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### COMPARISON BETWEEN RAE, FLEXOMETALLIC AND PVC MACINTOSH ENDOTRACHEAL TUBES USED IN CLEFT PALATE SURGERY

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#### ABSTRACT

**Introduction:** Cleft lip/palate are the most common craniofacial anomalies in children, with an incidence of CLP worldwide is 1 in 700 live births. The risk factors are considered as Family history etc. Anaesthesia during cleft lip and palate surgery carries a high risk and difficult airway management in children. Because of other associated congenital anomalies, the anaesthetic management becomes more complicated. Flexometallic endotracheal tubes, PVC macintosh tube, RAE tube are have their own risks and benefits when compared with each other. This study was undertaken to compare ease of intubation, ease of ventilation, intra operative maintenance of respiratory parameters, intra-operative airway complication, post extubation complication by using 3 different types of tubes (1) RAE (Ring Adair Elwyn) tube (2) flexometallic tube (3) PVC (Polyvinyl Chloride) macintosh tube in pediatric cleft palate surgeries.

**Material & Methods:** A randomized controlled trial was conducted on 90 ASA I and ASA II pediatric patients of age group 9 month to 5 years undergoing cleft palate surgeries. Patients were randomly allocated in three groups of 30 each. Group 1: intubated with R A E endotracheal tube, Group 2: intubated with flexometallic tube and Group 3: intubated with P V C macintosh endotracheal tube. The power of study on choosing such sample size was found to be at 90% level. Time taken for intubation, No. of attempt taken for intubation, Monitoring of capnography, SPO<sub>2</sub>, pulse rate and mean airway pressure every 15 minutes during the surgical procedures, Endobronchial intubation, Inadvertent extubation, Ease of passing of suction catheter after application of dingman retractor and Post extubation cough and croup was observed.

**Results:** The significant differences were observed in stylet used, ease of passing suction catheter and post extubation cough and heart rate after retractor among the groups ( $p < 0.05$ ). All other differences were found to be insignificant.

**Conclusion:** RAE tube provides a good approach for airway management in routine cleft lip surgeries. It possesses advantage over flexometallic tube and PVC tube. As it is a preformed tube passing suction catheter is technically difficult.

Key words: RAE tube, Flexometallic tube, PVC tube, Cleft palate

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#### INTRODUCTION

Cleft lip/palate are the most common craniofacial anomalies in children, with an incidence of CLP worldwide is 1 in 700 live births and it is nearly 1 in 500 in India.<sup>1</sup> In 2008, the World Health Organization included cleft lip and palate in their Global Burden Disease (GBD), as these birth defects lead to significant infant mortality

and childhood morbidity.<sup>2</sup> In India, over 35,000<sup>3</sup> infants are born with cleft lip or palate every year. The risk factors are considered as:

Family history- Cleft lip (cheiloschisis) is more likely to be inherited than a cleft palate (palatoschisis). Chances of offspring suffering from an affected parent, range from 3-5% and the sibling risk is 20-40% with one affected child.

The incidence of the defect is 40-50% in Monozygotic twins and 5% in Dizygotic twins.<sup>4</sup>

- Sex - Male female ratio is 2:1 for a cleft lip and 1:2 for a cleft palate.<sup>5</sup>
- Left to right sided unilateral cleft lip ratio 2:1<sup>5</sup>
- Unilateral clefts are nine times as common as bilateral clefts<sup>5</sup>
- 86% of bilateral cleft lips and 68% of unilateral cleft lips occur with a cleft palate<sup>5</sup>
- Race as American Indian, Asians<sup>6</sup> are more prone.

The successful outcome following cleft repair depends on the age of the patient, associated morbidities, anaesthetic expertise and post-operative care. Without repair these children suffer from facial disfigurement and potentially social isolation, feeding problems and abnormal speech. Anaesthesia for cleft surgery in infant and children carries a higher risk with general anaesthesia and airway complications due to associated respiratory problems.

Anaesthesia for cleft lip and palate repair is associated with complications which may include difficult airway inadvertent extubation, kinking of endotracheal tube, aspiration of blood and secretions, laryngospasm, bronchospasm and acute airway obstruction.<sup>7,8</sup>

Anaesthesia during cleft lip and palate surgery carries a high risk and difficult airway management in children. Because of other associated congenital anomalies, the anaesthetic management becomes more complicated.

Flexometallic endotracheal tubes are one of these safer techniques have advantage of being resistant to kinking and compression making them useful in surgeries in head and neck surgeries, for better surgical access.

PVC macintosh tube is cheap and easily available and more common tube used in the anesthetic procedures.

RAE tube are used increasingly now a days because they provide better space for surgical manipulation in maxillo facial surgeries.

All these three endotracheal tube have their own risks and benefits when compared with each other. Since not much work has been done on comparison of these tubes in paediatric maxillo facial surgery, we decided to compare between RAE, Flexometallic and PVC Macintosh

Endotracheal Tubes in Cleft Palate Surgeries to achieve the best outcome.

To avert the adversities in future, a comparison of per-operative complications of anesthesia was done in cleft palate repair surgeries within a specified age group using three different types of endotracheal tubes (ETT) viz south facing RAE (Ring, Adair, Elwyn), PVC Macintosh and Flexometallic only which are available in the institution. This study was conducted during the period of January 2014 to August 2015 in L.L.R. Hospital G.S.V.M. Medical College Kanpur U.P. and Leelamani hospital India.

## MATERIAL AND METHODS

This study was conducted during the period of January 2014 to August 2015 in L.L.R. Hospital G.S.V.M. Medical College Kanpur U.P. and Leelamani hospital India

This is a prospective study of 90 facial cleft patients in the age group of 9 months to 5 years who presented for surgical repair. All patients were ASA 1 or 2 [Table 1]. Operating room records were the source of data which included age, sex, body weight, diagnosis, associated complications, and the anesthetic equipments used. Patient selection during pre-operative assessment for facial cleft surgery is critical in relation to the safety of general anesthesia. Patients with congenital anomalies or packed cell volume less than 30%, underweight or those with clinical signs of malaria or respiratory tract infection were excluded from the surgery. Waiting until 3 months of age<sup>9</sup> gives time to detect most congenital abnormalities and allows anatomical and physiological maturation. Upper respiratory tract infections are particularly common at this age. Routine treatment of low grade nasal infections with antibiotics reduces the incidence of postoperative complications<sup>10</sup> and impaired wound healing. Some of these children had a continuous nasal discharge without overt infection. Anaemia detected in some of the children was probably from a combination of nutritional and physiological causes. Pre-anaesthetic check-up allowed time to assess general and specific problems and prepare the children for the repair surgeries concerned. Parents were communicated about the induction

technique, provision of analgesia, possibility of additional measures such as postoperative nasopharyngeal airway insertion and postoperative feeding.

After sanction from hospital ethical committee informed consent will be taken and the patient will be randomly divided in to 3 groups of 30 patients each.

Group A: - Patients intubated with R A E endotracheal tube of their adequate size.

Group B: - Patients intubated with P V C Macintosh endotracheal tube of their adequate size.

Group C:- Patients intubated Flexometallic endotracheal tube of their adequate size.

All cases will be conducted under general anaesthesia, after proper preanaesthetic check-up.

In the preanaesthetic holding room, child will be sedated with syrup midazolam (0.5 mg/Kg), and premedication will be done with inj. glycopyrrolate (10µg/kg), fentanyl 2µ/kg and per rectal paracetamol suppositories (10-15 mg/kg)

Prior to induction, electrocardiograph (ECG) leads, noninvasive blood pressure cuff, pulse oximeter probe, and precordial stethoscope will be applied and pre-induction values obtained. Fluid management was done using holiday segar formula. We used ringer lactate as a maintenance fluid.

Induction will be done with either inhalational (halothane or sevoflurane) or intravenous (propofol 2-3.5 mg / Kg) route. When the depth of anesthesia was judged to be adequate, the trachea was intubated with an appropriate size RAE/PVC MACINTOSH/ Flexometallic endotracheal tubes with muscle relaxants, ARTACURIUM (0.3-0.5 mg/Kg) or VECURONIUM (0.08 – 0.12mg/Kg). The tube was connected to DRAGER FABIUS PLUS workstation.

Correct placement of the tracheal tube was confirmed by auscultation and capnography, the tube was securely fixed and connected to ventilator on PCV.

Difficult laryngoscopy (Cormack and Lehane views grade III or IV)<sup>9</sup> occurs in upto 10% of ASA- I patients for CLP repair.<sup>11</sup>

In the surgery for cleft palate the head was put more or less in hanging position by putting a roll under the patient's shoulder blades to extend the

neck. The occiput of the head put on a head ring. A Dingman retractor was used for the palate repair that keeps the mouth open and tongue clear. Care was taken

(1) ET tube should not snare within the blades of the retractor, and

(2) Endotracheal tube should not kink or push down into a bronchus when the retractor was opened.

In palate reconstruction, a pharyngeal pack is avoided for surgical convenience, but is a must in cleft lip repair surgeries to prevent soiling of the airway by ingestion of blood as the ET tubes used were non-cuffed.

Protection given to the eyes using eye pads. The surgeon did Millard rotation advancement method for repair of cleft lip and two flap with the posterior alveolar ridge technique for cleft palate.<sup>12</sup> An infiltration with short acting local anaesthetic and vasoconstrictor, injected in palate repair.

Maintenance is done by inhalational- O<sub>2</sub> + N<sub>2</sub>O + sevoflurane / halothane and intravenous- (Muscle relaxant) Artracurium (0.1-0.4) mg/kg OR Vecuronium (0.01 – 0.02) mg/kg.

Depending on the group to which the patient belongs, the patient was either Intubated with PVC tube, Flexometallic tube or RAE tube.

In group 1: patient were intubated with R A E endotracheal tube of their adequate size.

In group 2: patients were intubated with P V C Macintosh endotracheal tube of their adequate size.

In group 3: patients were intubated with Flexometallic endotracheal tube of their adequate size.

SPO<sub>2</sub> and pulse rate were noted down before intubation.

Parameters like, No. of attempt taken for intubation, the number of patients those had endobronchial intubation, inadvertent extubation and the ease of passing of suction catheter in different tubes were noted down. [Table No.2]

Monitoring of heart rate, capnography, peak airway pressure, mean airway pressure, and saturation, was noted down at four different times i.e on before intubation, after intubation, after retractor placement and after ten minutes. [Table No.3]

At the end of the surgery, muscle relaxation was reversed with inj. glycopyrrolate 0.01mgkg<sup>-1</sup> and inj. neostigmine 0.05mgkg<sup>-1</sup> after adequate attempts were confirmed. The child was extubated after through suctioning once the child was fully awake with wail and protective reflexes returned. In postoperative period patient was followed for post-operative croup/cough in different groups. Supplementary oxygen was given and then was sent to the ward. At 4-6 h post-operative, feeding with clear fluids started which was usually comforting for the child as the parents were also encouraged to join at this time. All children were nursed in lateral position.

Careful monitoring performed for the first 12 h after surgery for the early detection of airway obstruction or post-operative bleeding. All anesthetic complications were documented. The results were analyzed and presented in Tables.

This prospective study groups were compared and outcomes measure for the groups were summarized as Mean±SD (standard deviation) and proportion & percentages. The mean scores of the Groups were compared by ANOVA test. Categorical (discrete) data from the groups was compared by chi-square ( $\chi^2$ ) test. Statistical Package for Social Sciences Software Version 18.0 was used. p-value < 0.05 was considered to be significant.

**RESULTS**

The results for this prospective study were comparable with the demographic data of age and weight as shown in the [Table 1].

**Table1: Comparison of Age and Weight among the Groups**

Variable	RAE [A]		PVC [B]		FLEXOMETTALIC [C]		F-value	p-value
	Mean	SD	Mean	SD	Mean	SD		
Age (yrs)	1.81	0.42	1.84	0.42	1.82	0.42	0.07	0.933
Weight (kg)	10.97	2.72	11.03	2.67	11.00	2.69	0.005	0.995

All the groups were age and weight matched as there was no significant difference in the mean age and mean weight was found among the three groups (p>0.05 using ANOVA test).

**Table 2: Comparison of Post Extubation complications & Ease of Intubation among the Groups**

Ease Of Intubation	RAE [A]		PVC [B]		FLEXOMETTALIC [C]		chi square	P-value
	No.	%	No.	%	No.	%		
Styilet used	0	0.0	8	26.7	30	100	65.95	<0.001
Endobronchial intubation	0	0.0	4	13.3	2	6.7	4.29	0.117
Inadvertent extubation	0	0.0	2	6.7	0	0.0	4.09	0.129
Ease of passing suction catheter	0	0.0	30	100	26	86.7	75.25	<0.001
Post extubation cough	0	0.0	5	16.7	8	26.7	8.81	0.012
Intubation attempt more than one time	2	6.7	8	26.7	5	16.7	4.32	0.115
Adjustment of endotracheal tube Intraoperatively	7	23.3	12	40.0	4	13.3	5.72	0.057

**Table 3: Changes in Heart rate, ETCO<sub>2</sub>, peak airway pressure & mean airway pressure among the groups**

Parameter		After intubation	After Retractor	After 10 Minutes
<b>HEART RATE ( per minute)</b>				
RAE	Mean	134.46	131.16	116.16
	SD	6.45	6.36	5.51
PVC	Mean	137.13	135.36	116.66
	SD	5.95	4.75	5.46
Flexo metallic	Mean	136.73	133.53	116.66
	SD	5.69	5.75	5.46
<b>F, p-value</b>		1.701, 0.188	3.671, 0.029	0.083, 0.920
<b>ETCO<sub>2</sub> (mm Hg)</b>				
RAE	Mean	33.63	34.33	33.03
	SD	1.19	1.32	1.27
PVC	Mean	33.63	34.83	33.03
	SD	1.19	1.78	1.27
Flexo metallic	Mean	33.63	34.70	33.03
	SD	1.19	1.88	1.27
<b>F, p-value</b>		0.00, 1.000	0.71, 0.493	0.00, 1.000
<b>PEAK AIRWAY PRESSURE (mm Hg)</b>				
RAE	Mean	15.80	17.30	15.93
	SD	0.76	1.78	0.69
PVC	Mean	15.80	17.30	15.93
	SD	0.76	1.78	0.69
Flexometallic	Mean	15.80	17.13	15.93
	SD	0.76	1.80	0.69
<b>F, p-value</b>		0.00, 1.000	0.09, 0.917	0.00, 1.000
<b>MEAN AIRWAY PRESSURE (mm Hg)</b>				
RAE	Mean	6.20	7.00	5.93
	SD	0.66	1.41	0.64
PVC	Mean	6.33	8.30	5.93
	SD	0.84	2.96	0.64
Flexometallic	Mean	6.33	8.30	5.93
	SD	0.84	2.96	0.64
<b>F, p-value</b>		0.29, 0.752	2.60, 0.080	0.00, 1.000

The intraoperative comparison between the group was done and the results between the group was obtained using chi square Test and ANOVA. The results of different parameter were:

A. Ease of intubation that is [Table 2]

1. More than one attempts was less in RAE tube as compared to Flexometallic tube and was less in

Flexometallic tube when it is compared to PVC tubes. Though the difference in proportions among the three groups were not found to be significant ( $p=0.115$ ).

2. Stylet used was less in RAE tube as compared to PVC tubes while stylet has to be used in all the cases of Flexometallic tube. The difference in proportions among the three groups were found to be highly significant ( $p<0.001$ ).

B. Increase in heart rate was found to be significantly less in RAE group as compared to other groups after retractor placement ( $p=0.029$ ). [Table 3]

C. Intra operative maintenance of respiratory parameters that is [Table 3]

a. No significant differences were found in increase of Mean Airway Pressure among the groups after intubation, after retractor and after 10 minutes ( $p>0.05$  in all the cases)

b. No significant differences were found in increase of Etco<sub>2</sub> among the groups after intubation, after retractor and after 10 minutes ( $p>0.05$  in all the cases).

c. No significant differences were found in increase of peak airway pressure among the groups after intubation, after retractor and after 10 minutes ( $p>0.05$  in all the cases).

D. Intra-operative airway complication that is [Table 2]

a. Endobronchial intubation was less in RAE tube as compared to Flexometallic tube and was more in PVC tubes as compared to all other tubes. PVC (6) > FLEXOMETALLIC (4) > RAE (2). Though the difference in proportions among the three groups were not found to be significant ( $p=0.117$ ).

b. Inadvertent extubation was found in PVC tubes while it was absent in flexometallic and RAE tubes. The difference in proportions among the three groups were not found to be significant ( $p=0.129$ ).

c. Intraoperative tube adjustments was have to be done more frequently in PVC (40.0%) tube as compared to RAE tubes (23.3%) tube adjustments were least in Flexometallic (13.3%) tubes but if kinking of tube is noticed in this case the tube has to be immediately replaced as done in 3 cases. But the difference in proportions among the three groups were not found to be significant ( $p=0.057$ ).

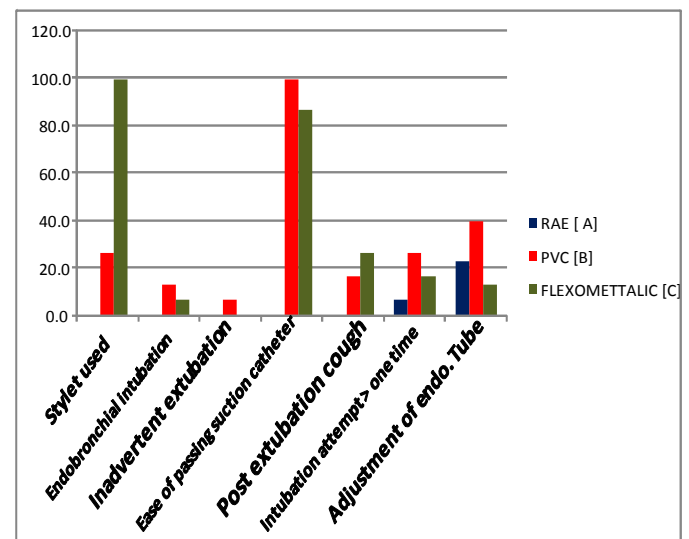
E. Post Extubation complication i.e [Table 2]

a. Ease of passing suction catheter: suction catheter was passed with difficulty in RAE tubes while PVC tubes gave easy passage for suction catheter. The difference in proportions among the three groups were found to be highly significant ( $p<0.001$ ).

b. The incidence of post extubation cough was noticed more in Flexometallic (26.7%) tubes as compared to PVC tubes (16.7%). This complication was not found in RAE tubes (0). The difference in proportions among the three groups were found to be significant ( $p=0.012$ ).

c. The saturation was comparable in all the three groups.

**Graph 1: Ease of Intubation & Post Extubation complications**



## DISCUSSION

In our study comparison was done between the three tubes namely RAE, Flexometallic and PVC tubes for various parameters during cleft palate surgeries done on patient with comparable demographic data (age and weight). Intergroup observations were made using student t test for various parameter at before intubation, after intubation, after retractor placement and after 10 mins and it was observed that heart rate showed no change at retractor placement in RAE tubes as compared to PVC and Flexometallic tubes. Peak airway pressure was constant at all times. With PVC tube an increase in Etco<sub>2</sub> and moderate

increase in heart rate was observed after retractor placement when compared to RAE. The disadvantage that was encountered with RAE tube was that suction catheter was not passed through the tube easily when required and being a preformed tube RAE was found to be incompatible with stylet. Despite the disadvantage of fixed intraoral length RAE tube<sup>13</sup> was preferred over the other two tube by anesthesiologist as well as surgeon due to maintain of a patent airway and providing clear operation field. Based on the result of the present study, we recommend the use of RAE Tube over Flexometallic tube and PVC tube in cleft lip repair to provide good surgical field view. This study is first of its kind to the best of our knowledge as we could not find any previous study from literature search for comparison. Some patients presenting late in childhood were due to poverty, ignorance, and long distance from cleft care surgical facilities. The increase in the number of patients is primarily because the surgeries are done free of cost to the patients by a visiting plastic surgeon under the banner of a SMILE TRAIN.

## CONCLUSION

The RAE tube has many added advantages like no use of stylet, less no. of attempts taken for intubation, least endobronchial intubation and inadvertent extubation, less no. of cases with post-operative cough, least rise in values of ET<sub>CO<sub>2</sub></sub>, heart rate and mean airway pressure over Flexometallic and PVC Tubes. Thus we emphasize the use of RAE tube in patients with cleft palate repair.

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