Perioperative respiratory complications in cleft lip and palate repairs: An audit of 1000 cases under ‘Smile Train Project’

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ABSTRACT

Background and Aim: Anaesthesia for cleft surgery in children is associated with a variety of airway related problems. This study aims to review the frequency of associated anomalies and other conditions as well as perioperative respiratory complications during the cleft lip/palate repair surgeries. Methods: An audit of 1000 cleft surgeries in children enrolled under “Smile Train” is presented. Following informed consent, general anaesthesia was induced with endotracheal (ET) intubation using halothane in O₂ and/or intravenous thiopentone 5 mg/kg or propofol 1.5 mg/kg, suxamethonium 1.5 mg/kg or rocuronium 0.8 mg/kg and maintained with halothane/isoflurane 0.4-1% in 50% N₂O in O₂ with rocuronium. The observational data regarding the occurrence of perioperative complications in 1000 cleft surgeries are mentioned as mean (standard deviation), number and percentage as appropriate. ‘Two sample t-test between percentage’ is applied for significance. Results: The frequency of isolated cleft lip was 263 (36.4%), cleft palate 183 (25.3%) and combined defect 277 (38.3%) of the operated cases. Other congenital anomalies were present in 21 (2.8%) of the children. The intraoperative airway complications occurred in 13 (2.4%) of cleft lip and 40 (8.7%) of cleft palate repairs \((P < 0.05)\). Post-operative respiratory complications were observed in 9 (1.7%) and 34 (7.4%) patients of cleft lip and palate repairs respectively \((P < 0.05)\). Mortality occurred post-operatively in 2 (0.2%) of cleft repairs \((n = 1000)\). Conclusion: Cleft deformities in children when associated with other congenital anomalies or respiratory problems pre-dispose them to difficult airway and pulmonary complications. Frequency of perioperative respiratory complications were significantly higher with cleft palate repair than with cleft lip repair. Anaesthetic expertise, optimum monitoring facility and specialised post-operative care is necessary to decrease the morbidity.

Key words: Anaesthesia, cleft deformities, respiratory complications

INTRODUCTION

Cleft lip/palate are the most common craniofacial anomalies in children, with an incidence of 1:800 live births. Cleft palate alone occurs in 1:2000 live births.\(^{[1]}\) It occurs due to the failure of fusion or break in fusion of nasal and maxillary processes with the palatine shelves, which form during 8\(^{th}\) week of the embryonic period. About 150 syndromes may be associated with cleft deformities. The most well-known are the Pierre Robin’s, Treacher Collins and Goldenhar syndrome. Congenital heart disease (CHD) occurs in 5-10% of these patients.\(^{[1]}\) Surgical repair of cleft lip is usually done at 1-3 months of age for cosmetic purpose and cleft palate at 6 months to 1 year of age to promote facial growth and the speech. The successful outcome following cleft repair depends on the age of the patient, associated morbidities, anaesthetic expertise and post-operative care.\(^{[1]}\) Infants with facial deformities are usually associated with abnormal dentition/hearing defect, recurrent ear/upper respiratory tract infection (URTI), pulmonary aspiration and poor

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nutrition. Until recently criteria for cleft repair in infants was 10 pounds of weight, 10 weeks of age and haemoglobin of 10 g%.[2] Recent concepts of early repair in neonates are based on improvements in parent-infant bonding, feeding, growth and speech development.[2]

Anaesthesia for cleft surgery in infant and children carries a higher risk with general anaesthesia and airway complications due to associated respiratory problems. Review of literature mentions higher incidence of perioperative respiratory complications when associated with the common cold symptoms in children for cleft repairs.[1,4] Morbidity during general anaesthesia is associated with the difficult airway, endotracheal (ET) tube compression/disconnection and post-operative airway obstruction.[1,4]

This audit aims to present the frequency of associated congenital defects, other conditions and the perioperative airway related morbidity with the anaesthetic management of 1000 cleft lip/palate surgeries, conducted at our institution during 2003-2007.

**METHODS**

The ‘Smile Train’ (March 2005) guidelines,[5] which are designed to promote the safety of children undergoing general anaesthesia for cleft lip and palate repairs were strictly followed. Patients were thoroughly assessed by the paediatrician and the anaesthesiologist.

Surgeries in children with URTI having symptoms of nasal discharge, sneezing, sore throat, cough and with lower respiratory tract infection (LRTI) were postponed for 2 weeks and 4 weeks respectively. They were treated with antibiotics, steam inhalation and bronchodilators if necessary.

Afebrile children with optimised cardio-respiratory status were accepted for the surgery.

They were examined for head size, neck movement, extent of oral defect, type of dentition and tongue size. Airway was assessed with modified Mallampati score in older co-operative children. Informed consent was obtained following explanation to the parents about the potential complications of the procedure. Availability of cross matched blood was ensured for cleft palate repairs. Routine blood investigations (complete blood count, platelets, prothrombin time/partial thromboplastin time for cleft palate repair) and urine examination (routine, microscopic) was done. Electrocardiogram (ECG), X-ray chest was performed whenever indicated.

**Anaesthetic management**

Pre-operative fasting was observed for 4 h for milk, 6 h for solid food and 2 h for clear fluid. Baseline vital parameters like heart rate (HR), non-invasive blood pressure (NIBP), (ECG), pulse oximetry (SpO₂) were noted inside the O.T. All the anaesthetic equipments and drugs were checked. The ET tubes (Ring, Adair and Elwyn (RAE) south polar tube for cleft lip, Oxford/Armoured for cleft palate) and LMAs of appropriate sizes were kept ready.

EMLA cream (1:1 eutectic mixture of prilocaine and lidocaine) was applied with occlusive dressing at the proposed venepuncture site 60 min prior to the surgery. Following pre-oxygenation for 3 min, intravenous (IV) line was secured with 22G/24G cannula. In uncooperative children, cannula was secured following inhalational induction with halothane (0.5-2.5%) in O₂ with Jackson Rees modification of Ayre’s T piece. Patients were premedicated with IV glycopyrrolate 0.004 mg/kg, midazolam 0.05 mg/kg and tramadol 1 mg/kg and induced with IV thiopentone 5 mg/kg or propofol 1.5 mg/kg. After ensuring mask ventilation, intubation was carried out using rocuronium 0.8 mg/kg. Suxamethonium 1.5 mg/kg was used in infants and in children with syndromic/wide cleft deformity/anticipated difficult intubation having easy mask ventilation. Bilateral equal air entry was confirmed and the tube fixed in the centre of the lower lip.

Paracetamol 40 mg/kg suppository was inserted after induction of anaesthesia. Anaesthesia was maintained with 50% N₂O in O₂ with halothane/isoflurane 0.4-1% and intermittent positive pressure ventilation. Top up doses with 0.15 mg/kg of rocuronium were administered at the recovery of train of four (TOF 20%) with TOF watch® (Organon Teknika) following ulnar nerve stimulation.

Ringers lactate was infused (considering 4-2-1 rule), 8-12 ml/kg/h throughout the procedure and 4-6 ml/kg/h for 4-6 h post-operative period. Intra-operative continuous monitoring included HR, NIBP, ECG, SpO₂, end tidal carbon dioxide (EtCO₂), TOF response at the thumb, temperature and blood loss. Blood loss up to 20% of total blood volume was
corrected with crystalloids (in 1:3 ratio) and if >20% with blood transfusion (in 1:1 ratio). Surgical site was infiltrated with 2-4 ml of lignocaine (1-1.5%) with adrenaline (1:100,000). At the end of palate repairs tongue stitch was placed to avoid the post-operative obstruction and gentle suction done. Control of bleeding and removal of throat packs was ensured. Reversal was achieved with 0.05 mg/kg of neostigmine with 0.01 mg/kg of glycopyrrolate and exubated following satisfactory clinical recovery and TOF (T4/ T1 ratio > 90% and with no fade on double burst stimulation). O₂ was supplemented in the recovery room for 1 h and child shifted to paediatric intensive care unit (PICU) for observation and vital monitoring for 8-12 h and later shifted to the paediatric ward. Post-operative pain control was provided with tramadol 1 mg/kg IV 4 hourly for 8 h, later orally with paracetamol or ibuprofen syrup. Older children >1 year received diclofenac suppositories after 12 h. Any adverse event during the course of anaesthesia and surgery was noted. For the study purposes, fall in SpO₂ <90% was considered as desaturation, laryngospasm as partial or complete airway obstruction with fall in SpO₂ <90% with no relief after jaw thrust, chin lift, use of the airway and 100% O₂ support by face mask.

Presence of wheeze/ronchi on auscultation was considered as bronchospasm.

Requirement of more than three attempts at intubation by an anaesthesiologist having expertise in dealing with paediatric airway was considered as difficult intubation and failure to intubate after three attempts as failed intubation.

Bradycardia was defined as HR < 20% of baseline, tachycardia if HR >30% of baseline, hypotension when mean arterial blood pressure (MBP) <20% and hypertension if MBP >30% of the baseline value.

Statistical analysis
The data was analysed as mean (standard deviation [SD]), frequency and percentage as appropriate for the study. Basic statistics was assessed by using MS Excel Office 2007 data analysis Tool Pack. For preparation of tables of frequency distribution and percentages, SPSS software (Version 20) was used.

For comparison of percentage in two groups, ‘two sample t-test between percentages’ was applied for significance. P<0.05 was considered as statistically significant.

RESULTS
The demographic profile is shown in Table 1 as distribution of patients in the three age groups with their mean (±SD) of height and weight. A total of 723 patients were screened and were operated for cleft lip and palate repairs for a total of 1000 surgeries.

Table 1: Demographic profile

| Age in years | ¼-3 | 3-8 | 8-20 | Total (M/F) |
|--------------|-----|-----|------|-------------|
| Height (cm)  | 85±15 | 115±15 | 155±20 | - |
| Weight (kg)  | 10±5 | 22.5±8 | 40±10 | - |
| Lip repair   | 337 | 188 | 15 | 540 (337/203) |
| Palate repair| 205 | 228 | 27 | 460 (285/175) |

Values for height and weight are mentioned in means±SD; Number of lip and palate repairs in the three age groups; Total cases and M/F ratio. SD – Standard deviation

Table 2: Pre-operative associated conditions

| Associated conditions | Cleft lip (n=540) | Cleft palate (n=460) | Total frequency (%) |
|-----------------------|------------------|---------------------|---------------------|
| Rhinorhea             | 18               | 31                  | 49 (4.9)            |
| URTI                  | 38               | 73                  | 111 (11.1)          |
| Bronchitis            | 8                | 12                  | 20 (2)              |
| Asthma                | 7                | 5                   | 12 (1.2)            |
| Pneumonia             | 5                | 9                   | 14 (1.4)            |
| Otitis media          | 7                | 12                  | 19 (1.9)            |
| Anaemia (Hb<10 g%)    | 23               | 38                  | 61 (6.1)            |
| Undernutrition (weight<50th percentile) | 17 | 22 | 39 (3.9) |
| Feeding problem       | 39               | 73                  | 112 (11.2)          |
| Total (%)             | 160 (29.6)       | 275 (59.8)          | 435 (43.5)          |

T=9.601; P=0.0000<0.05 (significant); URTI – Upper respiratory tract infection; Hb – Haemoglobin
manoeuvres, oxygenation or subsequent injection of muscle relaxant for intubation. Bronchospasm developed during induction in 0.5% of patients, which was relieved with deepening of the plane of anaesthesia with inhalational agent, IV hydrocortisone 1 mg/kg and/or deriphyllin (theophylline and etophylline) 2 mg/kg.

Difficult laryngoscopy due to wide cleft palate requiring more than one attempt for intubation was associated in 1.6% of patients. Failure of intubation after three attempts, due to poor visualisation of the larynx occurred in 0.3% cases (Cormack Lehane [CL] Grade III/IV in two cases of Pierre Robin syndrome and in a case of retrognathia with wide cleft palate) in which surgery was postponed and performed after 3-6 months when intubation was possible on the first attempt (CL Grade II). Incidence of partial tube compression was observed in 1.3% (palate repair), endobronchial intubation in 1% and accidental extubation occurred in 0.4% of patients (palate repair 23, lip repair 4).

The frequency of intraoperative respiratory complications was 2.4% in cleft lip and 8.7% in cleft palate repairs \( (t = 4.43, P = 0.0000, P < 0.05) \).

Bradycardia was observed in 0.3% patients at the time of intubation that responded to injection atropine 0.01 mg/kg IV. Tachycardia and hypertension were encountered in 3.3% and 1.7% of patients respectively, that was transient following local anaesthetic infiltration. Intraoperative bleeding 15-20% of the total blood volume occurred in 0.4% patients and they responded to the infusion of crystalloids.

Intraoperative hyperthermia or hypothermia of ± 2° F change occurred in 0.4% and 0.3% cases, that was corrected with air cooling/sponging and warm drappings respectively. Table 3 depicts the frequency of immediate and late post-operative complications. Laryngospasm occurred in 0.3% and bronchospasm in 0.5% of cases resulting in desaturation in the range of \( \text{SpO}_2 \) 87-95% immediately after extubation that responded to oral suction, \( \text{O}_2 \) by mask and IV steroids/bronchodilators respectively.

Post-operative respiratory obstruction developed in 2.3% of cases requiring jaw manoeuvring/lateral positioning or insertion of nasopharyngeal airway. One patient (lip repair) had epiglottic oedema following two attempts for difficult intubation and needed reintubation immediately after extubation.

Post-operative respiratory complications occurred in 4.3% of cases, 1.7% with cleft lip and 7.4% with cleft palate repairs \( (t = 4.41, P = 0.0000, P < 0.05) \). Post-operative bradycardia occurred in one case and tachycardia in 2.8% of cases. Incidence of

![Figure 1: Associated congenital defects (PR syndrome: Pierre robin syndrome, SG stenosis: Subglottic stenosis, ASD: Atrial septal defect, VSD: Ventricular septal defect, PAD: Patent ductus arteriosus)](image)

| Respiratory complications          | Cleft lip (n=540) | Cleft palate (n=460) | Total frequency and (%) |
|-----------------------------------|-------------------|----------------------|-------------------------|
| Laryngospasm                      | 1                 | 2                    | 3 (0.3)                 |
| Bronchospasm                      | 2                 | 3                    | 5 (0.5)                 |
| Epiglottic oedema/ re-intubation   | 1                 | -                    | 1 (0.1)                 |
| Respiratory obstruction           | 2                 | 21                   | 23 (2.3)                |
| URTI                              | 2                 | 5                    | 7 (0.7)                 |
| Bronchopneumonia                  | 1                 | 3                    | 4 (0.4)                 |
| Total (%)                         | 9 (1.7)           | 34 (7.4)             | 43 (4.3)                |

URTI – Upper respiratory tract infection; \( T=4.41; P\) value 0.0000<0.05 (significant)

![Figure 2: Frequency of intra-operative airway complications \( T=4.433, P=0.0000<0.05 \) (significant)](image)
vomiting, shivering and moderate hyperthermia was 1%, 1.3% and 1.7% respectively. Post-operative bleeding occurred in two cases of palate repair and required re-exploration and blood transfusion at 6-8 h post-operative period. Frequency of post-operative URTI, bronchopneumonia was 0.7% and 0.4% respectively. Wound dehiscence occurred in 0.4% cases of lip repair and palatal fistula in 2.8% requiring surgical correction at later dates. One patient, aged one year, after lip repair, died 12 h post-operatively; the child required two attempts for intubation for respiratory obstruction immediately after extubation that was associated with desaturation (SpO₂ <85%) and bradycardia. On laryngoscopy during reintubation oedematous epiglottis was visualised and she developed hyperpyrexia with convulsions. ABG was suggestive of respiratory and metabolic acidosis with raised creatine phosphokinase levels, urine was positive for red blood cells and proteins. The child could not be resuscitated after all necessary interventions. Another patient, an 8 years old girl with ventricular septal defect (VSD) had lip repair successfully at the age of two, also underwent palate repair uneventfully this time. On second post-operative day following bath she developed central cyanosis (SpO₂ 70%) and, tachycardia. Echocardiography (ECHO) revealed large perimembranous VSD with 50% overriding of aorta with shunt from the right ventricle to the aorta.

Immediate transfer to cardiac centre was advised by paediatrician but the child succumbed to thromboembolic episode at 72 h.

**DISCUSSION**

Hereditry plays a significant role in cleft deformity besides parents’ age, nutrition, radiation and certain drug therapies. 25% of cleft lips are bilateral and 85% of them have associated cleft palate. The surgical repair of cleft requires a team approach. We aimed to present an audit of 1000 cleft surgeries, evaluated on the basis of medical records regarding perioperative complications. In our study, the incidence of URTI was 7.01% and 15.9% in cleft lip and palate cases respectively. Acute URTI is the leading cause of postponement of elective surgeries and there are no confirmatory laboratory tests or X-ray findings to diagnose URTI. It increases the risk of laryngospasm from 1.7% to 9.6% and a threefold increase in bronchospasm in children. Tiret et al. reported incidence of anaesthesia related complications within 24 h in 4.3/1000 infants and 0.5/1000 in children with 0.01% death. Cohen et al. reported higher peri-

anaesthesia morbidity in paediatric patients (35%) compared to adults (17%). Majority of the anaesthetic morbidity in cleft repair is related to the airway such as difficult intubation, ET tube compression, disconnection or accidental extubation. Assessment of the degree of difficulty during intubation is not always possible preoperatively. Any child with hypoplastic mandible or wide cleft palate increases the risk of tongue prolapse into the nasopharynx and pose a problem during induction of anaesthesia. Gunawardhana in his study of 800 cleft lip/palate repairs reported difficult intubation and need for external laryngeal pressure in 86% of cases with Cormack and Lehane Grade III and IV airway grades. The incidence of difficult laryngoscopy was 2.95% in unilateral, 45.7% in bilateral cleft lip and 34.6% in retrognathia with significant association of the lower age with difficult laryngoscopy.

In our study, intubation related problems occurred in 2.4% in cleft lip repair and 8.7% in palate repair. Failure of intubation occurred in three cases of which one had retroganathia and two had Pierre Robin syndrome (PRS) with micargnathia. They could be intubated after 3-6 months of growth. LMA can be used to facilitate intubation in such cases and have been used successfully in craniofacial anomalies undergoing reconstructive plastic surgeries.

Fillies et al. reported major complications such as laryngospasm, arrhythmia, excessive bleeding, hyper/hypothermia in 45.2% of lip repairs and 29.8% in palate repairs respectively. McQueen et al. noted incidence of the anaesthetic complications in 31% of the overall reported complications in the data reviewed during 2005-2006. Difficult intubation, bronchospasm and airway obstruction accounted for majority (76%) of these reported studies.

In the post-operative period, there is a higher chance of developing mucosal oedema in any part of the airway especially following pharyngeal flap with palate repair or after surgeries lasting longer than 2 h. Patients with Pierre Robin syndrome present with severe airway problems intra/postoperatively such as difficult intubation, mucosal oedema of the oropharynx/larynx or tongue due to the prolonged pressure on these structures following extension of head and dissection/manipulation during repair operations. In our study, an 1-year-old child for lip repair needed two intubation attempts and had epiglottic oedema resulting in post extubation respiratory obstruction.
Post-operative respiratory obstruction may result following the closure of wide cleft palate or syndromic cleft associated with hypoplasia of mandible, haematoma or due to accidental left-over packs. Aspiration of the secretions or blood collected in the nasopharynx is possible following removal of head extension (that brings down the larynx) and with the emergence of reflexes. There is also change in oral/nasal airway dynamics especially in children with PRS that may present with the problem of respiratory obstruction in the post-operative period. Use of nasopharyngeal airway or/and tongue suture to allow forward traction can help in such a situation.17

Fillies et al.15 observed average blood loss of around 15 ml and 45 ml during cleft lip and palate closure. We observed average blood loss of 21 ml with cheiloplasty and 46 ml with palatoplasty (3-12% of expected blood volume). Doyle and Hudson19 reported requirement of blood transfusion in 10% patients of cleft lip and 16% of palate repair in their series of 244 cleft surgeries. They used post-operative opioids for pain-relief and noted respiratory depression in 3/97 patients and total respiratory arrest in one case. In our series, blood transfusion was needed in 0.2% patients of palate repair who required re-exploration. There was no incidence of respiratory depression in our patients as we avoided the use of potent opioids intra and post-operatively.

Infra orbital nerve block offers better pain relief following lip repair.20 Incidence of post-operative bleeding was 4.3% in old literature,15 which has come down to 0.5% in recent studies due to improved techniques and use of cautery.21 The incidence of palatal fistula formation is reported to be 6%.22 We observed incidence of wound dehiscence in 0.4% patients and palatal fistula in 2.8% patients. Hyperthermia was frequently reported in 1950s in infants undergoing cleft surgeries.22 Association of hyperpyrexia with raised creatinine phosphokinase, subclinical myopathy of autosomal dominant inheritance resulting in malignant hyperpyrexia is known. In infants it responds well to dantrolene sodium, and its use has resulted in the drop in mortality from 80% 30 years ago to less than 5% now.23 We had a case of hyperpyrexia with laboratory findings positive for MH; however, due to non-availability, we could not administer dantrolene sodium.

Fillies et al. reported no death in 174 infants of cleft repair.15 McQueen et al. reported one death (0.012%) at 72 hours post-operatively probably due to CHD in 8000 cases of repair.16 VSD is the most common (30%) of the CHD. Small defect (pulmonary to systemic systolic pressure ratio < 0.3 and Qp: Qs < 1.4) causes negligible haemodynamic changes. Large defect (systolic pressure ratio more than 0.3 and Qp: Qs more than 2.2) leads to the eventual development of pulmonary vascular obstructive disease – Eisenmenger’s syndrome. Morbidity in these patients is due to chronic cyanosis, thromboembolic events, cerebrovascular complications and the hyperviscosity syndrome.24 In our study 0.2% mortality is reported, in a case due to hyperpyrexia with convulsions within 24 h and in the other case at 72 h of the post-operative period due to reversal of shunt at VSD and subsequent episode of thromboembolism.

CONCLUSION

Surgical repair of the cleft lip/palate in infants and children is a great challenge to the anaesthesiologist due to its peculiar site and association of variety of developmental anomalies and perioperative complications. In our study, we observed congenital defects in 2.9% and other associated diseases in 43.5% of the patients of cleft lip/palate. Intra and post-operative respiratory complications occurred in 5.3% and 4.3% of patients respectively with significantly higher incidence reported in cleft palate repairs. Anaesthetic management of cleft repair needs skilled personnel, meticulous monitoring and post-operative care in an intensive care unit setup to minimise the complications.

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