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Original Research Article

Flexometallic versus RAE Endotracheal Tube in Cleft Lip and Palate Surgery

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Abstract

Aim and Objectives: The present study was carried out with an objective to evaluate ease of insertion of catheter and suctioning through Flexo-metallic tube versus Ring Adair Elwin (RAE) tube, to know the incidence of kinking of RAE tube and to note down the endo-bronchial placement of Flexo-metallic versus RAE tube and surgeon's comfort zone.
Methods: A prospective observational randomized study was conducted on 60 ASA grade I and II pediatric patients of age group 4 month to 16 years undergoing cleft lip and palate surgeries. Patients were randomly allocated in two groups of 30 each. Group R: intubated with RAE South pole tube and group F: intubated with flexo-metallic tube. The ease of insertion of suction catheter, ease of suctioning of secretions, refixation required, kinking of tracheal tube, incidence of displacement, airway complications and surgeons' feedback- Comfort zone were noted.
Results: The ease of suctioning through lumen of Tracheal tube was easier in group 'F' as compared to RAE tube. No kinking of tracheal tube was found in any group. The displacement of tracheal tube was observed in 2 patients in group 'R'. Refixation of tracheal tube was required in 2 patients in group 'R'. Bronchospasm and cough was noted in 1 patient in group 'R'. No variations in vitals (e.g. blood pressure and heart rate) were observed in any group. Surgical team was comfortable in both groups but more so with Flexo-metallic tracheal tube group. On extubation we found retained secretions at distal portion of RAE tube in 2 patients.
Conclusion: Flexometallic tracheal tube provides advantage of easy suctioning of tracheal secretions. Do not kink in mouth gag of surgical field, provides better airway security and stability, less intra-operative manipulation by anaesthetist, less airway complications, provides better surgical field.
Keywords: Flexo-metallic tube, RAE tube, Cleft lip or palate surgery, Intraoperative issues, Airway management.

1. Introduction

Cleft lip, Cleft palate and or both are common congenital malformations. The world-wide incidence is 1 per 700 live births and it is nearly 1 per 500 in India [1]. Accumulation of un-repaired clefts in lip and palate has proved a health care problem in India. The risk factors are considered as: Sex – Male: female ratio is 2:1 for a cleft lip and 1:2 for a cleft palate [2]; Left to right sided unilateral cleft lip ratio 2:1 [2]; Unilateral clefts are nine times as common as bilateral clefts [2]; 86% of bilateral cleft lips and 68% of unilateral cleft lips occur with a cleft palate [2]. In 2008, 'World Health Organization' included cleft lip and cleft palate in their Global Burden Disease group. Such birth defects cause significant infant mortality and child-hood morbidity [3].

In India, over 35,000 infants are born with Cleft lip/ Cleft palate and or both every year [4]. These congenital anomalies are frequently associated with other congenital mal-formations e.g. VSD/ASD, meningo-myelocoele, meningocoele and hydrocephalus. Also, in India, amongst rural and urban population, the awareness about cleft lip/ cleft palate surgery at the indicated age is less as compared western world. It is probably be due to a) Low literacy rate and social taboo, b) Issues of social taboo are much more in rural population, c) Small age for surgery; Due to fear of death of their children, parents are not visiting the tertiary care centre in early ages of their children even after consultation with plastic surgeons and e) Some time rural parents are gender bias while providing health facility to their kids [5-7].

Inequalities exist in urban versus rural accessibility and surgical set up for surgical repair of congenital anomalies and more so in relation to plastic surgery [8].

There is scarcity of plastic surgeons at rural level and even very less number at district levels too. Many super specialty consultants are well established at metro and big cities in view of availability of facilities, access to blood bank and other surgical support and needs. These factors lead to increased burden of clefts lip and cleft palate patients over health care system in rural area [9-12]. Apart from facial disfigurement and significant psycho-social consequences, congenial cleft leads to feeding problems in infants. Nutritional deficiencies, anaemia speech/ phonation and dentition development are common if cleft lip/ cleft palate repair surgeries are ignored till late childhood [8].

In past, to administer general anaesthesia, trachea was secured with simple red rubber plain/ cuffed endotracheal tubes (Magill's tracheal Tube). Later on, preformed Oxford tracheal tube was being in use for cleft lip/ palate surgery cases [8]. The common technical issues were difficulty in laryngoscopy and intubation due to cleft palate, fixing of tracheal tube at angle of oral cavity, access to proximal end of endotracheal tube for suctioning of tracheal secretions, kinking of tube due to retractor, disconnection, hurdle of extra length of proximal end of tracheal tube outside the oral cavity and aseptic issues as well.

2. Materials and Methods

It was a prospective observational open randomized single centre study conducted during the period January 2013 to March 2017 at Government Medical College and Hospital, Nagpur Maharashtra, India. Before starting the study Institutional Ethical committee approval and written inform consent from parents was obtained. Total 60 patients of either sex, age between 4 months to 16 years, ASA grade I and II and children nil by mouth were included for the study. Exclusion criteria were- No consent, age group of patient between <4months - >16 years, children with upper and lower respiratory infection, cardiac congenital anomalies e.g. VSD, ASD etc and other facial anomalies. Children's were randomized into two groups of 30 patients in each. Group R: intubated with RAE South pole tube and group F: intubated with flexo-metallic tube. A detail history and systemic examination were done for all the patients.

Thorough pre-anaesthetic evaluation was done for fitness of anaesthesia and to rule out associated other congenital anomaly if any; Consent of parents was checked; IV access with 22 or 20 G intra-catheter was obtained preferably over wrist or forearm with proper splint. Multipara Monitor was attached to patient with monitoring cables (ECG, Heart Rate, SpO_2, NIBP, $EtCO_2$, temp), Stethoscope was fixed over maximum intensity area of heart sounds in precordial area of chest. Each patient was premedicated with Inj. Glycopyrrolate 4 mcg/ kg IV, Inj. Midazolam 0.03 mg/ kg IV, Inj. Fentanyl 0.5 - 1 mcg/ kg IV. Preoxygenation was done 3 minutes.

Induction of general anaesthesia was done with Inj. Propofol 2 mg/ kg IV + Inj. Suxamethonium 2 mg/ kg IV in pts where cleft palate defect was minimal in width. In infants, the induction & intubation was done on inhalational anaesthesia. As per the computerised random selection, the trachea of patient was secured with appropriate size flexo-mettalic or RAE tracheal tube. Confirmation of tracheal tube placement was done by chest auscultation and capnography (EtCO2). [Confirming air entry to both lungs: In Infant patients few cms difference can lead to endobronchial intubation/ extubation. In RAE tube, length adjustment is not possible due to preformed curvature. In Flexo-metallic tube, length adjustment is possible]. Tracheal tube was fixed; throat was packed with sterile moist roller gauze. In each patient per-rectal Paracetamol suppository (20mg/ kg) was placed before the surgical procedure was started. Maintenance of General Anaesthesia was done with Sevoflurane (2-4%) + Oxygen & N_2O (50:50%) + Inj Vecuronium IV and manually intermittent positive pressure ventilation. Surgical position of patient**:** Supine, elevated trunk and neck extension. After positioning- Placement of tracheal tube was rechecked for equal air entry by auscultation and capnography. In cleft palate surgery, on application of mouth gag by surgeon, proper placement and non-kinking of tracheal tube was confirmed by auscultation and capnography and thus at this point of care, surgeon was allowed to start the surgery. On completion of surgery, reversal of anaesthesia was done with Inj. Neostigmine 0.05mg/ kg IV and Inj. Glycopyrrolate 4 mcg/ kg IV. Gentle laryngoscopy was done to check active bleeding if any; oral suction done; throat pack removed; extubated. The patient was turned to lateral decubitus position with slight head low position to prevent airway obstruction and aspiration of oozing blood if any. In postoperative period, patient was monitored for vital parameters, airway obstruction and bleeding for a period of 60 minutes. Later patient was shifted to respective ward.

Observations noted were ease of insertion of catheter and suctioning through tracheal tube, incidence of kinking of RAE tube, refixation of tracheal tube required, incidence of displacement (Endobronchial/Accidental Extubation), vital Parameters (Heart rate, Blood pressure, SpO_2, $EtCO_2$, ECG, NIBP), ventilation issues if any, Airway complications: Laryngo-spasm, Broncho-spasm, Surgeons' feedback- Comfort zone: Satisfactory or Distracting.

2.1 Statistical Analysis

Haemodynamic and Demographic variables were presented on mean ± SD. Categorical data were expressed in Frequency and Percentages. Haemodynamic parameters

and Demographic variables were compared between two groups by performing independent t-test. Pearson chi - square was used to compare categorical data. $p<0.05$ was considered as statistically significant. Statistical software STATA version 14.0 was used for data analysis.

3. Observations and Results

Total 60 patients were enrolled in the study, among them 38 (63.33%) were males and 22 (36.37%) were females. The demographic profiles of the patients were comparable in both the groups and difference was statistically insignificant, (Table 1).

Table 1: Demographic profile of patients

Parameters	Group F	Group R	P value
Age (years)	2.30±2.88	2.31±2.58	0.9850
Weight (kg)	11.16±3.06	11.45± 4.51	0.7772
Sex (Male/Female)	18/12	20/10	0.0592

Table 2 show the comparison of surgical procedure performed among 2 groups and difference found between two groups was statistically not significant.

Table 2: Comparison of Surgical Procedure between two groups

Surgical Procedure	Group- F	Group - R	Total
Cleft Lip Repair	12 (40%)	13 (43.33%)	25 (41.67%)
Cleft Palate Repair	18 (60%)	17 (56.67%)	35 (58.33%)
Total	30	30	60
p- Value: 0.793 ; Statistically insignificant			

Intra-operative vital parameters were comparable between two groups. Thus there was no statistically significant difference observed between two groups as shown in table 3.

Table 3: Intra-Operative Vital Parameters

Vital Parameters	Group - F	Group - R	p-Value
Heart Rate: bpm	108.43±18.58	106.30±18.55	p- 0.6592
SpO_2: %	98.58 %	98.47 %	p- 0.0821
ECG	No change	No change	--
SBP (mm/ Hg)	85.83±2.26	85.44± 2.83	p- 0.5586
DBP (mm/ Hg)	50.21±2.00	51.11±2.87	p- 0.1654
EtCO2 (mm/Hg)	35.9±0.17	35.85±0.14	p- 0.2187
Temp. (Degree C.)	36.74±0.06	36.78±0.13	p- 0.1314

Table 4 show the all intraoperative parameters observed during surgical procedure. Ease of insertion of catheter/ suctioning through tracheal tube was statistically highly significant, (p-Value: < 0.0001). Table 5 show the surgeon's feedback about tracheal tubes.

Table 4: Intraoperative Observations

Intraoperative Observations	Group: F	Group: R	p- Value
• **Ease of insertion**: a) Suction catheter & b) Suctioning via lumen of tracheal Tube	Easy	Difficult	0.0001 (HS)
• Kinking of tracheal tube	--	--	--
• Displacement of tube	nil	4	p- 0.112 (NS)
• Refixation of tube	nil	4	p- 0.112 (NS)
• Bronchospasm	nil	2	p- 0.492 (NS)
• Laryngospasm	--	--	--
• Postoperative Cough	nil	2	p- 0.492 (NS)
HS- Highly Significant, NS- Not significant			

Table 5: Surgeons' Comfort Zone

Surgeon's: Feed back	Group F	Group R
Surgeons' Comfort Zone	100%	90%
Surgical area clearance	100%	100%
Distraction (Tracheal suctioning)	Nil	05%

Figure 1: Flexo-metallic tracheal tube in situ

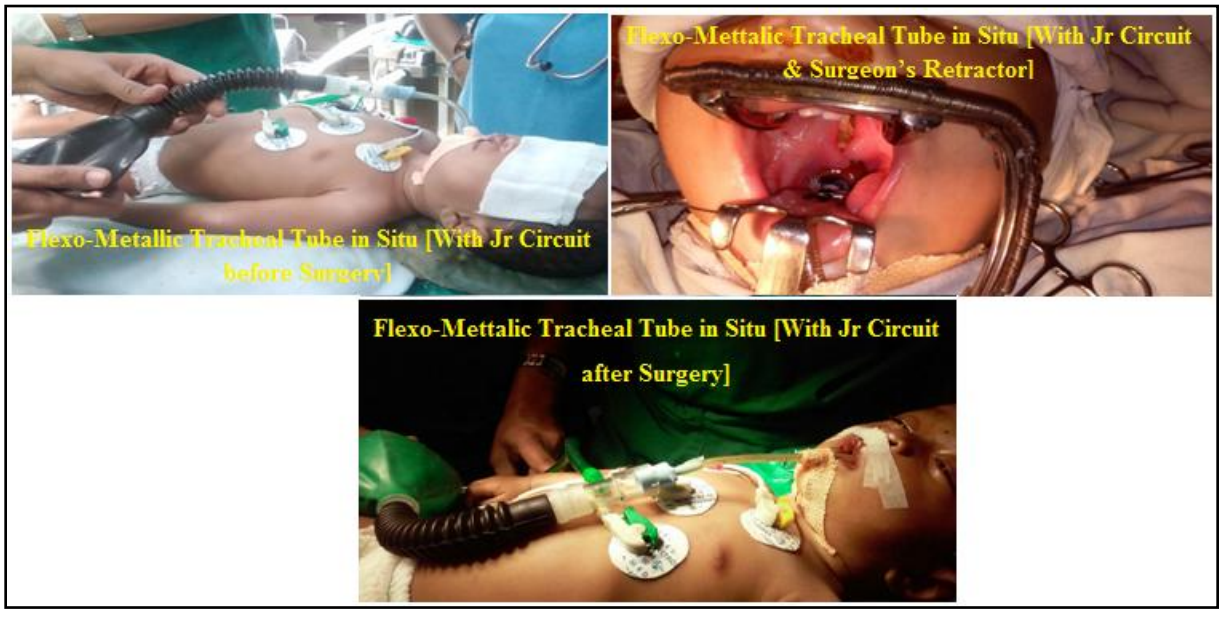
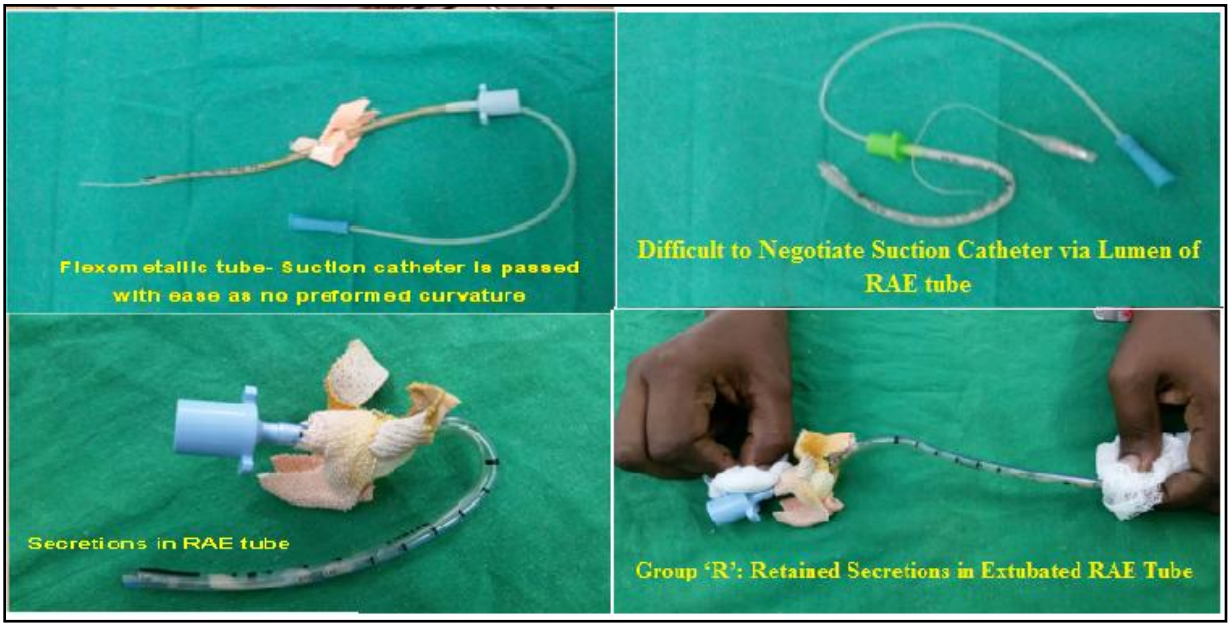


Figure 2: Retained Secretions in Extubated Tracheal Tubes



4. Discussion

In the present study, maximum number of patients was in the age group of 4 months to 2yrs (60%). Thirty three percent patients were in the age group of 2yrs to 4yrs. Only 4 patients were above the age of 5yrs in the study group. There were 18 (60%) and 20 (66.67%) male patients in group 'F' and group 'R' respectively. Out of thirty patients in each group, there were 12 (40%) and 10 (33.33%) female patients in group 'F' and group 'R' respectively. Twelve patients (40%) of cleft lip and 18 (60%) patients of cleft palate were operated in group 'F'. In group 'R', 13 (40.33%) patients of cleft lip and 17 (56.67%) of cleft palate had undergone surgical repair under general anaesthesia.

During surgery, intraoperative vital parameters were comparable to preoperative baseline values with no much variation in both the groups. While the tracheal tube is in situ, in group 'F' insertion of suction catheter through tracheal tube was much easier without any resistance as compared insertion of suction catheter through tracheal tube in group 'R'. No kinking of tracheal tube was noted in group 'R' or group 'F'. Displacement of tracheal tube: 2 (6.67%) patients, Refixation of tube: 2 (6.67%) patients & Bronchospasm in 1 (3.33%) patients was noted in Group 'R'. On extubation, we found thick secretions in the RAE tube group in 5 patients. In our study, no endobronchial intubation or accidental extubation occurred in any group.

In relation to tracheal tube & study, surgeons were asked about the opinion; they were comfortable with both groups. Normally endotracheal tube is fixed at length by formula: Age/2+12 & by clinical assessment i.e. on auscultation equal air entry on both sides of chest (2^{nd} inter-costal spaces). However in patients with anatomical variation, these formulas are not applicable.

In paediatric patients, just few centimetres difference can lead to greater variation leading to either endobronchial intubation or extubation with flexion / extension of neck. In cases of preformed RAE tracheal tubes, Due to preformed curvature of RAE tube, if endobronchial intubation was detected after intubation, the tracheal tube was to be removed & replaced by smaller size tube to ventilate the patient & to prevent further complications of collapse of non ventilated/ other side lung. Whereas just by withdrawing the Flexo-mettalic tracheal tube slightly (Few centimetres) outside the angle of mouth can solve the problems of ventilation & no need to replace the tube & or/ re-intubation. In case of tracheal secretions, insertion of suction catheter was very easy via lumen of flexo-mettalic tube without any resistance as compared to via lumen of RAE tracheal tube.

We tried to search the references and the similar type of study on net but could not find such study till date. Hence possibly this study is the unique original study.

5. Conclusion

- The insertion of suction catheter and suctioning via flexo-mettalic tube is easier as compared to RAE tube.
- Flexo-mettalic tube does not kink in surgical mouth gag.
- No worry about endobronchial intubation and re-intubation.
- Flexometallic tracheal tube is preferable over RAE tube and can safely be used without any hindrances in surgical field in cases of cleft lip and cleft palate surgery.

Risk Factors:

RAE tube has to be replaced if endobronchial intubation occurs and same as in other patients in relation to General Anaesthesia.

Limitation of study:

Small sample size & single centre study.

Conflict of Interest: Nil

Funding for study: Nil

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