

Comparative Evaluation of Fentanyl-Sevoflurane VS Fentanyl-Sevoflurane-Atracurium in Cleft Lip and Cleft Palate Surgeries- A Prospective Comparative Study

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Abstract

Background: Cleft lip and palate surgeries require optimal anaesthetic management to ensure adequate surgical conditions, hemodynamic stability, and rapid postoperative recovery. While fentanyl and sevoflurane are widely used for paediatric anaesthesia, the role of atracurium as an adjunct for muscle relaxation remains a subject of interest.

Aim: To compare the efficacy and safety of fentanyl–sevoflurane anaesthesia with fentanyl–sevoflurane–atracurium anaesthesia in patients undergoing cleft lip and palate surgeries.

Material and methods: This prospective comparative study included patients undergoing elective cleft lip and palate repair under general anaesthesia. Patients were allocated into 2 groups: Group FS received fentanyl and sevoflurane, while Group FSA received fentanyl, sevoflurane, and atracurium. Hemodynamic parameters, intubation conditions, surgical field quality, recovery characteristics, post extubation NBM time, and postoperative complications were evaluated.

Results: Group FS demonstrated significantly better extubation time, recovery score, post extubation NBM time compared with Group FSA. Hemodynamic parameters remained comparable between groups. Intubation conditions and surgical field quality were comparable. No major perioperative complications were observed in either group.

Conclusion: The addition of atracurium to fentanyl–sevoflurane anaesthesia provides superior operating conditions and airway management during cleft lip and palate surgery, although recovery and extubation time may be slightly prolonged. Both techniques were safe and effective.

Keywords: Cleft lip, cleft palate, fentanyl, sevoflurane, atracurium, paediatric anaesthesia, muscle relaxants.

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Introduction

These are the most severe of congenital anomalies which affect the mouth and related structures. The roof is shaped from the palate and flooring from the constructions at the floor of the mouth. Laterally, it's bounded from the cheeks. A cleft is a congenital abnormal space or gap in the upper lip, alveolus, or palate.

Cleft lip: The failure of fusion of the frontonasal and maxillary processes, resulting in a cleft of varying extent through the lip, alveolus, and nasal floor (an incomplete cleft does not extend through the nasal floor, while a complete cleft implies lack of connection between the alar base and the medial labial element). [1]

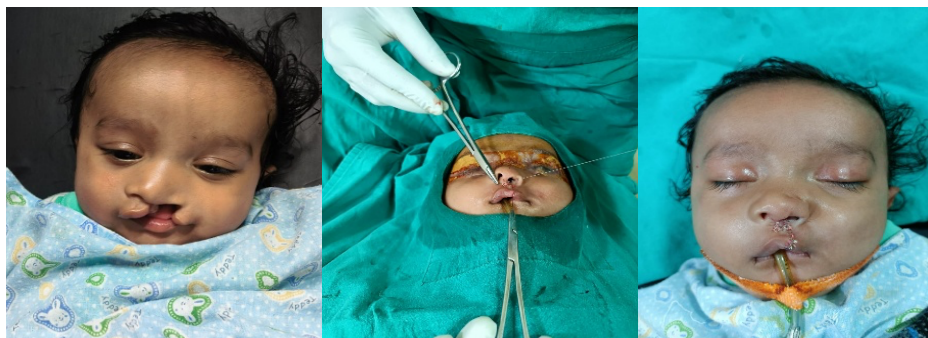


Figure 1:

Cleft palate: The failure of fusion of the palatal shelves of the maxillary processes, resulting in a cleft of the hard and/or soft palates. Clefts arise during the fourth developmental stage. Exactly where they appear is determined by locations at which fusion of various facial processes failed to occur, this in turn is influenced by the time in embryologic life when some interference with development occurred. [2]

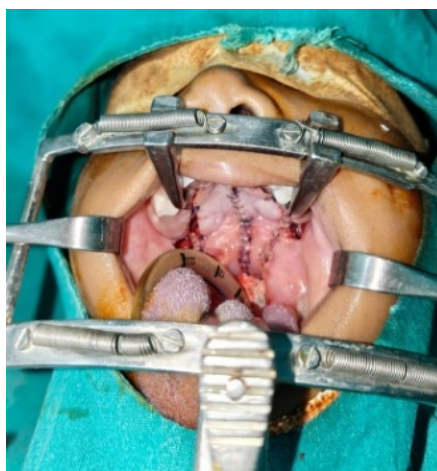


Figure 2:

Overall incidence of cleft lip and palate is approximately 1 in 600 to 800 live births (1.42 in 1000) and isolated cleft palate occurs approximately in 1 in 2000 live births. Thus, the typical distribution of cleft types is [3]

1. Cleft lip alone – 15%
2. Cleft lip and palate – 45%
3. Isolated cleft palate – 40%.

The potential problems of the condition include social handicaps such as impaired suckling and resultant failure to thrive, speech impediment, deafness, malocclusion, gross facial deformity and severe psychological problems. The clefting of lip and/or palate occurs at such a strategic place in the orofacial region, at such a crucial time (before birth) that it becomes a complex congenital deformity.

Patient with Oro-facial cleft deformity needs to be treated at right time and at right age to achieve

Functional and aesthetic well-being. The treatment process is complex, multidisciplinary and interdisciplinary approach. Successful management of the child born with a cleft lip and palate requires coordinated care provided by a number of different specialties including oral/maxillofacial surgery, otolaryngology, genetics/dysmorphology, speech/language pathology, orthodontics, prosthodontics, and other.

This successful reconstruction routinely requires multiple phases of surgical intervention.

Tessier Craniofacial Clefts: In 1976, Paul Tessier developed a comprehensive numerical classification system to categorize craniofacial clefts based on precise anatomic location. In order to comprehend craniofacial cleft development, it is crucial to understand embryologic development of the face. Craniofacial clefts can be classified into 4 main categories:

1. oral-nasal (number 0-3),
2. oral-ocular (number 4-6),
3. lateral face (number 7-9),
4. cranial (number 10-14).



Tessier-7

Figure 3:

Etiology: The etiology of cleft lip and palate is complex and thought to involve genetic influences with variable interactions from environmental factors. The etiological factors of cleft lip and palate can be grouped as under:

A. Genetic: Genetic cause includes:

1. **Syndromic:** Here cleft is associated with other malformation. Usually, it is due to a single gene (monogenic or Mendelian) disorder.

- Waardenburg syndrome, type IIA
- Di George syndrome
- Treacher -Collins
- Mandibulofacial dysostosis

2. **Non-syndromic:** Here the cleft is mostly an isolated feature and occurs in the vast majority of individuals having a cleft lip or palate (up to 70% cases). In this form, a cleft is neither a recognized pattern of malformation nor a known cause for the disorder can be identified.[4] Possible genes whose mutation may result in non-syndrome clefting.

- TGF- Alfa
- Methylene tetra -hydro folate reductase
- Blood clotting factor XIII gene

B. Non-genetic: Besides genetic factor environmental factors also play a very important role in etiology of CL/P. [5] various environmental factors include:

Smoking: The relationship between maternal smoking and CLP is not strong, but it is significant. Several studies have consistently yielded a relative risk of about 1.3–1.5. When maternal smoking was considered together with a positive genetic background, the combined effect was more significant.

Alcohol use: Heavy maternal drinking, apart from causing foetal alcohol syndrome, also increases the risk of CLP. Munger et al. (1996) showed that maternal drinking increased the risk for CLP by 1.5–4.7 times in a dose-dependent manner Low-level alcohol consumption, however, did not seem to increase the risk of orofacial clefts. The link between alcohol consumption and genotypes on the risk of CLP has yet to be demonstrated.

The various clinical findings in patient with cleft lip and palate can be categorized under two headings:

Dental problems in cleft lip and palate

Natal and neonatal teeth: Presence of neonatal teeth does not appear to influence primary or secondary dentition in clefts. Most natal teeth among clefts are located in the lateral margin of the premaxillary and maxillary segments unlike in non-cleft neonates.

Microdontia: Small teeth (microdonts) frequently are found with CL/P. This is usually more common in cases where lateral incisors are not missing (van der Wal, 1993; Stahl et al). Generally, peg shaped upper lateral incisors are seen. [6]

Enamel hypoplasia: Enamel hypoplasia was found to occur more frequently in CL/P subjects compared with non-cleft populations, especially involving the maxillary central incisors (Vichi and Franchi, 1995).

Delayed tooth maturation: Several growth factors are of major importance during craniofacial development, and these factors may be overexpressed or under expressed when a cleft defect occurs. This aberrant expression can modify odontogenesis and cause abnormalities of the dental lamina. [7]

Other associated conditions

Speech difficulties: Due to the dysfunction of m. levator Veli palatini muscle phonation is affected. Retardation of consonant sound (p, b, t, d, k, g) is most common findings. Abnormal nasal resonance and difficulty in articulation are another characteristic feature in most individuals with cleft lip and palate.

Ear infection: Due to improper function of m. tensor Veli palatini muscle, which opens the Eustachian tube, otitis media is observed in these patients. In a case where infections frequently occur, results that can lead to hearing loss may occur. The incidence, however, increases sharply when there is associated submucous cleft palate.

Feeding problems: A child with a cleft palate can have difficulty sucking through a regular nipple due to the gap in the roof of the mouth. An infant's ability to suck is related to two factors: the ability of the external lips to perform the necessary sucking movements and the ability of the palate to allow the necessary build-up of pressure inside the mouth so that foodstuff can be propelled into the mouth. Most babies require a personalized or special nipple to properly feed. It may take a couple of days for the baby and parents to adjust to using the nipple before going home. Most babies learn to feed normally with a cleft palate nipple. [8]

Surgical correction is the definitive treatment and is typically performed during infancy or early childhood. These procedures present unique anaesthetic challenges due to airway abnormalities, limited surgical access, potential blood loss, and the need for a motionless surgical field.

Sevoflurane – It is less pungent than isoflurane & desflurane, so superior to halothane for inhaled anaesthesia. Rate of induction is more rapid. The incidence of coughing during induction with sevoflurane (~6% vs ~10%) is smaller & a 33% more frequent incidence of excitement occurs during emergence (21% vs ~15%). Sevoflurane decreases both the Respiratory Rate & Tidal Volume. So, respirations may need to be assisted during the early induction stage in sevoflurane-anaesthetized children. Children > 3 years – increases H.R & no change in SBP. The children most vulnerable to anaesthetic overdose are the age groups that have the least increase in H.R & the largest decrease in SBP ($34\% \pm 16\%$ & $26\% \pm 20\%$ respectively for neonates & infants younger than 6 months of age).

Risk of exothermic reactions with dry desiccant, [9] which has resulted in fires & explosions (Sevoflurane + baralyme). Production of toxic metabolites as a result of an interaction with the CO₂ absorbent. Major concern is the more frequent incidence of emergence agitation (decreases with midazolam / clonidine / ketorolac / fentanyl / dexmedetomidine). Report of seizure like activity. (Halothane > Sevoflurane for bronchoscopy).

Fentanyl – most commonly used opioid in infants & children. Its major advantages relate to its rapid onset & brief duration of action. Fentanyl induces a very stable cardiovascular response while providing an anaesthetic state. The dosage required to produce anaesthesia varies considerably, depending on the child's age, the surgical procedure, the health of the child, & the use of anaesthetic adjuvants. [10] Much smaller dose (2–10 µg/kg) should be used with other anaesthetics if ventilation is not to be controlled postoperatively. Because the cardiac output of neonate is determined by the HR, fentanyl-induced

bradycardia may require the administration of a vagolytic drug such as atropine or even pancuronium during long procedures.

Atracurium – is a non-depolarizing muscle relaxant (intermediate acting).[11] Useful for shorter procedures in infants & children. They may also be administered as a constant infusion. The method of excretion of atracurium (Hofmann elimination & ester hydrolysis) makes these relaxants particularly useful in newborns & children with immature liver/hepatic & renal function.

- Dose: 0.5 mg/kg – induction
- mg/kg – maintenance

Despite the frequent use of these agents, limited literature directly compares fentanyl–sevoflurane anaesthesia with fentanyl–sevoflurane–atracurium anaesthesia in cleft lip and palate surgery. This study was undertaken to evaluate the relative advantages and disadvantages of these two anaesthetic techniques.

Materials and Methods

Study Design: Prospective comparative study.

Study Setting: Department of Anaesthesiology, L.N Medical College, Bhopal, (M.P), India.

Study Duration: 1/1/2024 to 2/2/2026.

Ethical Approval: Approval was obtained from the Institutional Ethics Committee. Written informed consent was obtained from parents or legal guardians.

Inclusion Criteria

- Patients aged [4 month to 2 years]
- Scheduled for elective cleft lip or cleft palate repair.
- American Society of Anaesthesiologists (ASA) Physical Status I–II.
- Informed consent from parents/guardians.

Exclusion Criteria

- Significant cardiopulmonary disease.
- Known neuromuscular disorders.
- Allergy to study medications.
- Anticipated difficult airway requiring alternative management.

Sample Size: A total of [146] patients were enrolled and equally divided into 2 groups.

Sample Size Calculation

Formula (Comparing Two Proportions — Charan & Biswas, 2013): $n = [Z\alpha/2 \sqrt{(2PQ)} + Z\beta \sqrt{(P_1Q_1 + P_2Q_2)}]^2 / (P_1 - P_2)^2$

Where:

P₁ (with atracurium / muscle relaxant): (0.97) Mencke et al. 2014 (rocuronium group: 97% acceptable intubating conditions)

P₂ (without muscle relaxant): (0.82) Mencke et al. 2014 (sevoflurane group: 82% acceptable intubating conditions)

Z α /2 (95% confidence, two-tailed): 1.96

Z β (80% power): 0.84

Anticipated dropout: 10%

Calculation:

$$\bar{P} = (0.97 + 0.82)/2 = 0.895; Q^- = 1 - 0.895 = 0.105$$

$$P1Q1 = 0.97 \times 0.03 = 0.0291; P2Q2 = 0.82 \times 0.18 = 0.1476$$

$$\text{Term 1: } Z\alpha/2 \times \sqrt{(2 \times 0.895 \times 0.105)} = 1.96 \times 0.43353 = 0.84972$$

$$\text{Term 2: } Z\beta \times \sqrt{(0.0291 + 0.1476)} = 0.84 \times 0.42036 = 0.35310$$

$$\text{Numerator} = (0.84972 + 0.35310)^2 = (1.20282)^2 = 1.44678$$

$$\text{Denominator} = (0.97 - 0.82)^2 = (0.15)^2 = 0.0225$$

$$n = 1.44678 / 0.0225 = 64.30 \approx 65 \text{ per group}$$

$$\text{Dropout Adjustment: } 65 / (1 - 0.10) = 65 / 0.90 = 72.22 \approx 73 \text{ per group}$$

Study Groups

Group FS

- Fentanyl 2 μ g/kg IV.
- Induction with sevoflurane.
- Endotracheal intubation without muscle relaxant.
- Maintenance with oxygen, air, fentanyl, sevoflurane.

Group FSA

- Fentanyl 2 μ g/kg IV.
- Atracurium 0.5 mg/kg IV.
- Endotracheal intubation after adequate relaxation.
- Maintenance with oxygen, air, fentanyl, sevoflurane, and supplemental atracurium as required.

Outcome Measures

Primary Outcomes

- Extubation time
- Recovery score (activity, respiration, circulation, consciousness, Spo2)
- Post extubation NBM time

Secondary Outcomes

- Heart rate / min
- Mean arterial pressure, SBP, DBP
- End-tidal CO₂ (EtCO₂)
- Intubation condition
- Surgical field quality
- Postoperative complications (emergence agitation, airway events)



Figure 4:

Statistical Analysis: Data will be entered into Microsoft Excel and analysed using SPSS version 25.0.

Descriptive Statistics

- Continuous variables: Mean $\pm$ Standard Deviation (SD)
- Categorical variables: Number and Percentage

Inferential Statistics

- Independent Student's t-test for comparison of quantitative variables.
- Chi-square test or Fisher's exact test for categorical variables.

- P-value <0.05 considered statistically significant.

Results

Table 1: Recovery Characteristics

Variable	FS(n-73)	FSA(n-73)	p-value
Extubation Time (min)	5.2 ± 1.5	8.8 ± 1.8	<0.001
Recovery Score at 30 min	7.9 ± 0.8	5.7 ± 0.9	<0.001
Post extubation NBM Time (Hour)	2.5 ± 0.5	4 ± 0.4	<0.001

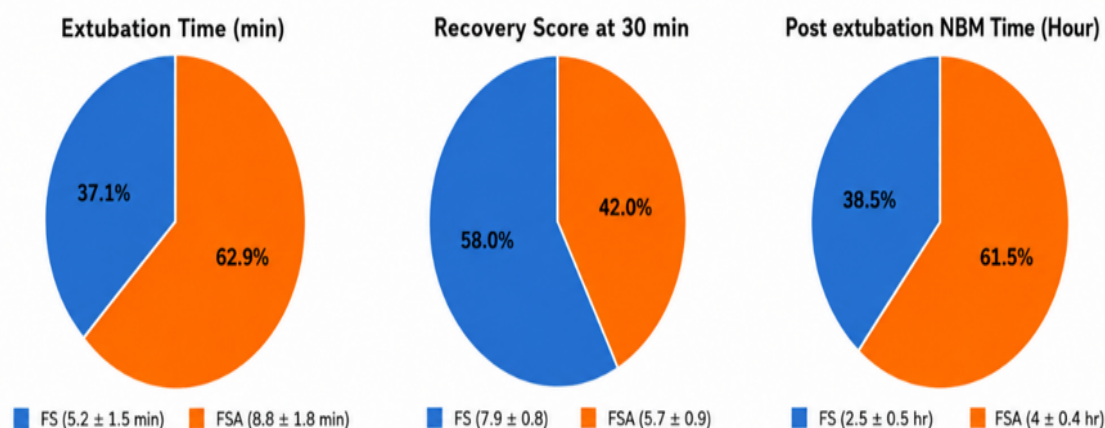


Figure 5:

Interpretation: Extubation time, post extubation NBM time was significantly longer in the FSA group; however, recovery score is significantly higher in FS group.

Table 2: Heart Rate (beats/min)

Time	FS(n-73)	FSA(n-73)	p-value
Baseline	114 ± 10	112 ± 10	0.23
Post-induction	108 ± 10	106 ± 16	0.53
Post-intubation	128 ± 12	122 ± 10	0.001
5 min	120 ± 10	114 ± 10	0.001
10 min	114 ± 8	112 ± 9	0.18
15 min	118 ± 9	114 ± 12	0.06
20 min	116 ± 10	110 ± 9	0.002
25 min	110 ± 9	112 ± 10	0.34
30 min	116 ± 10	110 ± 9	0.12
35 min	108 ± 10	112 ± 10	0.01
40 min	116 ± 11	110 ± 9	0.002
45 min	118 ± 10	114 ± 10	0.09
50 min	112 ± 9	108 ± 8	0.07
55 min	114 ± 8	116 ± 10	0.21
60 min	116 ± 10	112 ± 8	0.18
Extubation	122 ± 11	118 ± 9	0.02

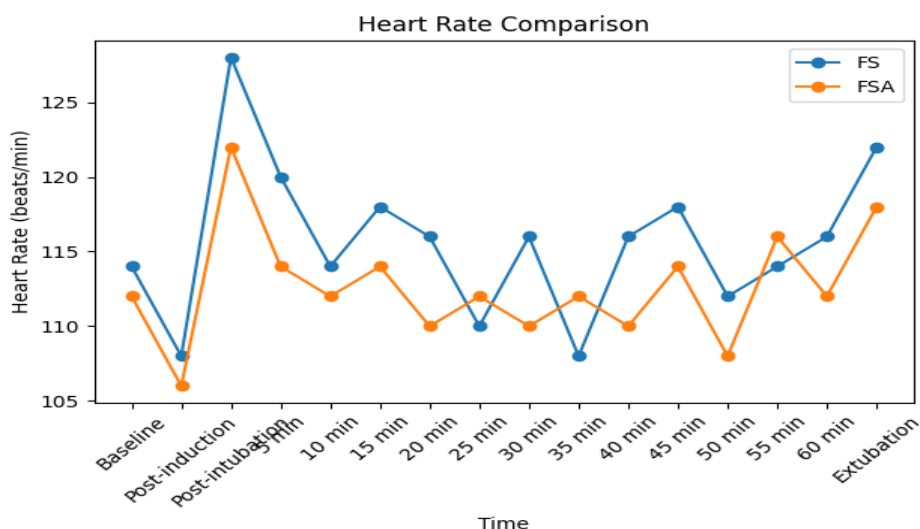
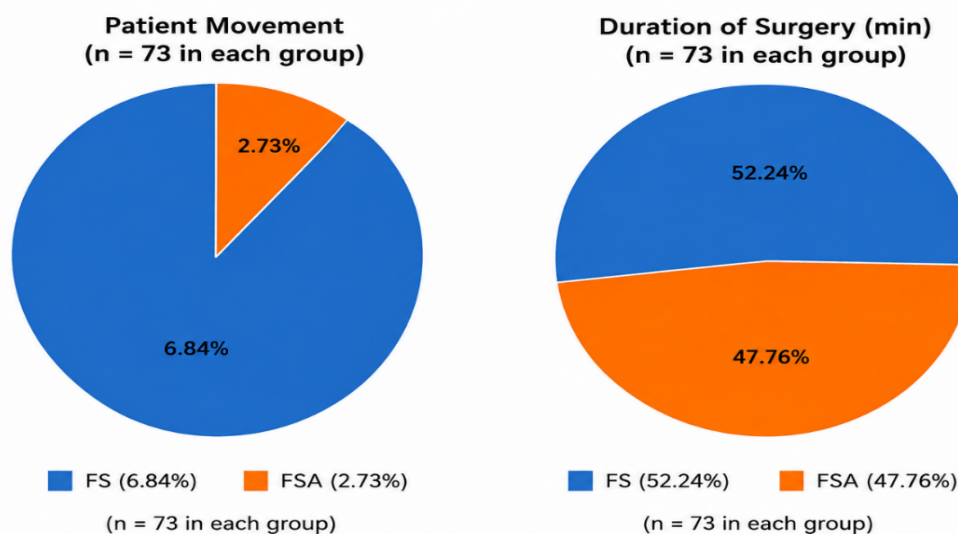


Figure 6:

Interpretation: The increase in heart rate following intubation was significantly lower in the FSA group.

Table 3. Intraoperative Surgical Conditions

Variable	FS(n-73)	FSA(n-73)	p-value
Patient Movement	5 (6.84%)	2 (2.73%)	0.44
Surgeon Satisfaction Score	3.1 ± 0.7	3.8 ± 0.4	<0.001
Duration of Surgery (min)	70 ± 10	64 ± 9	<0.001



Note: Percentages for Patient Movement are calculated out of total 73 patients in each group.

Figure 7:

Interpretation: Patient movement was comparable in both the group and surgeon satisfaction score was significantly higher in the FSA group while duration of surgery was significantly higher in FS group.

Table 4: Intubating Conditions

Intubation Score	FS (n=73)	FSA (n=73)	p-value
Excellent	62 (84.9%)	65 (89%)	
Good	8 (10.9%)	7 (9.58%)	
Poor	3 (4.1%)	1 (1.36%)	
Overall Comparison	—	—	0.62

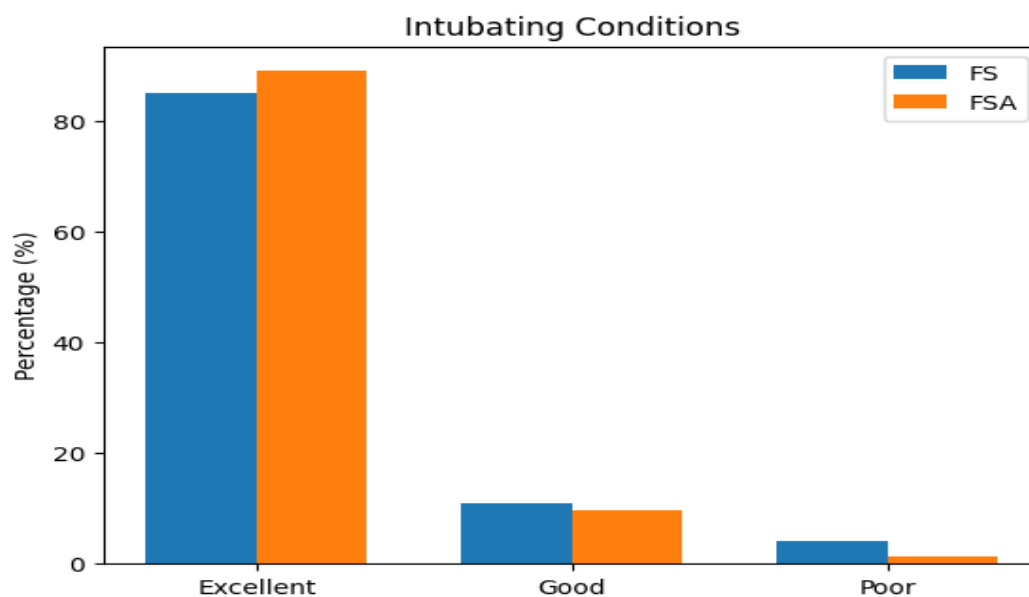


Figure 8:

Interpretation: Intubating conditions were not statistically significant in the FSA group compared with the FS group ($p=0.62$).

Discussion

The main emphasis of this study is early smooth recovery and discharge of the patient.

Cleft lip and cleft palate surgeries are commonly performed in the paediatric population and present specific anaesthetic challenges because of the age of the patients, shared airway, requirement for an unobstructed surgical field, and the need for smooth emergence from anaesthesia. In these patients, an ideal anaesthetic technique should provide satisfactory intubating conditions, adequate surgical conditions, haemodynamic stability, rapid emergence, and early postoperative recovery. These considerations become particularly important in paediatric surgical camps, where efficient anaesthetic management and early patient turnover are desirable.

Traditionally, neuromuscular blocking agents such as atracurium have been used to facilitate tracheal intubation and provide adequate muscle relaxation during cleft lip and palate surgery.

Although neuromuscular blockade provides reliable muscle relaxation, its use may increase the complexity of anaesthetic management and necessitate reversal of neuromuscular blockade before satisfactory recovery. With the introduction and widespread availability of sevoflurane, inhalational induction and maintenance of anaesthesia can be achieved with rapid changes in anaesthetic depth and relatively rapid recovery. This raises the possibility of performing selected paediatric procedures without routine administration of a muscle relaxant. The present study compared a fentanyl–sevoflurane technique

without neuromuscular blockade with a fentanyl–sevoflurane–atracurium technique in children undergoing cleft lip and cleft palate surgery. The primary focus was on the recovery profile and the possibility of achieving earlier readiness for discharge while maintaining acceptable intubating and surgical conditions.

In the present study, the intubating conditions obtained with fentanyl and sevoflurane without atracurium were [comparable to / slightly inferior to] those observed with the atracurium group. This finding is clinically relevant because satisfactory intubating conditions without administration of a neuromuscular blocking agent may simplify the anaesthetic technique in appropriately selected paediatric patients. Sevoflurane has a low blood-gas solubility coefficient, allowing rapid adjustment of anaesthetic depth and relatively rapid elimination after discontinuation. In combination with an opioid such as fentanyl, adequate anaesthetic depth and suppression of airway responses may facilitate acceptable tracheal intubation in suitable patients.

Another important consideration is the quality of the surgical field. Adequate surgical relaxation is particularly important during cleft lip and cleft palate procedures because even minor patient movement can interfere with the surgeon's work. In our study, the surgical conditions were comparable between the two groups. If comparable surgical conditions are demonstrated, this supports the feasibility of avoiding routine neuromuscular blockade in selected cases without compromising the surgical procedure.

A major finding of clinical importance in this study was the recovery profile. Patients receiving the fentanyl–sevoflurane technique demonstrated [earlier emergence / shorter time to eye opening / earlier extubation / shorter recovery time] compared with patients receiving atracurium. Early recovery is particularly advantageous in paediatric patients because prolonged residual effects of anaesthetic and neuromuscular blocking drugs may delay return to normal activity and increase the duration of postoperative observation. Avoidance of a neuromuscular blocking agent and the consequent requirement for pharmacological reversal may contribute to a simpler and potentially faster recovery pathway.

The possibility of earlier discharge is particularly relevant in paediatric surgical camps. In a high-volume camp setting, rapid and predictable recovery allows efficient utilization of operating-room and recovery-room resources and facilitates earlier turnover of patients. A technique that provides adequate anaesthesia while allowing early recovery may therefore be advantageous from both clinical and logistical perspectives.

Haemodynamic parameters were also evaluated in the present study. e.g., “Heart rate and mean arterial pressure remained within clinically acceptable limits in both groups, with no statistically significant difference between the groups. Maintenance of stable haemodynamic is important in paediatric patients, particularly during induction, laryngoscopy, intubation, and emergence.

From a practical perspective, avoiding atracurium may simplify drug administration and reduce the need for neuromuscular monitoring and reversal, depending on the institutional protocol and clinical circumstances. This may also have cost implications. In resource-limited settings and paediatric surgical camps, even small reductions in drug use, equipment requirements, recovery-room occupancy, and postoperative observation time can contribute to overall cost-effectiveness. However, the economic benefit should be interpreted in relation to the actual drug, equipment, staffing, and recovery-room costs at each institution.

It is important to emphasize that avoidance of neuromuscular blockade should not be considered appropriate for every paediatric patient or every cleft surgery. Patient selection, airway characteristics, depth of anaesthesia, surgical requirements, and the anticipated duration and complexity of the procedure must be considered. A neuromuscular blocking agent should remain readily available whenever clinically indicated. Thus, the present technique may be considered as an alternative approach in appropriately selected patients rather than a universal replacement for

neuromuscular blockade. Overall, the findings of the present study suggest that a fentanyl–sevoflurane technique without atracurium may provide acceptable anaesthetic and surgical conditions while offering the potential advantage of faster emergence and earlier postoperative recovery. This may make the technique particularly attractive in paediatric cleft surgery performed in high-volume or surgical-camp settings, where safe anaesthesia, efficient recovery, early discharge, and cost-conscious practice are important considerations.

Conclusion

The present study suggests that fentanyl–sevoflurane anaesthesia without routine neuromuscular blockade can be a feasible alternative to fentanyl–sevoflurane–atracurium anaesthesia for selected paediatric patients undergoing cleft lip and cleft palate surgery.

When adequate intubating and surgical conditions are achieved, avoidance of atracurium may facilitate a simpler anaesthetic technique and contribute to faster emergence and postoperative recovery. The potential for earlier discharge is particularly relevant in paediatric surgical camps, where efficient patient turnover, reduced recovery-room occupancy, and cost-effective anaesthetic management are important.

Thus, a sevoflurane-based technique without routine muscle relaxation may offer a useful approach for appropriately selected paediatric cleft surgery patients, provided that adequate anaesthetic depth, airway management, and surgical conditions can be maintained. Larger studies with standardized recovery and discharge endpoints are required to further establish its safety, efficacy, and cost-effectiveness.

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