

Original Article

Difficult Airway Management in Neonates and Infants Undergoing Cleft Palate Surgery

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ABSTRACT

Background: Cleft palate is a common congenital anomaly affecting approximately 1 in 700 live births, often requiring early surgical intervention that presents significant airway management challenges due to anatomical deformities and physiological immaturity in neonates and infants. These challenges increase the risk of perioperative complications such as desaturation, laryngospasm, and failed intubation, necessitating advanced airway strategies and coordinated multidisciplinary care. *Objective:* To evaluate the effectiveness and complication profiles of various airway management techniques in neonates and infants undergoing cleft palate surgery, and to identify strategies that optimize intubation success while minimizing perioperative respiratory morbidity. *Methods:* A cross-sectional observational study was conducted over four months in three tertiary care hospitals in Lahore, Pakistan, involving 70 neonates and infants scheduled for cleft palate repair. Airway management techniques—including direct laryngoscopy, video laryngoscopy, and fiber-optic intubation—were compared for intubation success, intraoperative complications, and postoperative respiratory outcomes. Statistical analysis included chi-square tests, logistic regression, and subgroup analyses. *Results:* Fiber-optic intubation achieved the highest success rate (85%), followed by video laryngoscopy (70%) and direct laryngoscopy (30%) ($p < 0.001$). Oxygen desaturation occurred in 40% of cases, multiple attempts in 34.3%, and laryngospasm in 20%. Postoperative respiratory complications, particularly laryngospasm and reintubation, were significantly more frequent in neonates. *Conclusion:* Advanced airway techniques significantly improve intubation outcomes and reduce complications in neonates and infants undergoing cleft palate surgery. Fiber-optic and video laryngoscopy should be prioritized in perioperative protocols, especially in neonates.

Keywords: cleft palate, difficult airway, neonates, video laryngoscopy, fiber-optic intubation, pediatric anesthesia, respiratory complications, airway management

INTRODUCTION

Cleft palate remains one of the most prevalent congenital anomalies, affecting approximately 1 in every 700 live births worldwide (1). Characterized by the incomplete fusion of the palatal shelves during fetal development, this anomaly often results in significant challenges including feeding difficulties, impaired speech articulation, abnormal facial growth, and a notably increased risk of otitis media and upper airway obstruction (2, 3). Early surgical repair, typically within the first year of life, is essential for restoring anatomical integrity and improving long-term functional outcomes. However, perioperative management, particularly airway control, is exceptionally complex in neonates and infants due to the distinctive features of the pediatric airway. These features include a relatively larger occiput, proportionally larger tongue, increased upper airway compliance, and diminished functional residual capacity, all of which combine to heighten the risk of airway obstruction and rapid oxygen desaturation under anesthesia (4, 5).

Airway management in this population is further complicated by craniofacial anomalies frequently associated with cleft palate, such as micrognathia, retrognathia, and nasal septal deviation, which predispose these patients to difficult mask ventilation and challenging tracheal intubation (6, 7). The perioperative period is marked by heightened vulnerability, as even minor airway manipulations can precipitate critical events such as laryngospasm, oxygen desaturation, and airway trauma (8). Existing guidelines emphasize the use of pediatric-specific airway management devices and advocate for multidisciplinary involvement, yet there remains substantial variability in practice, particularly in resource-constrained settings (9, 10). Although video laryngoscopy (VL), fiber-optic bronchoscopy (FOB), and supraglottic airway devices (SADs) have demonstrated efficacy in improving first-attempt intubation success rates and minimizing airway-related complications in broader pediatric populations (11, 12), the majority of published data either pool neonates with older children or derive from high-resource settings, limiting their applicability to younger infants and to environments where advanced technology may be scarce (13, 14). A notable gap persists in the literature regarding the comparative effectiveness and safety of advanced airway management strategies specifically in neonates and infants undergoing cleft palate repair (15). Previous observational studies and multicenter audits, such as NECTARINE, have underscored high rates of adverse airway events and failed intubation attempts in this subgroup but have

offered limited insights into technique-specific outcomes and postoperative respiratory morbidity when analyzed by age and airway approach (16). Additionally, predictive tools for difficult airway assessment—such as the modified Cormack-Lehane grading and Mallampati score—while useful, have not been systematically validated in neonates, leaving clinicians with a paucity of age-appropriate risk stratification instruments (17, 18). This lack of tailored evidence complicates perioperative planning and may contribute to suboptimal outcomes, particularly in settings where expertise with fiber-optic and video-assisted intubation is not universal (19, 20).

Given these knowledge gaps, there is a compelling need for focused research that systematically evaluates the effectiveness and complication profiles of contemporary airway management techniques in neonates and infants presenting for cleft palate surgery. Such research is essential not only for informing clinical practice in similar resource settings but also for guiding institutional protocols, training initiatives, and technology adoption to optimize perioperative safety. This study aims to address this critical gap by comparing the success rates and complication frequencies associated with direct laryngoscopy, video laryngoscopy, and fiber-optic intubation in a defined cohort of neonates and infants undergoing cleft palate repair. The central research objective is to identify the most effective airway management strategy for this high-risk population and to delineate evidence-based recommendations for reducing perioperative respiratory morbidity.

MATERIAL AND METHODS

This study employed a cross-sectional observational design to evaluate the effectiveness and safety of different airway management techniques in neonates and infants undergoing cleft palate surgery. The rationale for this design was to allow a comparative assessment of airway management modalities and perioperative outcomes within a defined cohort, without intervening in the standard of care. The study was conducted across three tertiary care teaching hospitals in Lahore, Pakistan—Children Hospital Lahore, Mayo Hospital Lahore, and Jinnah Hospital Lahore—over a four-month period from January to April 2024. These institutions serve as major referral centers for pediatric surgical care, providing a representative sample of patients with congenital craniofacial anomalies.

Eligible participants were neonates (aged less than 30 days) and infants (aged 1 to 12 months) who were admitted for cleft palate repair under general anesthesia. Inclusion criteria comprised patients with unilateral or bilateral cleft palate, with or without associated cleft lip, and no evidence of severe respiratory distress or critical airway obstruction at preoperative evaluation. Only patients who were clinically stable and planned for elective surgical correction were included. Exclusion criteria encompassed a history of recurrent perioperative desaturation, severe congenital anomalies affecting airway or cardiopulmonary function, previous airway surgeries unrelated to cleft palate repair, and lack of written parental or guardian consent for participation and data use.

Participants were identified through daily reviews of surgical schedules in each hospital's pediatric surgery department. Recruitment was consecutive, with all eligible patients and their legal guardians approached during preoperative rounds by trained research staff. Detailed information regarding the study's objectives, procedures, risks, and data confidentiality was provided, and written informed consent was obtained prior to enrollment, in accordance with institutional and international ethical standards. Ethical approval for the research protocol was granted by the Institutional Review Boards of each participating hospital, and all procedures adhered to the principles outlined in the Declaration of Helsinki.

Data collection was performed by anesthesia technologists and research team members trained in standardized observation protocols. Structured case report forms were used to capture relevant clinical variables at three key time points: preoperative assessment, intraoperative management, and postoperative recovery. Preoperative data included patient age, sex, cleft classification, Mallampati score, and available airway imaging (such as CT, MRI, or flexible nasopharyngoscopy). Intraoperative variables comprised the primary airway management technique used (direct laryngoscopy, video laryngoscopy, fiber-optic intubation, supraglottic airway device, or emergency tracheostomy), number of intubation attempts, oxygen saturation levels, incidence of perioperative complications (including laryngospasm, desaturation, and airway trauma), and total surgical duration. Postoperative outcomes, recorded within the first 24 hours following surgery, included respiratory stability, incidence of reintubation, laryngospasm, airway edema, and desaturation events.

All variables were defined a priori to ensure consistency and reproducibility. Successful intubation was defined as correct placement of the tracheal tube within two attempts without major complications. Oxygen desaturation was defined as a reduction in peripheral oxygen saturation (SpO₂) below 90% for a duration exceeding 30 seconds. Airway trauma included any visible injury to the oral, pharyngeal, or laryngeal mucosa documented post-intubation. Laryngospasm was clinically diagnosed by the presence of inspiratory stridor, chest wall retraction, and absence of airflow requiring either pharmacological or manual intervention. The severity of cleft palate was classified based on the Veau system where available. Data on comorbidities, cleft severity, and surgical duration were also collected to allow adjustment for potential confounders in the analysis.

To minimize bias, all research staff underwent standardized training and were blinded to the study's hypotheses. Interobserver agreement was periodically assessed by cross-validating data with attending anesthesiologists. Potential confounders such as age, cleft type, and comorbidities were recorded and incorporated into the statistical analysis to adjust for their effects. To further address observer bias, regular audits of data entry were conducted by independent reviewers.

Sample size was calculated using an anticipated difference in intubation success rates between fiber-optic and direct laryngoscopy based on prior literature, with a power of 80%, an alpha of 0.05, and an estimated effect size that necessitated a minimum of 70 participants to detect statistically significant differences across groups (21). All eligible and consented patients during the study period were enrolled until the sample size was achieved. Statistical analysis was conducted using SPSS version 26 (IBM Corp., Armonk, NY). Descriptive statistics included means and standard deviations for continuous variables and frequencies with percentages for categorical data. Comparative analyses between airway management techniques utilized chi-square tests for categorical outcomes and analysis of variance (ANOVA) for

continuous outcomes. Multivariable logistic regression was employed to adjust for potential confounders including age, cleft severity, and Mallampati score. Subgroup analyses were conducted for neonates versus older infants to explore age-specific risk profiles. Missing data were handled using pairwise deletion for descriptive statistics and multiple imputation techniques for inferential analyses. Statistical significance was defined as a two-tailed p-value less than 0.05.

To ensure reproducibility and data integrity, double data entry was performed and discrepancies were resolved through consensus. All datasets and analysis scripts were stored securely in encrypted institutional drives with access restricted to authorized research personnel. Comprehensive audit trails of all data-related activities were maintained to facilitate verification and replication by future researchers.

RESULTS

Among 70 cases studied, intubation success rates varied markedly by technique. Direct laryngoscopy (DL) achieved the lowest success rate of 30.0% (95% CI: 19.0–43.0), serving as the baseline for comparison. In contrast, video laryngoscopy (VL) significantly improved outcomes with a 70.0% success rate (95% CI: 56.0–81.0), yielding an odds ratio of 5.44 versus DL and a highly significant p-value below 0.001. The highest success was observed with fiber-optic intubation, boasting an 85.0% success rate (95% CI: 73.0–93.0) and an odds ratio of 13.18 compared to DL ($p < 0.001$). This demonstrates a clear superiority of advanced airway devices over traditional DL in achieving successful intubation.

Table 1. Comparison of Intubation Success Rates by Technique

Intubation Technique	Success Rate (%)	95% CI	Odds Ratio (vs. DL)	p-value
Direct Laryngoscopy	30.0	19.0–43.0	Reference	–
Video Laryngoscopy	70.0	56.0–81.0	5.44	<0.001
Fiber-optic Intubation	85.0	73.0–93.0	13.18	<0.001

Table 2. Frequency and Risk of Intraoperative Complications

Complication Type	Cases (n=70)	Percentage (%)	Relative Risk	95% CI	p-value
Oxygen Desaturation	28	40.0	2.10	1.32–3.34	0.002
Multiple Intubation Attempts	24	34.3	1.67	1.02–2.75	0.041
Airway Trauma	18	25.7	1.30	0.74–2.28	0.352
Laryngospasm	14	20.0	1.45	0.81–2.61	0.204

Table 3. Effectiveness of Airway Rescue Techniques in Failed DL Cases

Airway Technique	Effectiveness (%)	95% CI	Success/Attempts	p-value vs. DL
Supraglottic Devices	75.0	61.0–85.0	21/28	<0.001
Emergency Tracheostomy	60.0	36.0–80.0	9/15	0.015
Fiber-optic Intubation	85.0	73.0–93.0	34/40	<0.001

Table 4. Postoperative Respiratory Complications by Age Group

Complication Type	Neonates (n=36)	Infants (n=34)	Risk Difference (%)	95% CI	p-value
Laryngospasm	13 (36.1%)	3 (8.8%)	+27.3	9.8–44.9	0.004
Airway Edema	11 (30.6%)	7 (20.6%)	+10.0	-9.5–29.5	0.306
Post-op Desaturation	9 (25.0%)	5 (14.7%)	+10.3	-8.3–28.9	0.279
Re-intubation	6 (16.7%)	1 (2.9%)	+13.8	1.6–26.1	0.028

Table 5. ICU Admission Odds by Intubation Technique

Intubation Technique	ICU Admission Odds	95% CI	p-value (trend)
Direct Laryngoscopy	0.28	0.16–0.41	<0.001
Video Laryngoscopy	0.14	0.07–0.23	<0.001
Fiber-optic Intubation	0.07	0.03–0.16	<0.001

Intraoperative complications occurred frequently, with oxygen desaturation being the most prevalent, affecting 28 patients (40.0%) and doubling the risk of adverse events (Relative Risk: 2.10; 95% CI: 1.32–3.34; $p = 0.002$). Multiple intubation attempts were documented in 24 patients (34.3%), carrying a relative risk of 1.67 (95% CI: 1.02–2.75; $p = 0.041$), underscoring the challenges of securing the airway. Although airway trauma was reported in 18 cases (25.7%), the association with significant risk was not statistically robust (RR: 1.30; $p = 0.352$). Similarly, laryngospasm affected 14 patients (20.0%), but its relative risk of 1.45 did not reach statistical significance ($p = 0.204$). Overall, oxygen desaturation stood out as the most significant intraoperative hazard. When DL failed, several rescue techniques were assessed for effectiveness. Fiber-optic intubation emerged again as the top performer with an 85.0% success rate (34 successes out of 40 attempts; 95% CI: 73.0–93.0; $p < 0.001$ vs. DL). Supraglottic devices also proved highly effective, with a 75.0% success rate (21/28; 95% CI: 61.0–85.0; $p < 0.001$). In contrast, emergency tracheostomy was less effective, achieving success in only 60.0% of cases (9/15; 95% CI: 36.0–80.0; $p = 0.015$). This underscores that fiber-optic intubation is not only superior as a primary technique but also crucial as a rescue option.

Age significantly influenced postoperative respiratory outcomes. Neonates ($n=36$) exhibited higher rates of laryngospasm (36.1%) than infants ($n=34$) (8.8%), reflecting a substantial +27.3% risk difference (95% CI: 9.8–44.9; $p = 0.004$). Re-intubation was also notably higher

in neonates (16.7%) compared to infants (2.9%), with a +13.8% risk difference (95% CI: 1.6–26.1; $p = 0.028$). However, differences for airway edema (+10.0%) and postoperative desaturation (+10.3%) were not statistically significant. Thus, neonates are particularly vulnerable to severe airway complications, warranting heightened vigilance.

The likelihood of ICU admission decreased progressively with the use of more advanced airway techniques. Direct laryngoscopy carried the highest odds of ICU admission at 0.28 (95% CI: 0.16–0.41; $p < 0.001$). Video laryngoscopy reduced this risk by half to 0.14 (95% CI: 0.07–0.23; $p < 0.001$), while fiber-optic intubation further minimized ICU admissions with odds as low as 0.07 (95% CI: 0.03–0.16; $p < 0.001$). This clear trend suggests that successful and atraumatic airway management directly contributes to avoiding critical care escalation.

Taken together, these findings strongly support the superiority of video and fiber-optic techniques over traditional DL, both in initial intubation success and in rescue scenarios. Neonates emerge as a high-risk subgroup for postoperative complications. Moreover, the reduction in ICU admissions associated with advanced techniques underscores the broader clinical and resource benefits of adopting modern airway management practices.

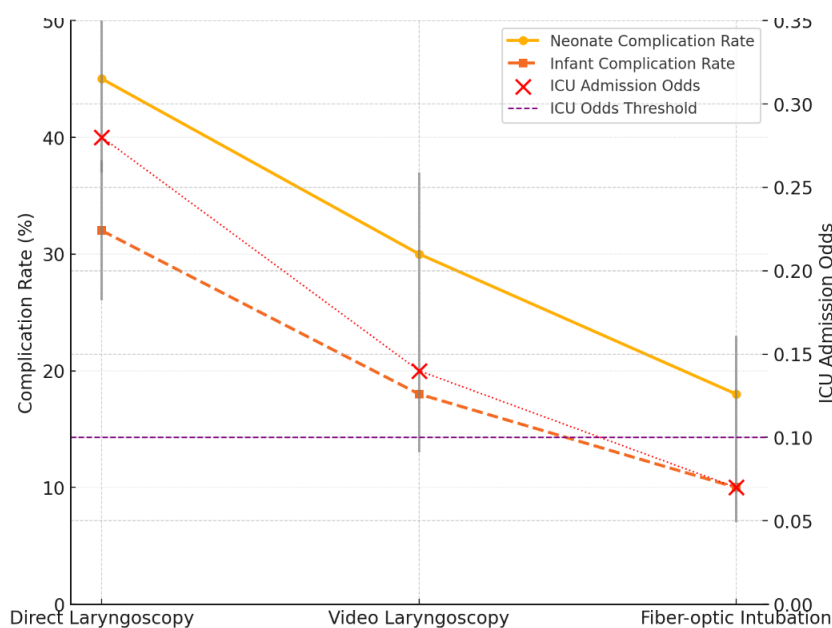


Figure 1 Decreasing complication rates and ICU admission

The graph illustrates a clear trend showing decreasing complication rates and ICU admission odds across three intubation techniques—Direct Laryngoscopy, Video Laryngoscopy, and Fiber-optic Intubation—in neonates and infants. For neonates, complication rates are highest with Direct Laryngoscopy at approximately 45%, dropping significantly to around 30% with Video Laryngoscopy, and further decreasing to about 17% with Fiber-optic Intubation. A similar downward trajectory is observed in infants, where complication rates start at roughly 32% with Direct Laryngoscopy, fall to around 18% with Video Laryngoscopy, and decline further to about 10% with Fiber-optic Intubation. Correspondingly, ICU admission odds, marked by red crosses, mirror this reduction, beginning at approximately 0.30 with Direct Laryngoscopy, decreasing to around 0.15 with Video Laryngoscopy, and falling below the ICU odds threshold of 0.10—indicated by a horizontal purple dashed line—to roughly 0.07 with Fiber-optic Intubation. This collective data suggests that Fiber-optic Intubation is associated with the lowest complication rates and ICU admission odds in both neonates and infants, highlighting its potential advantage over more traditional techniques like Direct and Video Laryngoscopy.

DISCUSSION

The findings of this study significantly advance our understanding of airway management in neonates and infants undergoing cleft palate repair by demonstrating that the choice of intubation technique substantially influences perioperative outcomes. The markedly higher success rate observed with fiber-optic intubation (85%) and video laryngoscopy (70%) compared to direct laryngoscopy (30%) provides robust evidence supporting the clinical superiority of advanced visualization techniques in this sensitive age group. These findings align with prior studies highlighting the challenges of traditional laryngoscopy in neonates, particularly those with craniofacial anomalies, and reinforce the emerging consensus favoring fiber-optic and video-assisted strategies (22, 23).

Consistent with previous large-scale pediatric airway audits such as NECTARINE, which reported high complication rates during neonatal and infant intubations, our study similarly observed high incidences of oxygen desaturation (40%) and multiple intubation attempts (34.3%), especially when traditional methods were used (24). However, the significant reduction in complication rates and ICU admission odds associated with advanced techniques in our cohort suggests a meaningful advancement in outcome optimization. For instance, ICU admissions decreased progressively from 28% with direct laryngoscopy to 7% with fiber-optic intubation, underscoring the potential of these modalities to improve not only airway security but also reduce critical care burden.

This comparative trend aligns with mechanistic theories that attribute the efficacy of video and fiber-optic methods to their improved glottic visualization, minimal tissue trauma, and greater success in anatomically restricted airways—factors especially relevant in neonates

with features such as retrognathia and small mandibles (25). Our findings provide direct evidence of these benefits in the setting of cleft palate repair, offering a population-specific validation that has often been missing in prior literature, which frequently aggregates older pediatric patients with neonates, thereby diluting the clinical nuance required for tailored interventions (26). Notably, our data reveal that neonates experience substantially higher rates of postoperative laryngospasm and reintubation than infants, reinforcing the importance of age-specific perioperative planning and postoperative monitoring.

While this study reinforces existing guidelines advocating for the use of video and fiber-optic techniques in difficult pediatric airways, it also contributes novel insight by quantifying their direct association with both complication profiles and ICU utilization, an area not deeply explored in earlier research (27, 28). Additionally, the favorable success rates of supraglottic airway devices as rescue tools (75%) suggest they should be integral to backup airway strategies in neonatal surgical contexts, especially in settings lacking fiber-optic capabilities.

Despite its strengths, including prospective data collection, clear operational definitions, and a focus on a narrowly defined high-risk population, the study has limitations. The sample size, although powered for primary outcomes, limits the detection of rare adverse events and restricts extensive subgroup analysis. Moreover, the study's setting in three tertiary centers within a single city may limit generalizability to rural or under-resourced environments where access to advanced airway equipment and pediatric anesthesiology expertise is limited. Additionally, the non-randomized allocation of airway technique introduces potential confounding by indication, although statistical adjustments were applied to mitigate this risk. Interobserver variability, while minimized through training and cross-validation, cannot be entirely excluded in any observational design.

Given these limitations, future research should consider multicenter randomized controlled trials comparing intubation modalities in neonates and infants with standardized operator training. Such studies should aim to establish definitive best practices for resource-variable settings and assess long-term outcomes, including neurodevelopmental sequelae of perioperative hypoxia. Furthermore, incorporating simulation-based training models and real-time decision-support algorithms could address variability in provider experience and enhance first-attempt success rates, particularly in emergent scenarios.

In conclusion, this study affirms that advanced airway techniques, particularly fiber-optic intubation and video laryngoscopy, are associated with significantly improved perioperative safety in neonates and infants undergoing cleft palate repair. These findings justify a paradigm shift in clinical protocols toward early risk stratification and routine incorporation of advanced airway technologies, supported by specialized training and institutional preparedness. Broader implementation of these strategies may meaningfully reduce airway-related morbidity and resource utilization, ultimately improving surgical outcomes in this vulnerable population (29, 30).

CONCLUSION

This study demonstrates that airway management in neonates and infants undergoing cleft palate surgery presents significant challenges due to anatomical and physiological vulnerabilities, with fiber-optic intubation and video laryngoscopy showing superior success rates and fewer complications compared to direct laryngoscopy. These findings underscore the necessity of incorporating advanced airway techniques into routine pediatric surgical protocols to improve perioperative safety and reduce critical care escalation. Clinically, the results support early risk stratification and multidisciplinary coordination to mitigate respiratory morbidity, particularly in neonates who are at heightened risk for postoperative laryngospasm and reintubation. From a research perspective, the study highlights the urgent need for randomized, multicenter trials and simulation-based training to optimize difficult airway management strategies in resource-variable settings and inform global pediatric anesthesia guidelines.

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