poorly designed. ETTs from Kimberly Clark and Parker tubes for children suit paediatric tracheal dimensions. All cuffed tubes including Kimberly Clark tubes need close cuff pressure monitoring.

Keywords: Cuff, margin of safety, paediatric endotracheal tubes

Introduction

Conventionally, uncuffed endotracheal tubes were used until 8 years of age. Cuffed endotracheal tubes in children are nonprevalent because of fear of laryngeal mucosal injury, necrosis and ulceration. However, cuffed endotracheal tubes are useful. The extent of growth in children varies considerably, especially in developing countries. Rate of tube changes are high due to disparity between calculated tube size and the required tube size requiring repeat laryngoscopy. Cuffed endotracheal tubes may reduce the incidence of repeat laryngoscopy and tube change, provide protection against aspiration, allow low flow anaesthesia techniques, make reliable capnography possible and reduce operating room pollution. Cuffed endotracheal tubes are also required when higher airway pressures are needed to ventilate patients with bronchial asthma and acute lung injury. New cuffed endotracheal tubes (microcuff – Kimberly Clark) have become available for use in small children that provide a reliably sealed airway at cuff pressures of 10 to 20 cm H_2O. Since they are made of very thin material (polyurethane), they should not increase the risk for postextubation stridor.

A variety of cuffed paediatric endotracheal tubes are marketed in India and whether these endotracheal tubes are suitable for the intended airway needs evaluation. This study aimed to compare cuffed and

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uncuffed paediatric endotracheal tubes currently available in India from different manufacturers with respect to dimensions, depth markings, cuff characteristics, margin of safety and cost.

Methodology

Endotracheal tubes of 3 to 7 mm internal diameter (ID) were procured from different manufacturers and suppliers (both indigenous and international brands) including cuffed, uncuffed, regular and preformed (Ring, Adair and Elwyn - RAE oral).

Tube characteristics: Each of these endotracheal tubes was compared with similar endotracheal tubes from other manufacturers with respect to their dimensions and depth markings. All linear measurements were made using Vernier calipers. The patient end of the endotracheal tube was placed on a paper such that its bevel could be traced on to the paper. The edges of this angle were then extended and the angle measured using a protractor. Presence or absence of Murphy's eye was also noted.

Cuff characteristics: The cuff was inflated with air to 20 cm H_2O using an aneroid Mallinckrodt® manometer and the volume of air required was noted. Cuff length when inflated to 20 cm H_2O was measured. Cuff distance (upper and lower edge) from tube tip was measured (*Figure 1*). The shape of the inflated cuff (cylindrical, conical, oval or cuboidal), presence of folds in the cuff after insertion into the simulated trachea and inflated to 20 cmH_2O, and leak protection of the cuffs were noted. Cuff diameter was measured at inflation to 20 cm H_2O.

Endotracheal tubes meant for each specific age group were placed such that the tips of the tubes (patient end) were aligned along a line representing mid-trachea (x-axis), after inflation of the cuffs to 20 cm H_2O with air and photographed. A horizontal line representing the glottis as per Ho *et al* was drawn parallel to the x-axis.[1] These pictures illustrate the variation in the presence, position and number of depth markers between various tubes. So also, the cuffs vary in their length, position and diameter when inflated to 20 cm H_2O.

Margin of safety: The paediatric population was divided into different age groups and the corresponding mean tracheal lengths are shown in *Figure 2*. Margin of safety (MOS) for all the cuffed endotracheal tubes was calculated. MOS was defined by Ho *et al* as the difference between tracheal length and the distance from the proximal edge of the cuff to the tip of the endotracheal tube.[1]

Based on the measurements obtained, line diagrams were drawn representing the trachea as well as the endotracheal tubes. The endotracheal tubes meant for each specific age group were placed inside the trachea (line diagram drawn to scale) as they would be used clinically. The tubes with a depth marker were placed with the depth markers at the glottis. When the tubes had two depth markers, they were

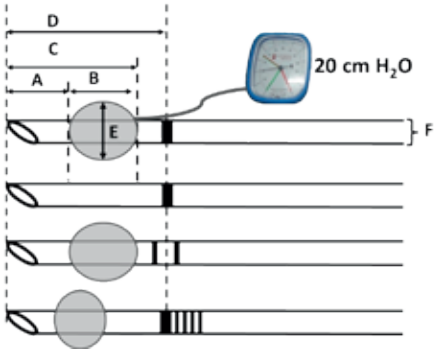

Figure 1: The various dimensions of the ETT studied. A = Distance from tip of the tube to the lower edge of the inflated cuff; B = Length of the inflated cuff; C = Distance from the tip of the tube to the upper edge of the cuff (A + B); D = Distance from the tip of the tube to the depth marker. E = Diameter of the cuff inflated to 20 cm H_2O. F = External diameter. All measurements are in mm.

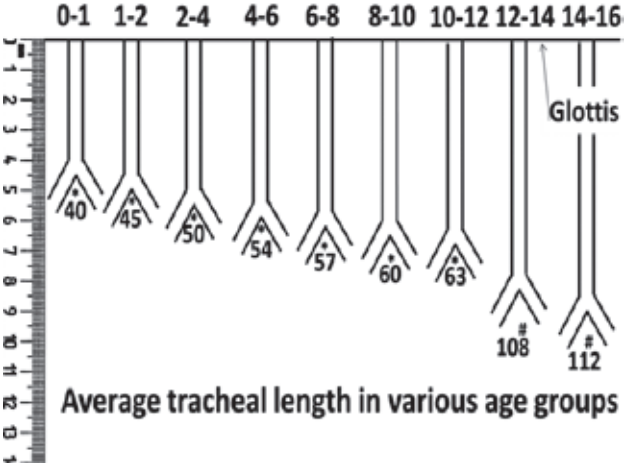

Figure 2: Line diagram showing average tracheal length (cm) in various age groups (years).[*1,#3]

placed with the glottis midway between the two depth markers. Tubes with no depth markers were placed with the upper edge of the inflated cuff placed 0.5 cm below glottis with the surmise that the cuffs would be inserted at least half a cm below the glottis, to prevent injury to the inferior surface of the vocal cords from the inflated cuff. We calculated the margin of safety (MOS) of the endotracheal tubes as follows: Margin of safety = Length of the trachea – distance from the glottis to the tip of the endotracheal tube when placed as described above *(Figure 3)*. The numbers shown alongside the tubes in *Figures 4 – 8* represent the margin of safety.

The MOS was then compared with the downward displacement of the endotracheal tube which was expected during neck flexion in that age group.[2] The endotracheal tube was considered safe for clinical use if the margin of safety thus calculated was more than the maximum downward displacement of the tube in that age group. If the margin of safety was equal to or less than the maximum downward displacement of the tube, it was considered unsafe.

Cuff characteristics such as volume of air required to inflate it to 20 cmH_2O, its width at that pressure, whether it met the criteria for a high-volume, low-pressure (HVLP) cuff were checked.

Cost comparison: All available endotracheal tubes were compared with regard to maximum retail price (MRP) quoted by the vendor.

Results

A total of 103 paediatric tracheal tubes were studied. Of these, 65 were cuffed and 38 were uncuffed endotracheal tubes. *Table 1* shows the details of the endotracheal tubes studied, their manufacturers and cost.

Various dimensions of the tubes were studied as described in *Figure 1*. *Figure 2* shows a line diagram showing average tracheal length (cm) in various age groups (years)[1,3] The various distances as measured by Vernier Calipers are given *in Tables 2 and 3*.

Since ET tubes were made of different materials, outer diameter varied up to 0.6 mm for the same size from different manufacturers. Variation in tracheal tube wall thickness is related to the nature of the material and manufacturing. Tubes of the same internal diameter may have different external diameters. The cuffed tubes from 3 to 4.5 mm ID had outer diameter larger and cuffed tubes from 5 to 7 mm ID had outer diameter equal or lesser than the age related minimal tracheal diameter respectively.

Bevel angle was 43° in all tubes except in Kimberly Clark (50°). All endotracheal tubes had Murphy's eye

Table 1: Details of manufacturers and the sizes of various cuffed and uncuffed endotracheal tubes procured from them.

Sl No	Manufacturer	Cuffed ETT ID (mm)	Uncuffed ETT (mm ID)	Cost (Rupees)
1	Sumi	3 to 7	3 to 5.5	100
2	TuorenLifetrack	3 to 7	3 to 5	46
3	Sterimed	3, 3.5, 4.5, 5, 6, 6.5	-	172
4	Uno	4, 4.5, 5.5, 6.5	3	63.25
5	Sisco	5 to 7	3 to 6	Cuffed-42, uncuffed-36
6	Portex	5 to 7	3 to 5.5	Cuffed-215, uncuffed-195
7	Suruntrek	4, 4.5, 6	4, 5.5	70
8	Tyco	3	3, 3.5, 4	146
9	Excel	3.5	-	66.96
10	Rusch	5.5 to 7	3 to 6.5	100
11	Kimberly Clark	3 to 5	-	1083
12	Kimberly RAE	3 to 4	-	1083
13	Mallinckrodt RAE	4 to 7	3	613
14	Parker	3, 3.5, 4.5	-	Not yet available in India
	TOTAL	103		

except Kimberly Clark ETT which was of Magill type. The tips of the Parker tubes are extended into a soft leading edge, making them very suitable for atraumatic nasal intubation. Measurement of margin of safety is illustrated in *Figure 3*.

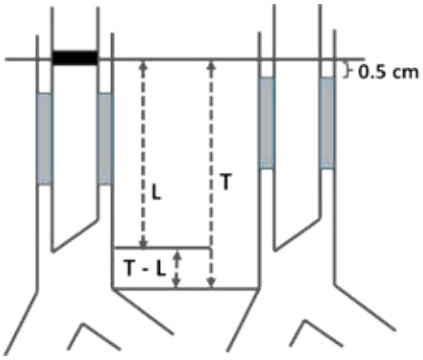

Figure 3: Illustration of calculation of margin of safety of endotracheal tubes

Out of 103 endotracheal tubes studied, 21 cuffed tubes and 5 uncuffed tubes did not have depth markings. The depth markings varied widely in their number and position. There was no consistency even from the same manufacturer. For *e.g.*, tubes of a certain internal diameter from a manufacturer had depth markings while tubes of a different internal diameter but from the same manufacturer did not have any depth markings. While some tubes have none, others have one or two depth markings. Kimberly Clark tubes have five depth markings, one thick distal mark and four thinner ones proximal to it. Parker tubes are similar with five depth markings, with the distal one being thick and the others thinner.

Diagrams and tables have been constructed for cuffed tubes of all sizes from various manufacturers. *Figures 4 to 8* and *Tables 4 – 8* represent cuffed endotracheal tubes from sizes 3 to 5 mm ID.

Tracheal tube cuffs seal better if inflated to a higher pressure. To avoid high cuff pressures, it is a standard recommendation to use high-volume, low-pressure (HVLP) cuffs in adult.[4] At 20 cm H_2O cuff pressure, the cross-sectional area of a HVLP cuff must correspond to about 150% of the internal cross-sectional area of the trachea. The cuffed tubes were evaluated as to whether they conform to this HVLP rule.

Table 2: Measured cuff related distances -distance from tube tip to lower edge of the cuff/ tube tip to upper edge of the cuff / tube tip to upper border of the proximal most depth marking if available in mm for cuffed tubes

ETTbrand	3	3.5	4	4.5	5	5.5	6	6.5	7
Kim Clark	5.2/18/36.4	7.3/22.5/40	7.4/22.5/43.1	12/24.1/48	9.6/23/54.1				
Kim Clark oral RAE	9/17.2/33.4	7.5/18.6/38	10.7/19.2/43.2	-	-	-	-	-	-
Parker	10.3/16.4/34.7	10.5/17.1/37	-	12.3/22.2/44.7	-	-	-	-	-
Excel	-	20.4/38.5/77	-	-	-	-	-	-	-
Tyco	15/23.5/-	-	-	-	-	-	-	-	-
Sumi	13/24.5/-	14/27.7	15.5/28.4/-	17/34/-	21.5/41.1/79	23.5/44/84.5	25.4/49.6/84.7	26.5/47/94.5	28.2/52/94.8
Tuoren	16/29/-	14/32/-	15.4/37.5/53	19.5/35.5/62.6	19.5/43.5/62.3	23.2/44.3/72.8	25.446.5/65.9	30.4/49.2/72.3	30.5/51.8/16
Sterimed	12.2/24.4/49.4	15/26.7/53.5	-	20/37.3/80.3	21.4/44.6/106.6	-	27.5/55.2/94.3	29.5/54.6/97	-
Mallinckrodt oral RAE	-	-	21.2/28.6/-	23.2/33.7/-	20.4/37.9/-	24.8/42.4/-	26.8/46.3/-	28.2/45.4/-	32/50/-
Uno	-	-	15/36.4/-	15.3/34.3/-	-	26/44.2//89.3	-	26.2/47.4/75.5	-
Suruntrek	-	-	24.4/40.3/-	18/41.1/-	-	-	24.5/50/-	-	-
Portex		-	-	-	29.5/40.4/78.4	28.5/40.4/80	32.7/47.3/85	34/48/87.5	36/52.4/91
Rusch	-	-	-	-	-	25.5/45.6/78.7	26.3/ 50.4/84.3	28.7/50.7/87	33.2/61/ 92.2
Sisco	-	-	-	-	21.2/45.5	24.4/41.6/65.7	26.2/52/	29.6/47.5/75.5	32.4/49/80.5

Table 3: Measured distance from tube tip to upper border of the proximal most depth marking if available in mm for uncuffed tubes

ETT brand	3	3.5	4	4.5	5	5.5	6	6.5	7
Portex	27	30	39	40	47.5	52.5	-	-	-
Rusch	20.5	21	21.5	31.2	40.5	40.5	41.1	39.5	-
Tuoren Lifetrack	41	40	53	56.5	62.2	-	-	-	-
Sisco	27.7	27	50	54.5	28	65.5	69.7	-	-
Sumi	20.4	13	29.5	29.1	/-	/-	-	-	-
Uno	25	-	-	-	-	-	-	-	-
Tyco	49.4	51.2	52	-	-	-	-	-	-

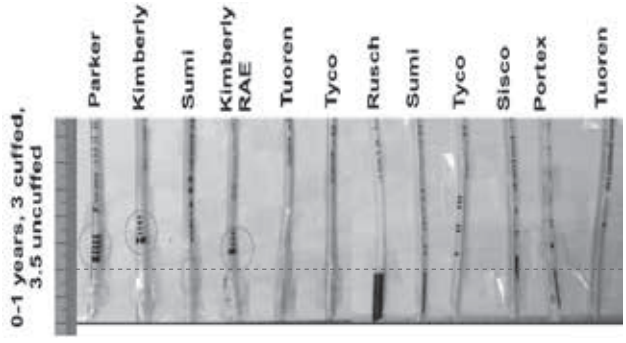

Figure 4a: This shows size 3 cuffed and 3.5 uncuffed endotracheal tubes obtained from different manufacturers and meant for use in the age group 0 – 1 year. The baseline represents midtrachea. The stippled line represents level of glottis. Average tracheal length is 40 mm.

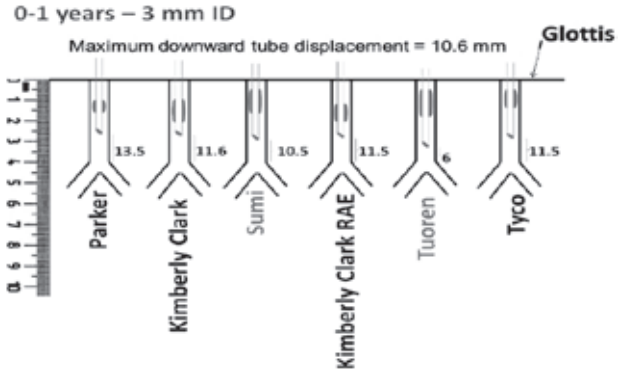

Figure 4b: Line diagram representing trachea of the age group 0 – 1 year with 3 mm cuffed endotracheal tubes placed inside the trachea (For details, see text).

Table 4: Volume of air required to inflate the cuff and the diameter achieved to inflate the cuff to 20 cm H_2O and whether the cuff was HVLP. (Y-Yes, N-No)

ETT	Sterimed	Parker	Kimberly	Sumi	Kimberley Clark RAE	Tuoren	Tyco
Cuff vol (ml)	1.7	3.1	1.3	2.8	1.15	1.6	1
Cuff diameter (mm)	7.7	10	9.4	8	9.3	7	7.5
HVLP	N	Y	Y	N	Y	N	N

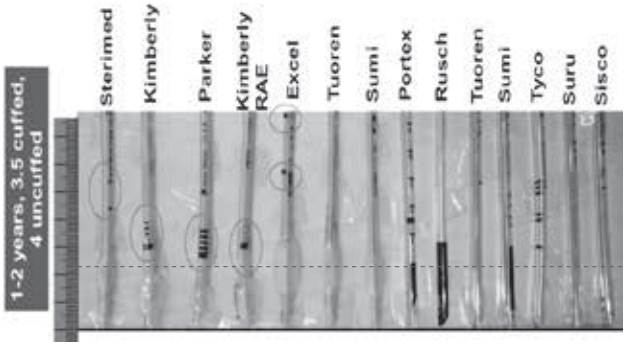

Figure 5a shows size 3.5 cuffed and 4 uncuffed endotracheal tubes obtained from different manufacturers and meant for use in the age group 1 – 2 years. The baseline represents midtrachea. The stippled line represents level of glottis. Average tracheal length in this age group is 45 mm.

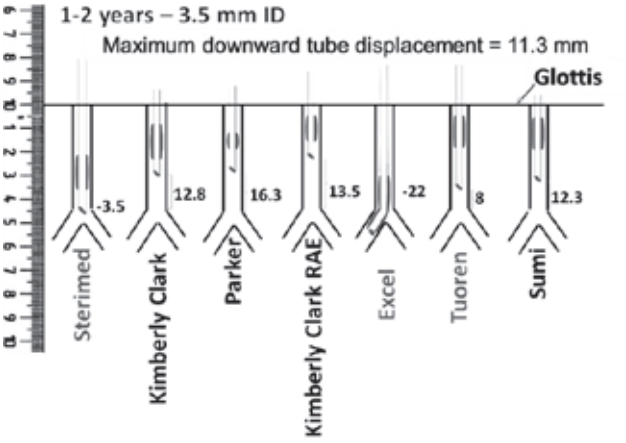

Figure 5b: Line diagram representing trachea of the age group 1 – 2 years with 3.5 cuffed endotracheal tubes placed inside the trachea (For details see text).

Table 5: Volume of air required to inflate the cuff and the diameter achieved to inflate the cuff to 20 cm H_2O and whether the cuff was HVL.P.

ETT	Sterimed	Kimberly Clark	Parker	Kimberly Clark RAE	Excel	Tuoren	Sumi
Cuff vol (ml)	1.7	1.75	2.1	2.1	3.3	1.8	3.4
Cuff diameter (mm)	8.4	12	10.4	12.2	11.1	10	9.5
HVLP	N	Y	Y	Y	Y	Y	Y

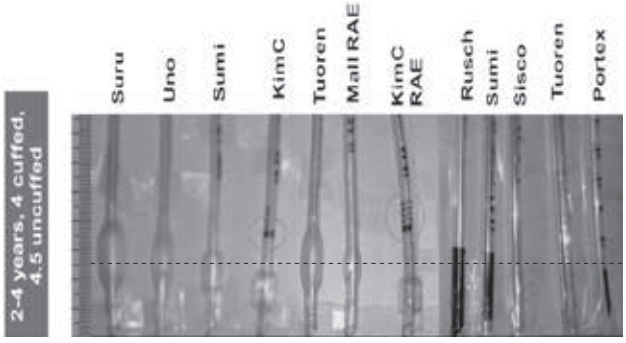

Figure 6a shows size 4 cuffed and 4.5 uncuffed endotracheal tubes obtained from different manufacturers and meant for use in the age group 2 – 4 years. The baseline represents midtrachea. The stippled line represents level of glottis. Average tracheal length in this age group is 50 mm.

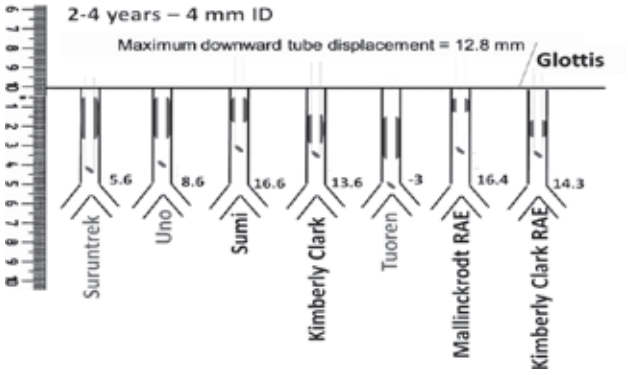

Figure 6b: Line diagram representing trachea of the age group 2 – 4 years with cuffed endotracheal tubes placed inside the trachea (For details, see text).

Table 6: The volume of air required to inflate the cuff and the diameter achieved to inflate the cuff to 20 cm H_2O, and whether the cuff was HVLP.

ETT	Suru	Uno	Sumi	Kimberly Clark	Tuoren	Mallinckrodt RAE	Kimberly Clark RAE
Cuff volume (ml)	4.1	1.4	3.3	1.5	3.5	0.9	01.65
Cuff diameter (mm)	12.8	11	10	12	9.6	9	11.6
HVLP	Y	N	N	Y	N	N	Y

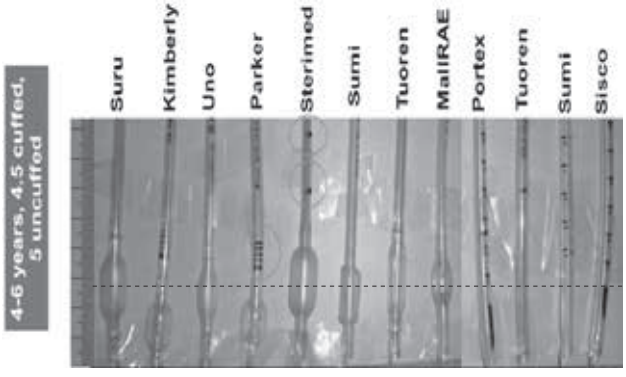

Figure 7 a shows size 4.5 cuffed and 5 uncuffed endotracheal tubes obtained from different manufacturers and meant for use in the age group 4 – 6 years. The baseline represents midtrachea. The stippled line represents level of glottis. Average tracheal length in this age group is 54 mm.

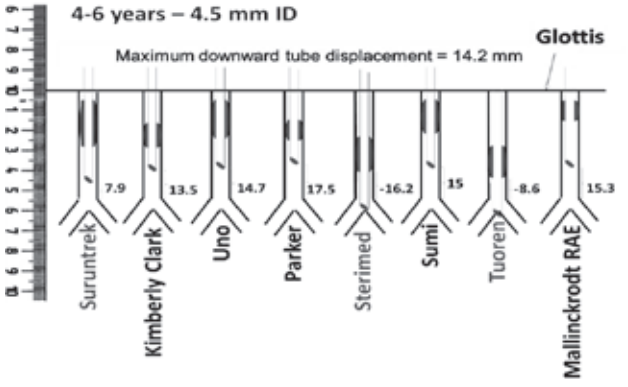

Figure 7b: Line diagram representing trachea of the age group 4 – 6 years with cuffed endotracheal tubes placed inside the trachea (For details, see text).

Table 7: Volume of air required to inflate the cuff and the diameter achieved to inflate the cuff to 20 cm H_2O, and whether the cuff was HVLP.

ETT	Suru	Kimberly Clark	Uno	Parker	Sterimed	Sumi	Tuoren	Mallinckrodt RAE
Cuff volume (ml)	2.7	2.7	.55	3.8	3.7	4.05	2	1.4
Cuff diameter (mm)	13.2	13.4	10.5	14	15.2	12.3	11.3	13.2
HVLP	N	Y	N	Y	Y	N	N	N

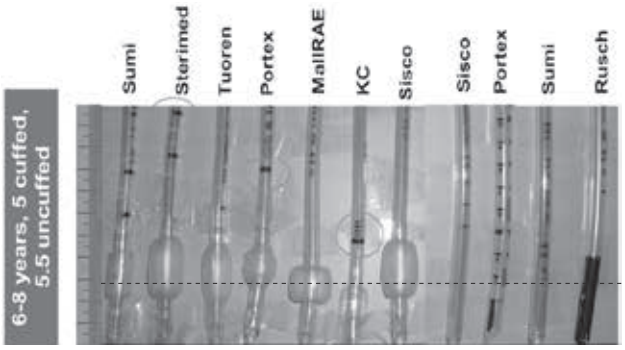

Figure 8a shows size 5 cuffed and 5.5 uncuffed endotracheal tubes obtained from different manufacturers and meant for use in the age group 6 – 8 years. The baseline represents midtrachea. The stippled line represents level of glottis. Average tracheal length in this age group is 57 mm.

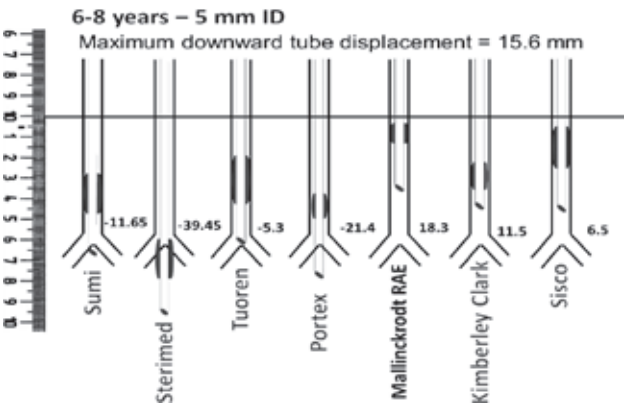

Figure 8b: Line diagram representing trachea of the age group 6 – 8 years with cuffed endotracheal tubes placed inside the trachea (For details see text).

Table 8: The volume of air required to inflate the cuff and the diameter achieved to inflate the cuff to 20 cm H_2O, and whether the cuff was HVLP.

ETT	Sumi	Sterimed	Tuoren	Portex	Mallinckrodt RAE	Kimberly Clark	Sisco
Cuff volume (ml)	4.2	5.7	0.3	4.5	1.4	2.5	4.55
Cuff diameter (mm)	13	17.3	12	15.5	13.2	14	17.6
HVLP	N	Y	N	Y	N	N	Y

Discussion

Cuffed endotracheal tubes have their own benefits when compared to uncuffed tubes. These benefits are rightly exploited in day to day practice in anaesthesia and critical care in adults. The use of cuffed tubes in children is less. Only 25% of the anaesthetists in France use cuffed tubes routinely in 80% of their paediatric patients.[5] There is a wide variation in outer diameter, cuff position, margin of safety, cuff diameter, depth markings and cuff compliance.

Outer diameters of endotracheal tubes (cuffed and uncuffed) varied widely up to 0.6 mm. The variation was due to the difference in materials used in their manufacture (PVC, polyurethane, Latex). The effective diameter of cuffed endotracheal tubes becomes larger when the cuff is taken in to account.[6] This results in disproportionately larger size endotracheal tubes when selection is made based on formulae derived for specific age groups which provide the internal diameter of the tracheal tube leading to subglottic damage.[7] This may not be recognised by many anaesthetists in clinical practice. Children have a wide variation in their growth rate and age-related choice of endotracheal tube may often not be appropriate.

Among the tubes we studied, 52% of cuffed tubes from 3 to 4.5 mm ID passed the HVLP rule and 75% of cuffed tubes from 5 to 7 mm ID passed the HVLP rule. Some of the cuff diameters were less than the maximal age related tracheal diameter of the specific age group in which it was intended for use. Therefore, more volume of air would be required to seal the trachea and chances of achieving intracuff pressures >20 cm H_2O might be higher. In adults, cuff pressures can go up to 25-30 cm H_2O whereas cut off limits for children are not clearly defined.[8]

The upper border of cuffs of most of the cuffed endotracheal tubes were at the level of the upper border of the depth marking of the corresponding uncuffed endotracheal tube intended for that age group. Weiss *et al* in their study stated that the cuffs of these tubes would either lie in the subglottic space or at the level of the vocal cords or in the supraglottic space when placed according to the formulae for depth of insertion or by radiological criteria for the specific age group.[9,10] This was probably the reason for Portex and Rusch providing cuffed endotracheal

tubes from 5.0 mm ID and 5.5 mm ID onwards respectively.[9] High subglottic pressure can cause mucosal ischaemia, fibrosis and lead to stenosis. It is important to ensure that the cuff is not intra-laryngeal for the same reasons. In addition, sharp folds and edges of the deflated cuff membrane can damage the airway by abrading the mucosa. This may lead to formation of granulation tissue, fibrosis and intra-laryngeal web formation around the tracheal tube.[11] The cuff should be located beneath the cricoid ring at the level of tracheal cartilages so that it can easily expand. A cuff within the larynx can cause vocal cord palsy by compressing the recurrent laryngeal nerve between the cuff and the thyroid lamina.[12] If cuffs are placed by external palpation or below the cricoid ring, some of the tube tips move further inside the trachea, especially those with the longer cuffs and Murphy's eye.[13]

Murphy's eye was originally designed to assure continuation of airway patency and ventilation in case the bevel of the endotracheal tube was abutting the tracheal wall. In Kimberly Clark (microcuff) tubes, the Murphy eye was removed so that the cuff could be shifted more caudad, thus reducing the chances of translaryngeal placement of the inflated cuff. Since the bevel angle is 50°, the tip of the tube is more rounded and flat, reducing its chances of abutting against the tracheal wall, especially when the cuff is inflated. The Parker tube has combined the advantages of both by placing a distal cuff similar to Kimberly Clark tubes while retaining the Murphy eye.

The length of the trachea in the paediatric population has been measured using rigid bronchoscopy[14] and computerised scans.[3] In the study by Griscom *et al*, computerised scan of the paediatric trachea was used to measure the length of the trachea.[3] In this study, tracheal length was measured from glottis to beginning of bifurcation of trachea, while in the study by Ho *et al*,[1] tracheal length that is mentioned is from glottis to carina. Thus, for corresponding age groups, the tracheal length mentioned in Griscom's study[3] is longer than in the article from Ho,[1] Thus, some tubes that were deemed unsafe when the margin of safety was calculated according to the dimensions from Ho *et al* became safe when the calculations were done based on Griscom's article. Which of them is applicable to Indian children is a matter of debate. No data on paediatric tracheal dimensions in the Indian population was available. An individual Indian child may resemble patients from either of these studies. However, Indian children in general are relatively smaller, undernourished and are likely to have smaller tracheas. They are also more likely to be intubated by the cheaper indigenous tubes rather than the expensive Kimberly Clark tubes. It would be prudent to exercise caution when cuffed endotracheal tubes are used in the paediatric population.

Depth markings on the cuffed endotracheal tubes are required to guide the intubator in achieving a cuff-free subglottic space. Out of 103 endotracheal tubes studied, 21 cuffed tubes and 5 uncuffed did not have depth markings. When the endotracheal tubes were placed with the upper border of the depth markings (when present) in line with a level representing vocal cords, some of the depth markings were found to be too high on the tube shaft such that the distance from this marking to the tube tip approximately equaled the minimal tracheal length for the corresponding age group. For appropriate placement of the cuffs below the cricoid ring and sufficient allowance of distance between the tube tip and carina, cuff position should be more distal.

The length of the cuff is important for two reasons: The intracuff volume is directly proportional to the length of the cuff and longer cuffs have longer transition areas at the ends.[15] The compliance curve of the polyurethane cuff in Kimberly Clark tube showed a unique steep pattern when compared to other tubes. This pattern necessitates cuff pressure monitoring for these tubes.

Conclusions

Children vary in their growth and the tracheal tube size chosen entirely according to their age will never be always accurate. Cuffed tubes have to be used with caution although when properly used, cuffed tubes have been shown to be safe. Cuff pressure and cuff position have to be closely monitored to avoid high

intracuff pressures and consequent tracheal damage, endobronchial intubation and translaryngeal placement of the cuff. Tubes with better design such as Kimberly Clark and Parker are ideal but the cost is likely to prevent their widespread use in a developing country such as India. However, they also need cuff pressure monitoring. Data of tracheal dimensions from Indian paediatric population may be helpful.

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