IMPACT OF VARIOUS AIRWAY DEVICES USED IN INFANTS UNDER GENERAL ANAESTHESIA ON PERIOPERATIVE RESPIRATORY COMPLICATIONS:

A PROSPECTIVE OBSERVATIONAL STUDY

THESIS

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DECLARATION

I hereby declare that the thesis titled **"Impact of various airway devices used in infants under general anaesthesia on perioperative respiratory complications: a prospective observational study"** embodies the original work carried out by me at All India Institute of Medical Sciences, Jodhpur.

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CERTIFICATE

This is to certify that the thesis titled "**Impact of various airway devices used in infants under general anaesthesia on perioperative respiratory complications: a prospective observational study**" is the bonafide work of Dr. P SACHITH RAJU carried out under our guidance and supervision, in the Department of Anaesthesiology and Critical Care, All India Institute of Medical Sciences, Jodhpur.

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Dr. P SACHITH RAJU

Dedicated To My Patients,

Teachers, Family

&

My Friends…

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LIST OF ABBREVIATIONS

Abbreviation	Full Form
ASA	American Society of Anesthesiologists
ETT	Endotracheal Tube
LMA	Laryngeal Mask Airway
PRAE	Perioperative Respiratory Adverse Events
SGA	Supra Glottic Airway
pLMA	Proseal Laryngeal Mask Airway
cLMA	Classic Laryngeal Mask Airway
URTI	Upper Respiratory Tract Infection
RCT	Randomised Control Trail
RR	Relative Risk
CI	Confidence Interval
OR	Odds Ratio
IQR	Inter Quartile Range
KG	Kilo Gram
Ml	Milli Liters
ENT	Ear Nose and Throat
n	Number of cases
FRC	Functional Residual Capacity
$\mathbf{X^2}$	Chi Square

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SUMMARY

Background: The most common critical incidents in paediatric anaesthesia are perioperative respiratory complications, which occur more frequently in infants. In older children (>1 year), using supraglottic airway devices is associated with fewer perioperative respiratory complications than using endotracheal tubes. The purpose of this study was to see how ETT, Ambu aura, Proseal, and i-gel affected the incidence of perioperative respiratory complications in infants and neonates.

Material and Methods: A total of 150 patients of either gender, belonging to ASA physical status 1 to 3, aged less than 1year, scheduled to undergo surgical or diagnostic procedure under general anaesthesia were included in the study. Anaesthesia management including type of induction, use of muscle relaxant, and airway device selection for airway management was left to the discretion of the anaesthesiologist in charge. Type of the airway device used was noted (cuffed/non-cuffed ETT, type of cuff, type of supraglottic airway: i-gel, Proseal, Ambu Aura used). Occurrence of any respiratory complication and its timing, right from insertion to the postoperative period, was recorded. These events include complications like laryngospasm, bronchospasm, desaturation, aspiration, blood staining of the device, postextubation croup. Number of attempts of the airway device placement, improper placement requiring re-insertion or adjustment of the airway device, leak, and patient position during the surgery (supine, lithotomy, lateral, prone) was documented. Primary outcome of the study was to compare the incidences of perioperative respiratory complications with the use of ETT, Ambu aura, Proseal and i-gel in infants under general anaesthesia. Secondary outcome was to find out the most commonly used airway devices during different types of surgeries particularly during thoracotomies, head and neck surgeries, laparoscopic surgeries and in lithotomy, lateral, prone positions.

Results: Out of 150 patients, 79 patients underwent surgical and diagnostic procedures under general anaesthesia received ETT whereas 22 patients received Ambu Aura, 22 patients received Proseal, and 27 patients received i-gel. Intraoperative respiratory complications in infants receiving ETT, Ambu aura, Proseal, and i-gel were not statistically significant (p=0.324). The infants who received ETT, Ambu aura, Proseal, and i-gel did not experience any instances of intra-operative laryngospasm. In contrast to the other study groups, post-operative laryngospasm occurred in 8 (10.13%) of the infants who underwent ETT, however this proportion of laryngospasm was not statistically significant (p=0.072). Bronchospasm episodes occurred intraoperatively in 3 of the infants (3.8%) who received ETT but not in the infants who received Ambu Aura, Proseal, or i-gel, and there was no statistically significant difference between the study groups (p=0.587). Patients who received Proseal and I gel had no complications, whereas patients who received Ambu aura and ETT had post-operative respiratory complications in 1 (4.55%) and 17 (21.52%), respectively. Post-operative oxygen requirement is the most significant respiratory complication in 20 (25.32%) of the patients who received ETT, which is statistically significant (p=0.005) when compared to other study groups (Ambu Aura, i-gel and Proseal).

Conclusion: It was found that ETT has greater incidence of post-operative respiratory complications than Ambu Aura, i-gel, and Proseal. In comparison to other study groups, oxygen supplementation was required in more number of patients in ETT group. Supraglottic airway devices such as Ambu Aura, Proseal, and i-gel are safe to use in neonates and infants undergoing surgical and diagnostic procedures under general anaesthesia.

INTRODUCTION

Among all patients who undergo sedation or anaesthesia for diagnostic and therapeutic purposes, the paediatric population has the highest risk and the lowest error of tolerance. Airway management is the most important aspect of paediatric anaesthesia. Children's airways expand and change as they grow. They differ from adult airways in several ways, including their narrower size and increased risk of swelling, which may increase airway resistance in a child who is breathing on their own after surgery.

Despite advancements in infant airway care over time, paediatric anesthesiologists continue to face challenges as a result of the distinct anatomical and physiological differences in newborns. Infant airways are more vulnerable to significant respiratory complications after surgery[1–3]. Recent respiratory tract infections, passive smoking, and a history of asthma are well-known risk factors for perioperative respiratory issues because they make airways more vulnerable[4] [5] up to 27% of perioperative cardiac arrests may be caused by respiratory complications. Aspiration, esophageal intubation, and difficult intubation are all major issues, laryngospasm is the most common respiratory cause of cardiac arrest [6]

Infant airways are managed using a variety of airway devices. Because of the risk of overinflated cuffs causing pressure necrosis of the airway mucosa, uncuffed tracheal tubes were previously used. Cuffed tubes were only advised for children over the age of eight. Uncuffed tubes frequently result in leaks, aspirations, and inhalational agent contamination of operating rooms. Cuffed and micro cuff tubes are being used in babies more frequently due to a better understanding of the infant's airway architecture.

Since Archie brain's invention of the LMA in 1981, a variety of supraglottic airways have become more widely used in the management of infant airways, including standard LMA, i-gel, Ambu Aura, and Proseal LMA. According to a study conducted by the association of paediatric anaesthetists of Great Britain and Ireland, supra glottic airway is used in more than 50% of infants undergoing general anaesthesia procedures in the United Kingdom[7]. Although they have a high rate of malpositioning and dislodgement, they are less invasive and can be used for a wide range of procedures.

Many studies have been conducted to compare the perioperative respiratory complications in paediatric patients when using endotracheal tubes and laryngeal mask airways, but none have specifically looked at the perioperative respiratory complications experienced by infants and neonates when using ETT, Ambu Aura, Proseal, and i-gel.

There are several supraglottic airway devices on the market; we used ET tube, Ambu Aura, Proseal, and i-gel because they are commonly used.

Pediatric respiratory adverse events are typically caused by the respiratory system's reaction to mechanical or pharmacological stimulation during surgery [2]. Common stimulants include aspiration, assisted ventilation, and nociception. Furthermore, it has been demonstrated that respiratory illnesses within the previous two weeks impair airway responsiveness[1].

Several studies have been conducted to determine the incidence of perioperative respiratory issues in infants and patient-related risk factors for these perioperative respiratory issues. More research is needed, however, to determine how different airway devices used to maintain newborns' airways affect perioperative respiratory complications.

AIMS AND OBJECVTIVES

Aim

Impact of various airway devices (ETT/i-Gel/Proseal/Ambu Aura) used in infants under general anaesthesia on perioperative respiratory complications.

Primary objective

To find out and compare the incidences of perioperative respiratory complications with use of various airway devices like ETT, i-gel, Proseal and Ambu Aura in infants under general anaesthesia.

Secondary objectives

To find out the most commonly used airway devices during different types of surgeries' particularly during

A) Thoracotomies

B) Head and neck surgeries

C) Laparoscopic surgeries

D) Devices used in lithotomy/lateral/prone position.

REVIEW OF LITERATURE

The invention of the laryngeal mask airway came in a time when tracheal intubation wasn't necessary for hands-free airway maintenance. Some attempt to offer an acceptable seal for positive pressure ventilation while others aim to provide an appropriate seal while lying outside the trachea. Supraglottic airway devices are the name given to all of these devices. With these devices, primary airway control can be achieved**.**

1. **i-gel:** The i-gel airway is a single use supraglottic airway that uses an anatomically designed mask to fit the perilaryngeal and hypopharyngeal structures. It has an integrated bite block and gastric port which allows direct suctioning or passage of a gastric tube**.**

Figure 1: i-gel

2. **Proseal:** The Proseal LMA has an inflatable cuff that extends onto the back of the device to improve the seal, as well as a gastric drain tube with an opening

at the tip designed to allow the passage of an orogastric tube. It has a built-in bite block and a prefabricated metal introducer to aid in insertion.

Figure 2: Proseal

3. **Ambu Aura:** Ambu Aura is an anatomically curved, single use second generation supraglottic airway device. It incorporates a gastric channel to allow drainage of gastric contents and the insertion of gastric tube. It has an inflatable cuff and high seal pressures can be achieved during positive pressure ventilation.

Figure 3: Ambu Aura

Endotracheal Tube: It provides a means of securing the patients airway, allowing spontaneous and controlled ventilation while reducing the risk of aspiration. It is the gold standard definitive airway. It is made of polyvinyl chloride which is clear and transparent. In infants micro cuff ETT was used as it reduces the risk of mucosal ischemia, it has modified short tip which reduces the risk of endobronchial intubation and a polyurethane cuff, it inflates and seals at lower pressures.

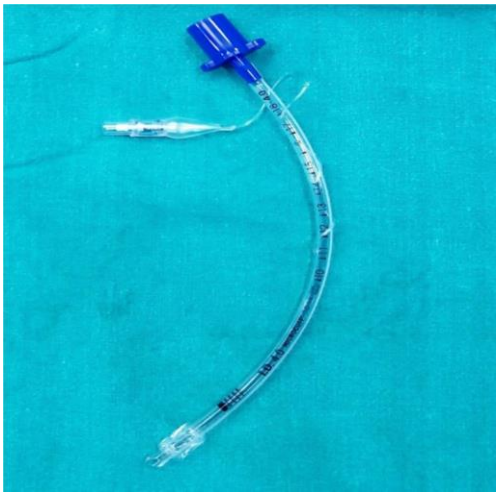

Figure 4: Micro cuff ET tube

Li L et al [8] found 12 RCT'S with a total of 1577 participants. In comparison to other airways, significant reductions in severe perioperative respiratory adverse events (RR 0.47, 95% CI 0.29-0.79; P = 0.004), minor PRAE (RR 0.57, 95% CI 0.45-0.74; P 0.0001), and total PRAE (RR 0.52, 95% CI 0.39-0.70; P 0.0001) were identified in patients managed with LMA's. LMA's considerably reduced PRAE in comparison to endotracheal tubes . Further research revealed that LMA's decreased the occurrences of postoperative cough, pulmonary rales, and infections in kids (RR 0.28, 95% CI 0.13-0.61, P = 0.001, RR 0.44, 95% CI 0.31-0.63, P 0.00001 each).

Engelhardt T et al [9] did a secondary analysis of the European multicenter observational trial (Anaesthesia practice in Children Observational Trial, APRICOT) of children from birth to 15 years of age of the airway and respiratory management data. Analysis was possible for the details of 31,024 anaesthetic procedures. In 120 children (0.9%) and 40 children (0.4%), tracheal intubation required three or more tries, respectively. Failure to intubate the trachea and failure to place the supraglottic airway in children occurred in 8/10 000 (0.08%; 0.03-0.13%) and 8.2/10 000 (0.08%; 0.03-0.14%) children, respectively, according to the incidence (95% confidence interval). Tracheal tube (2.1; 1.3-3.4) and supraglottic airway (4.3; 1.9-9.9) placements were more likely to result in a critical respiratory episode if the airway was difficult to secure. It was significantly associated with having a history of respiratory risk factors.

De Carvalho ALR et al [10] carried out a systematic review following the guidelines of the Cochrane Handbook and Preferred Reporting Items for Systematic Reviews and Meta-analyses . Only randomized clinical trials examining anaesthesia in kids who had a URTI and were given any of the breathing devices were included. 5 randomized clinical trials were included in the final analysis out of the 1030 studies that were found. There were no statistically significant differences between laryngeal mask airway (LMA®) and endotracheal tube (ETT) for breath holding or apnea (risk ratio [RR], 0.82; 95% confidence interval [CI], 0.41-1.65), laryngospasm (RR, 0.74; 95% CI, 0.18-2.95), and arterial oxygen desaturation (RR, 0.44; 95% CI, 0.16-1.17).

Drake-Brockman TFE et al [11] in an RCT titled "The Effect of Endotracheal Tubes versus Laryngeal Mask Airways on Perioperative Respiratory Adverse Events in Infants," discovered that 239 infants were evaluated and 181 eligible infants were

randomly assigned to receive either an LMA (n=85) or an endotracheal tube (n=95). The analysis did not include four newborns (two due to cancelled procedures, one did not meet inclusion criteria, and one with missing dataset). In the analysis with the intention to treat, 15 (18%) infants in the LMA group and 50 (53%) infants with endotracheal tubes both experienced PRAE (risk ratio [RR] 2.94, 95% CI 1.79-4.83, p0.0001). 18 (19%) infants in the endotracheal tube group and three (4%) infants in the LMA group experienced laryngospasm and bronchospasm (major PRAE) (RR 5.30, 95% CI 1.62-17.35, p=0.002). No deaths were noted.

Kleine-Brueggeney M et al [12] conducted a prospective observational study at Bern University Hospital in Switzerland. The three paediatric supraglottic airway devices listed below were evaluated: The Ambu Aura-i, Air-Q, and LMA Supreme are three examples. The mean airway leak pressures varied significantly between devices [LMA supreme 18.0 (3.4) cmh2o, Air-Q® 15.9 (3.2) cmh2o, and Ambu® Aura 17.3 (3.7) cmh2o, p 0.001], but no SGA had a mean airway leak pressure of 20 cmh2o 10%. There were also significant differences in first-try success rates (LMA Supreme 100%, Air-Q® 90%, Ambu® Aura 91%, p = 0.02) and overall success rates (LMA Supreme100%, Air-Q® 91%, Ambu® Aura 95%). The insertion times varied between 20 and 7 seconds (Air-Q®) and 24 and 6 seconds (LMA supreme, p = 0.005). LMA supreme was assessed as having the easiest insertion (very easy in 97% vs. Air-Q® 70%, Ambu® Aura 72%, p= 0.001). The SGA and fiberoptic perspective were similar. Adverse events were uncommon.

Van Esch BF et al [13] at the University Medical Center of Utrecht, carried out a thorough literature review. For pertinent randomised controlled studies, the internet databases pub med, Embase, and the Cochrane Library were searched. In conclusion,

there is no appreciable difference between LMA and ETT in the frequency of postoperative airway problems. Although a direct comparison between LMA subtypes and ETT is difficult because to the heterogeneity among the chosen studies, the LMA Supreme results may be linked to lower airway complication rates when compared to ETT. They emphasize the significance of taking device size and cuff inflation volume selection into account when reporting on airway problems and call for more study in larger, higher-quality randomised trials.

Subramanyam R et al[14] designed and validated a risk prediction tool, in order to estimate the likelihood of PRAE in children under the age of 18 years having elective ambulatory anaesthesia for surgery and radiography. They examined information from the department's quality improvement database related to 19,059 patients. Age, sex, ASA physical status, morbid obesity, pre-existing pulmonary disorder, pre-existing neurologic disorder, and the location of ambulatory anaesthesia were the predictive variables (surgery or radiology). Any one of the following events was considered a composite PRAE: intraoperative bronchospasm, intraoperative laryngospasm, postoperative apnea, postoperative laryngospasm, postoperative bronchospasm, or postoperative extended oxygen need. By employing a split sampling technique to divide the information into two distinct cohorts based on the year the patient had ambulatory anaesthesia for surgery and radiography, the risk prediction tool for PRAE was developed and validated. On the basis of the validation tool's regression coefficients, a risk score was created. Tests of discrimination and calibration were used to evaluate the performance of the risk prediction tool. According to their findings, the total incidence of composite PRAE was 2.8%.10, 155 patients made up the validation group, compared to 8904 individuals in the derivation

cohort. In the development cohort, the risk of PRAE was 3.9%, whereas it was 1.8% in the validation cohort. In a multivariate logistic regression model, age 3 years (against >3 years), ASA physical status II or III (vs. ASA physical status I), morbid obesity, previous pulmonary condition, and surgery (versus radiography) substantially predicted the likelihood of PRAE. Each significant variable in the logistic regression model received a risk score between 0 and 3, and a total score for all risk variables ranged from 0 to 11. The high-risk category was identified using a receiver operating characteristic curve and a cut-off score of 4. For the derivation and validation cohorts, the model C-statistic and the associated SE were 0.64 0.01 and 0.63 0.02, respectively. The risk prediction tool's sensitivity and SE for identifying kids at risk for PRAE were 77.6 0.02 in the derivation cohort and 76.2 0.03 in the validation cohort. The risk assessment created and verified from their study cohort identified 5 risk factors: age 3 years (vs. >3 years), ASA physical status II and III (versus ASA physical level I), morbid obesity, pre-existing pulmonary condition, and surgery (versus radiology) for PRAE. With the help of this tool, each patient can receive a unique risk score that can be used to estimate their preoperative risk of developing PRAE.

Michalek P et al [15] stated that the majority of complications related to the proper use of SGA'S are not life-threatening and are rather uncommon. They are strongly associated to a deviation from the makers' instructions for using their products. Aspiration is still a concern that can have detrimental, even fatal, effects. Although its incidence is exceedingly low and comparable to that of aspiration after tracheal tube anaesthesia, it's possible that the true number of cases is underreported. Although there is some preliminary data, rigorous studies are still needed to determine whether

newer devices with an additional stomach channel provide greater protection from regurgitation and aspiration. Device selection should be based on the assessment of the aspiration risk, which is a crucial part of the preanesthetic evaluation.

Luce V et al [16] in a meta-analysis, compared the laryngeal mask airway with TI for perioperative respiratory problems. In this, 19 randomised controlled studies comparing TI and laryngeal mask airways were considered. To determine the pooled odds ratios (OR), mean differences (MD), and 95% confidence intervals, data from each experiment were combined. Patients were given muscular relaxation in 12 studies, and breathing was controlled in 16 investigations. When a laryngeal mask airway was utilised to maintain the airway, the incidence of desaturation (OR = 0.34 [0.19-0.62]), laryngospasm (OR = 0.34 [0.2-0.6]), cough (OR = 0.18 [0.11-0.27]), and breath holding (0.19 [0.05-0.68]) was decreased. Laryngeal mask airway and TI had similar postoperative rates of sore throat (OR = 0.87 [0.53-1.44]), bronchospasm (OR = 0.56 [0.25-1.25]), aspiration (1.33 [0.46-3.91]), and blood stains on the device (OR = 0.62 [0.21-1.82]). With the exception of the device being stained with blood, their findings were consistent across all of the tests. According to this meta-analysis, there are fewer common post-anesthetic problems when laryngeal mask airways are used for paediatric anaesthesia. As a result, it is a useful tool for managing the paediatric airway.

Jagannathan N et al [17] and others In a single centre over a 4-year period, a retrospective analysis of SGA use for primary airway management in the challenging airway population was conducted. In a standalone paediatric facility, general anaesthesia was administered to 77 272 kids in total. The presence of a problematic airway was documented in 459 cases. Of those, 109 patients who met the inclusion

requirements for this study over a 4-year period had general anaesthesia and an SGA for primary management. 96% of these patients had success using an SGA. An alternate airway was required in four cases.

Goyal R et al [18] conducted a randomized prospective study in 120 children aged 2 to 5 years, weighing 10 to 20 kg, with ASA physical status I-II, who were scheduled for routine elective surgeries lasting one hour. They were divided into three groups of 40 people each (i-gel, pLMA, and cLMA). i-gel group had a 95% success rate on the first attempt, while the two laryngeal mask airway groups had a 90% success rate. In all groups, insertion was found to be simple in the majority of cases, and there was no change in blood pressure, heart rate, or oxygen saturation after insertion. The Oro pharyngeal sealing pressure for i-gel, pLMA, and cLMA was 26 2.6, 23 1.2, and 22 2.3 cm H2O, respectively. The difference in airway performance between the i-gel and both laryngeal mask groups was statistically significant (P 0.01). In the postoperative period, there were no clinically significant complications.

Hughes C et al [19] tested i-gel in children deemed suitable for a supraglottic device in sizes ranging from 1 to 2.5. Airway leak pressure, position confirmed by fiberoptic laryngoscopy, gastric tube placement, manipulations required, and complications were all evaluated. Over the course of a year, 154 children received i-gel. The median (interquartile range, IQR) age was 4 years and 11 months (2-7 years), the weight IQR was 19 kg (13-26), and the operation length IQR was 29 (30-45) minutes. The first attempt at insertion was successful in 93.5% of patients, and the second attempt was successful in 5.8% of patients. The median (IQR) time to implantation was 14 (13-16) s. The average leak pressure (IQR) was 20 (15-25) cmh20. The placement of a gastric tube was successful 90% of the time. A fiberoptic examination revealed vocal chords

in 97% of patients. Complications occurred in 20% of patients, but the vast majority was minor. The device had a tendency to move upward out of the mouth, and the proximal tube's extension toward the forehead and flexion toward the feet affected the quality of the airway. In total, seven (4.5%) patients had the device removed and a different airway was used instead.

Beringer RM et al [20] evaluated the i-gel in 120 anaesthetized children (92 boys, 28 girls; median (IQR [range]) age (3 -7 [0.4 -13]) years and weight 19 (15-26 [7-35]) kg). In 110/8/1 children, insertion was successful on the first, second, and third attempts, but failed in one. The median (interquartile range [range]) insertion time was 14 (9-16 [6-200]) s. Manual ventilation was possible in all cases, though excess leak prevented three children from achieving tidal volumes greater than 7 ml.kg1. In 40 of 46 cases (87%), fibreoptic inspection through the i-gel revealed a clear view of the vocal cords. The median (interquartile range) leak pressure was 20 (16-26 [8-30]) cmh2o. In 11 children, 16 manipulations were required during anaesthesia maintenance to improve the airway. One child regurgitated but did not aspirate. Other complications and side effects were extremely rare. In 113 (94%) of the children, the i-gel was inserted without complications, establishing a clear airway and allowing spontaneous and controlled ventilation.

Von Ungern-Sternberg BS et al colleagues [21] in a prospective cohort research, found correlations between family history, anaesthetic administration, and the occurrence of perioperative respiratory adverse events. They included every kid who underwent general anaesthesia for surgical or medical interventions, elective or urgent operations, at Princess Margaret Hospital for Children in Perth, Australia, between February 1, 2007, and January 31, 2008. An adaptation of the International Study

Group for Asthma and Allergies in Childhood questionnaire was filled out by anaesthetists in care of paediatric patients on the day of operation. A positive respiratory history (night time dry cough, wheezing during exercise, wheezing more than three times in the previous 12 months, or a history of present or past eczema) was linked to an increased risk of bronchospasm, laryngospasm, and perioperative cough, desaturation, or airway obstruction (relative risk [RR] 8.46, 95% CI 6.18-11.59; p<0.0001). Only when symptoms were present (RR 2.05, 95% CI 1.82-2.31; p<0.0001) or less than 2 weeks before the procedure (2.34, 2.07-2.66; p<0.0001) was upper respiratory tract infection linked to an increased risk for perioperative respiratory adverse events, whereas symptoms of upper respiratory tract infection 2-4 weeks prior to the procedure significantly reduced the incidence of perioperative respiratory adverse events (0.66, 0.53-0.81; p<0·0001). The likelihood of experiencing perioperative respiratory adverse events increased if at least two family members had a history of smoking, atopy, or asthma (all p<0.0001). Inhalational versus intravenous anaesthesia maintenance, airway management by a specialist paediatric anaesthetist against a registrar, and use of a face mask versus tracheal intubation were all associated with reduced risk than intravenous induction and inhalational induction (all p<0.0001). They came to the conclusion that preanaesthetic assessment might systematically identify children at high risk for perioperative respiratory adverse events and that these children could benefit from a focused anaesthesia care.

Mamie C et al [(1)] in a prospective study, wanted to determine the prevalence of perioperative respiratory adverse events (PRAE) associated with elective paediatric surgery as well as to identify their risk variables. Using the International Society on

Allergy and Asthma (ISAAC) questionnaire, they assessed potential risk factors (atopy, eczema, rhinitis, food allergy, prior allergic tests, pollens or animal allergy, passive smoking, obstructive sleep disorders) and gave the results to the parents as part of the preoperative anaesthetic assessment. Systematically recorded were anaesthetic and surgical conditions. 800 kids were analysed using a multivariate logistic regression to explain PRAE. They discovered that there were 21% more respiratory adverse events occurring during surgery than there were in the postanesthetic care unit. The multivariate analysis shows that there is a 1.7-fold greater risk of PRAE in children not under the care of a trained paediatric anesthesiologist (95% CI = 1.13-2.57). With respect to other operations, children who underwent ENT surgery while under anaesthesia had a 1.57-fold increased incidence of PRAE (95% CI = 1.01-2.44). The odds ratio (OR) of PRAE during non-ENT surgical procedures was 1.43 (95% CI = 0.91-2.24); however, when two risk factors, residents and ENT surgery, were combined, the OR increased to 2.74 (95% CI = 1.15-4.32). The incidence of PRAE dropped by 8% with each passing year of age and was considerably lower when the anaesthetic approach included tracheal intubation with relaxants (OR = 0.6, 95% CI = 0.45-0.95). They demonstrate a significant incidence of PRAE in paediatric surgery patients who do not have respiratory tract infections; this incidence appears to be primarily influenced by the child's age and the anaesthetic care provided rather than by the child's medical history

METHODOLOGY

Study setting

The study was conducted after taking approval from the Institutional Ethics Committee (vide letter no. AIIMS/IEC/2021/3341) and registration with the Clinical Trials Registry-India was done prior to recruitment of patients (CTRI/2021 /06/034277).

This observational study was carried out in the Department of Anaesthesiology and Critical Care, AIIMS Jodhpur.

Study participants

Inclusion criteria

All infants (<1year), ASA physical status 1 to 3 scheduled to undergo surgical or diagnostic procedure under general anaesthesia.

Exclusion criterion:

1. Tracheostomised or an infant with airway device already in place preoperatively
2. Patients planned to be kept intubated postoperatively for elective mechanical ventilation
3. Patients underwent airway surgeries
4. Refusal of informed consent

Methodology:

Patients of either gender, belonging to ASA physical status 1 to 3, aged less than 1year, scheduled to undergo surgical or diagnostic procedure under general anaesthesia were included in the study. Informed consent for participation in the study was taken from parents preoperatively. All the patients were assessed in the pre anaesthetic clinic by a qualified anaesthesiologist with at least two-year experience. Anaesthesia management including type of induction, use of muscle relaxant, and airway device selection for airway management was left to the discretion of the anaesthesiologist in charge. Type of the airway device used was noted (cuffed/non-cuffed ETT, type of cuff, type of supraglottic airway- i-gel, Proseal, Ambu Aura used). Occurrence of any respiratory complication and its timing, right from insertion to the postoperative period, was recorded. These events include complications like laryngospasm, bronchospasm, desaturation, and aspiration, blood staining of the device and postextubation croup. Duration of stay in post anaesthesia care unit and any intervention pertaining to the respiratory system was documented. Duration of the airway device placement, improper placement requiring re-insertion or adjustment of the airway device, leak, and patient position during the surgery (supine, lithotomy, lateral, prone) was documented.

Perioperative complications:

1. Laryngospasm was defined as partial or complete airway obstruction due to reflex constriction of laryngeal muscles requiring deepening of anesthetic plane or succinylcholine.

2. Bronchospasm was defined as increased respiratory effort, prolonged expiration, and bilateral wheeze on auscultation.

3. Upper airway obstruction: Partial airway obstruction along with use of accessory muscles of respiration, which is easily managed by jaw-thrust maneuver, or insertion of Guedel airway

4. Oxygen desaturation: SpO_2 of patient less than < 95% on room air requiring oxygen supplementation

5. Change in device is defined as change of one device with same type, with different size or different kind of device (Intraoperatively)

6. Displacement of device or accidental extubation means change in position of device leading to leak in case of SGA and extubation in case of endotracheal tube (Intraoperatively).

7. Type of Extubation –

   Deep extubation when patients are still in a deep plane of anaesthesia.

   Awake extubation when the infant's fully conscious and awake at the time of extubation.

8. Reintubation- patient once extubated at the end of surgery, again requires intubation.

9. Blood stained device- After completion of surgery when the airway device is removed, it is blood stained.

Anticipated difficult airway criteria:

1. Patients with micrognathia
2. Patients with macroglossia
3. Patients with cleft lip or cleft palate
4. Foreign body aspiration
5. History of trauma to face and neck
6. Patients with burns contracture
7. History of prior surgery to face and neck
8. Congenital disorders associated with difficult airways
    - A) Pierre Robin sequence
    - B) Treacher Collin syndrome
    - C) Hemi facial microsomia
    - D) Downs syndrome
    - E) Apert syndrome
    - F) Crouzon syndrome
    - G) Beckwith Wiedman syndrome
9. Poor mouth opening or mobility of jaw and neck

STATISTICAL ANALYSIS

Data collected during the study was compiled using Microsoft Excel spread sheets. Normality of data was tested with Kolmogorov-Smirnov one sample test. Data was presented as median (IQR) for ordinal variables, quantitive variables and absolute numbers or percentages for categorical variables. Mann Whitney u test was used to analyse ordinal and continous data. While Chi square test was used for categorical data. Probability was considered to be significant if less than 0.05.

RESULTS

A total of 150 patients were included in this study according to the inclusion criteria. All of the patients were assessed preoperatively for anticipated difficult airway and to rule out exclusion criteria. Anaesthesia management including type of induction, use of muscle relaxant, and airway device selection for airway management was left to the discretion of the anaesthesiologist in charge. Out of 150 patients ETT was used in 79 patients, Ambu aura was used in 22 patients, Proseal was used in 22 patients and I gel was used in 27 patients in general anaesthesia. All the patients were followed up and analysed.

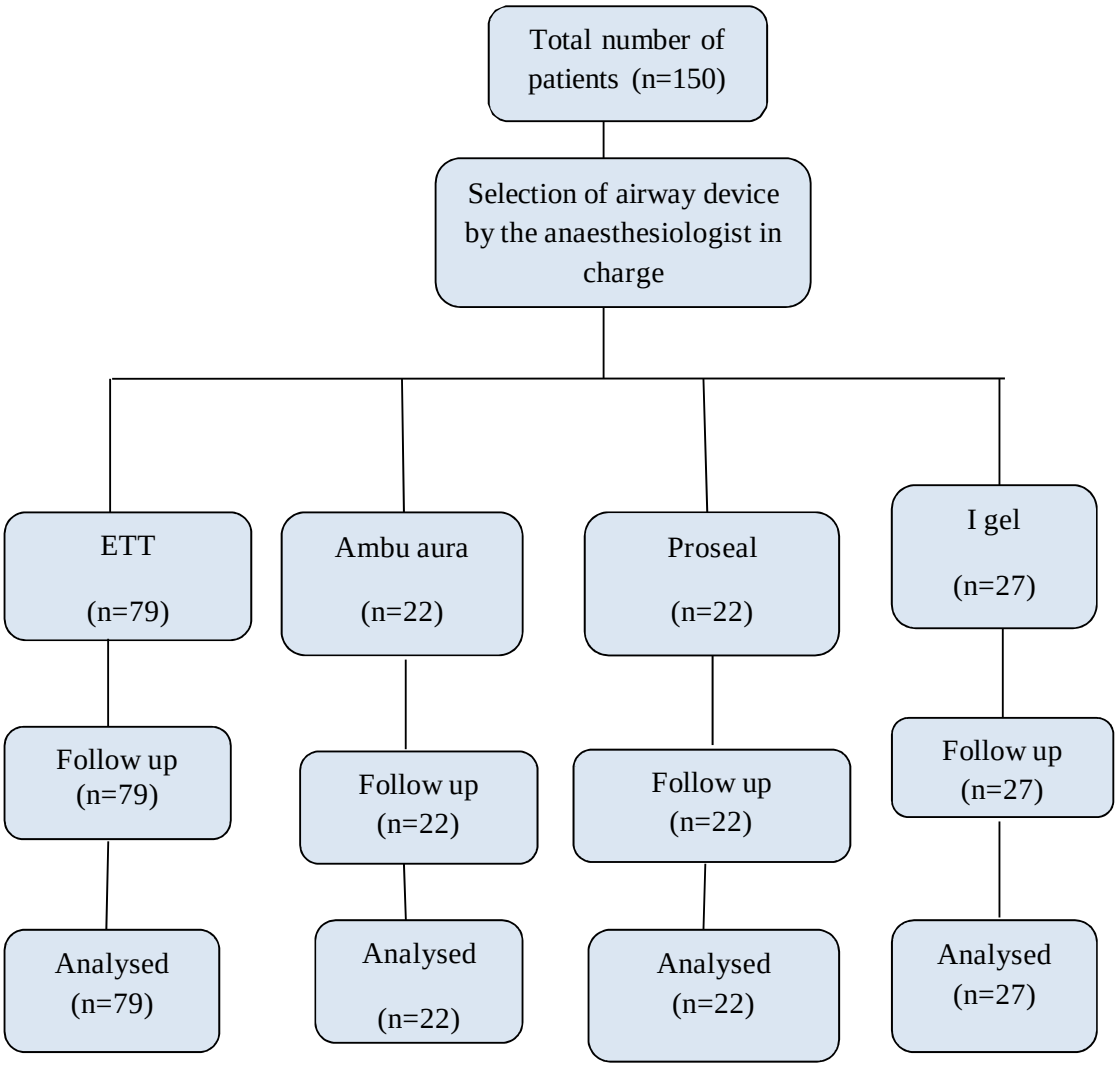

Figure 5: Flow chart

Table 1: Gender distribution of study groups

Gender	ET tube n (%)	Ambu Aura n (%)	Proseal n (%)	i-gel n (%)
MALE	48 (60.75%)	19 (86.36%)	16 (72.72%)	25 (92.59%)
FEMALE	31 (39.24%)	3 (13.63%)	6 (27.27%)	2 (7.40%)
TOTAL	79 (100%)	22 (100%)	22 (100%)	27 (100%)

The above table shows distribution of gender in four different groups of study. ET tube group has 48 (60.75%) male patients and 31 female patients (39.24%) where as in Ambu Aura group; there were 19(86.36%) male patients and 3(13.63%) female patients. In Proseal group male patients were 16(72.72%) and female patients were 6(27.27%) in number where as in i-gel group male patients were 25(92.59%) and female patients 2 (7.40%).

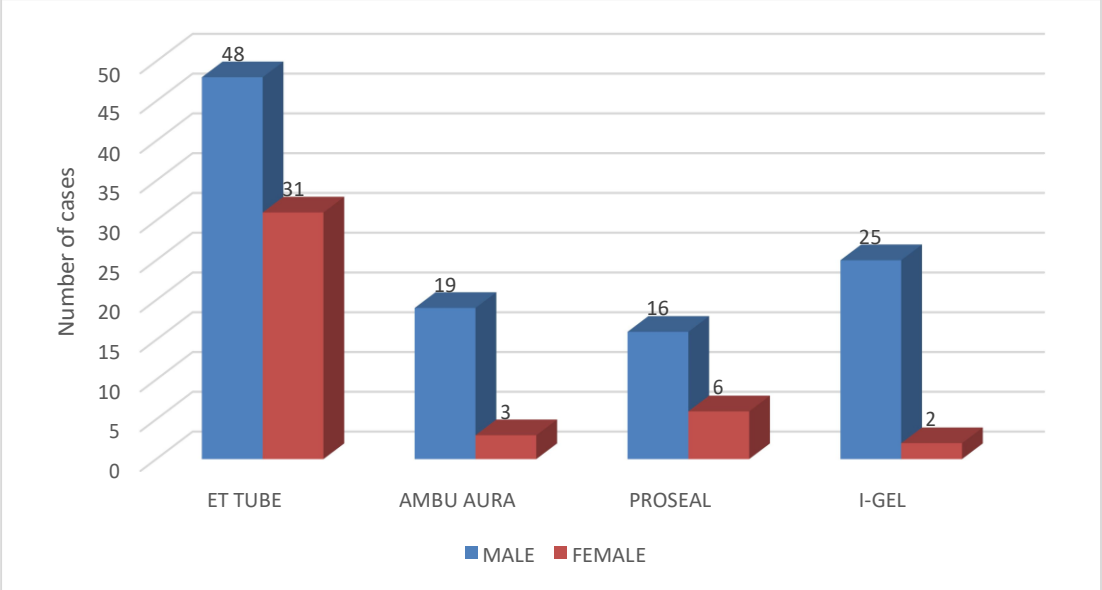

Figure 6: Gender distribution of study group

Table 2: Age distribution of study groups

Age	ET tube n (%)	Ambu Aura n (%)	Proseal n (%)	i-gel n (%)	P-value
< 1 month	12(15.19%)	0(0.00%)	3(13.64%)	2(7.41%)	0.282
≥ 1 month	67(84.81%)	22(100%)	19(86.36%)	25(92.59%)	
Total	79(100%)	22(100%)	22(100%)	27(100%)	
Median (IQR)	5 (2-8)	7 (5-8.75)	5.50 (3-8)	4 (2-10.50)	

The above table shows age distribution between the ET tube, Ambu Aura, Proseal and i-gel. The median (IQR) age in ET tube group, Ambu Aura group, Proseal group and in i-gel group were 5 (2-8), 7 (5-8.75), 5.50 (3-8), 4 (2-10.50). Mann Whitney u test was applied with corresponding p value of 0.282 which is statistically insignificant i.e., all four study groups were comparable with respect to age.

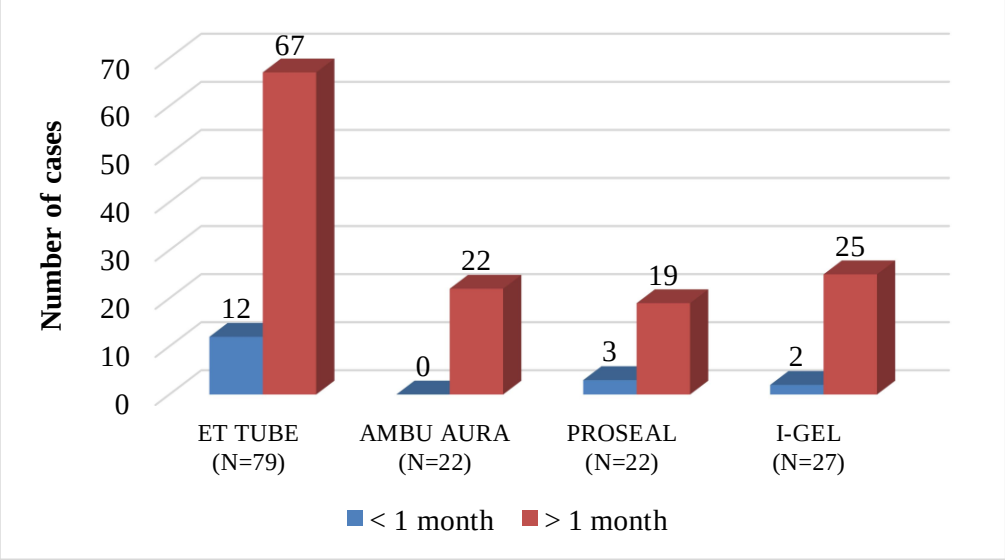

Figure 7: Age distribution of study groups

PREOPERATIVE

Table 3: Proportion of anticipated difficult airway preoperatively between the study groups

Anticipated difficult airway	ET tube n (%)	Ambu Aura n (%)	Proseal n (%)	i-gel n (%)	P, X^2
NO	44(55.70%)	21(95.45%)	18(81.82%)	21(77.78%)	0.001,16.488
YES	35(44.30%)	1(4.55%)	4(18.18%)	6(22.22%)	
TOTAL	79(100%)	22(100%)	22(100%)	27(100%)	

The above table shows proportion of anticipated difficult airway preoperatively in four different study groups. In ET tube group difficult airway was anticipated in 35(44.30%) patients and not anticipated in 44(55.70%) patients, in Ambu Aura group difficult airway was anticipated in 1(4.55%) patient and not anticipated in 21(95.45%) patients, in Proseal group difficult airway was anticipated in 4(18.18%) patients and not anticipated in 18(81.82%) patients and in i-gel group difficult airway was anticipated in 6 (22.22%) patients and not anticipated in 21(77.78%) patients. Chi square test was applied which showed a value of 16.488 with corresponding p-value of above association as significant ($p<0.05$) which indicates that ETT was used in majority of patients (44.3%) with anticipated difficult airway.

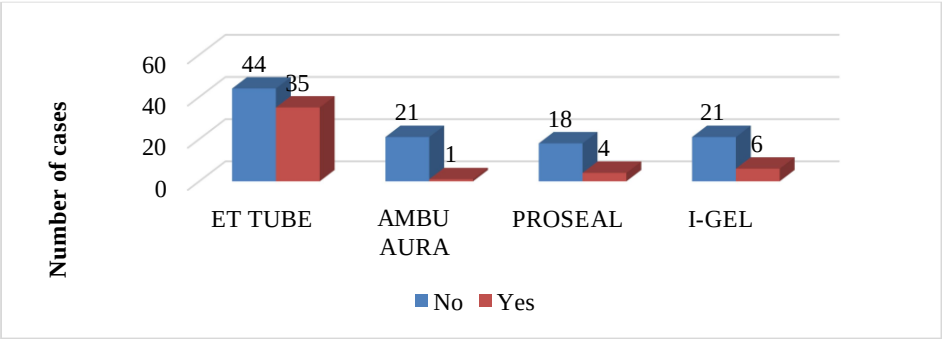

Figure 8: Proportion of anticipated difficult airway preoperatively

Table 4: Proportion of premedication used preoperatively between the study groups

Use of pre medication	ET tube n (%)	Ambu Aura n (%)	Proseal n (%)	i-gel n (%)
No	53(67.09%)	11(50.00%)	12(54.55%)	15(55.56%)
Yes	26(32.91%)	11(50.00%)	10(45.45%)	12(44.44%)
Total	79(100%)	22(100%)	22(100%)	27(100%)

The above table shows proportion of premedication used preoperatively in four different study groups. In et tube group premedication was used in 26(32.91%)patients and not used in 53(67.09%) patients , in Ambu Aura group premedication was used in 11(50.00%) patients and not used in 11(50.00%) patients , in Proseal group premedication was used in 10 (45.45%) patients and not used in 12(54.55%) patients and in I-gel group premedication was used in 12(44.44%) patients and not used in 15(55.56%) patients .

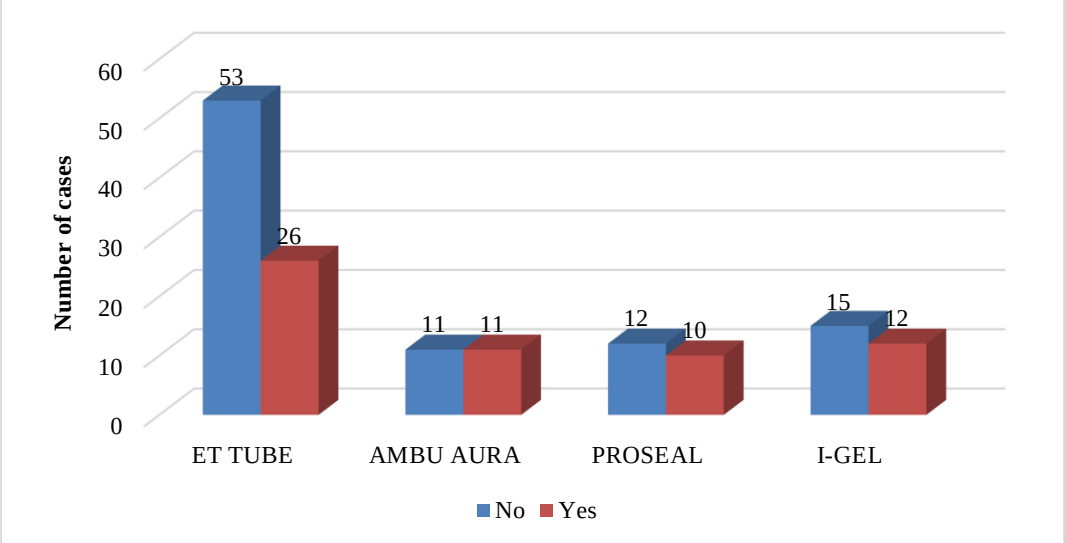

Figure 9: Proportion of premedication used preoperatively

INDUCTION

Table 5: Proportion of difficult or easy bag mask ventilation between the study groups

Bag and mask	ET tube n (%)	Ambu Aura n (%)	Proseal n (%)	i-gel n (%)	P, X^2
Easy	70(88.61%)	21(95.45%)	21(95.45%)	24(88.89%)	0.876,1.689
Difficult	9(11.39%)	1(4.55%)	1(4.55%)	3(11.11%)	
Total	79(100%)	22(100%)	22(100%)	27(100%)	

The above table shows proportion of difficult or easy bag mask ventilation in four different study groups. In et tube group bag mask ventilation was difficult in 9(11.39) patients and easy in 70(88.61%) patients, in Ambu Aura group bag mask ventilation was difficult in 1(4.55%) patient and easy in 21(95.45%) patients, in proseal group bag mask ventilation was difficult in 1(4.55%) patient and easy in 21(95.45%) patients and in i gel group bag mask ventilation was difficult in 3(11.11%) patients and easy in 24(88.89%) patients. Chi square test was applied which showed a value of 1.689 with corresponding p-value of above association is insignificant (p>0.05) i.e, there was no difference in the incidence of difficult bag and mask ventilation between the study groups

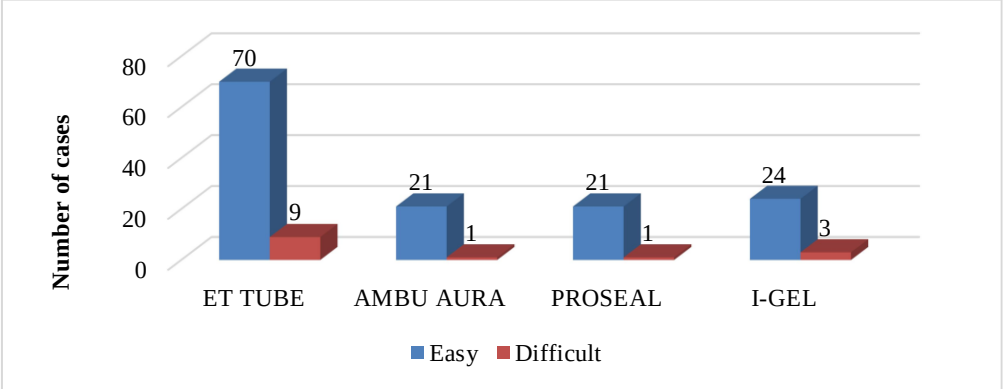

Figure 10: Proportion of difficult or easy bag mask ventilation

Table 6: Proportion of personal preference for selection of airway devices between the study groups

Personal preference	ET tube n (%)	Ambu Aura n (%)	Proseal n (%)	i-gel n (%)	P, X^2
No	70(88.61%)	0(0.00%)	2(9.09%)	3(11.11%)	<0.001,100.162
Yes	9(11.39%)	22(100%)	20(90.91%)	24(88.89%)	
Total	79(100%)	22(100%)	22(100%)	27(100%)	

The above table shows proportion of personal preference for selection of airway device in four different study groups. In ET tube group personal preference was in 9(11.39%) patients and no personal preference in 70(88.61%) patients, where as in Ambu Aura group personal preference was in 22(100.0%) patients, and in Proseal group personal preference was in 20(90.9%) patients and no personal preference in 2(9.09%) patients and in i-gel group personal preference was in 24(88.89%) patients and no personal preference in 3(11.11%) patients. Chi square test was applied which showed a value of 100.162 with corresponding p value of above association is significant ($p<0.05$) i.e., ET tube was more personally preferred in infants undergoing surgeries under general anaesthesia when compared to other study group.

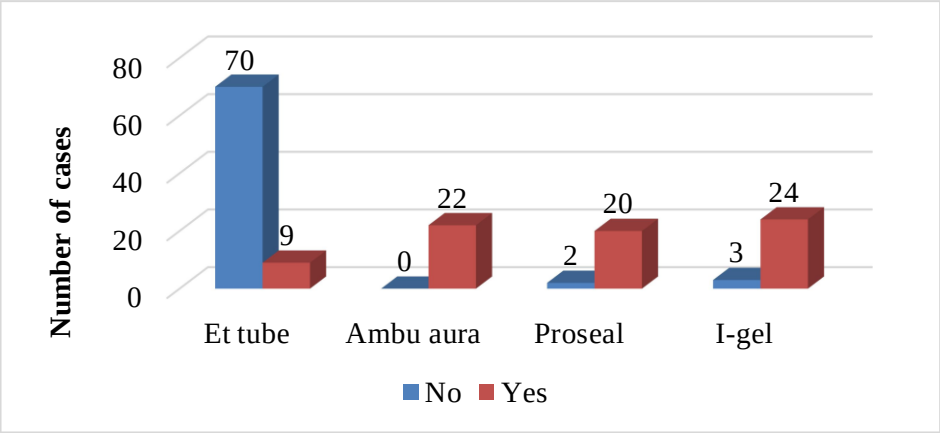

Figure 11: Proportion of personal preference for selection of airway devices

Table 7: Proportion of Indication for selection of ETT

Indication	Number of cases (%)
Bowel handling	26(35.14%)
Head and neck surgeries	10(13.51%)
Large head	2(2.70%)
Leak	5(6.76%)
Long surgical duration	3(4.05%)
Thoracotomy	1(1.35%)
Oral cavity surgery	3(4.05%)
Prone position	19(25.68%)
Thorascopic surgery	3(4.05%)
Operated case of cleft palate	2(2.70%)
Grand total	74(100.00%)

The above table shows the proportion of indication for selection ETT .major indication for selection of ETT was bowel handling in 26(35.14%) cases and the other indications were prone position in 19(25.68%) cases, head position manipulation in 10(13.51%) cases ,long surgery duration in 3(4.05%) cases, thoracoscopic surgery in 3(4.05%) cases, large head in 2(2.70%) cases, thoracotomy in 1(1.35%) case, oral cavity surgery in 3(4.05%) cases, operated case of cleft palate in 2(2.70%) cases and large head in 2(2.70%) cases.

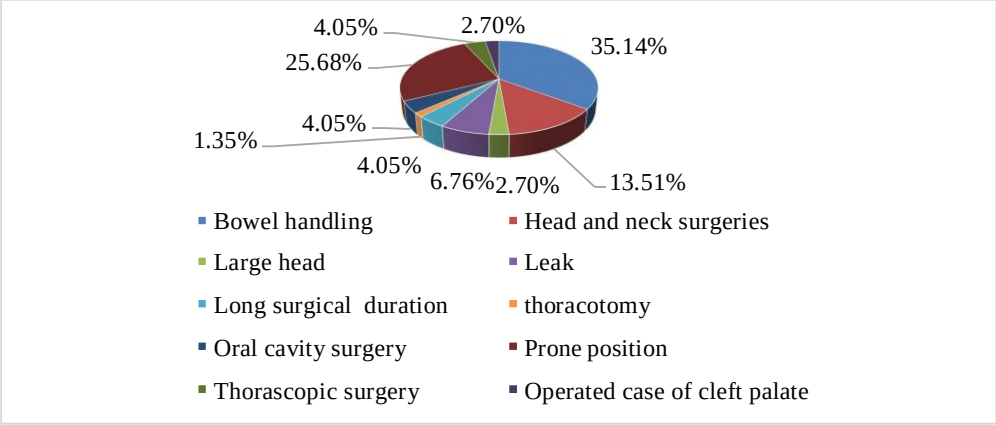

Figure 12: Proportion of Indications for selection of ETT

Table 8: Proportion of number of attempts for successful insertion airway device

No of attempts	ET tube n (%)	Ambu aura n (%)	Proseal n (%)	i-gel n (%)	P, X^2
1	66(83.54%)	20(90.91%)	22(100%)	27(100%)	0.401,9.480
2	11(13.92%)	2(9.09%)	0(0.00%)	0(0.00%)	
3	1(1.27%)	0(0.00%)	0(0.00%)	0(0.00%)	
4	1(1.27%)	0(0.00%)	0(0.00%)	0(0.00%)	
Total	79(100%)	22(100%)	22(100%)	27(100%)	

The above table shows number of attempts for successful insertion of airway device. Out of 79 patients in whom ET tube was used, it was successfully inserted in one attempt in 66 (83.54%) patients, two attempts in 11 (13.92%) patients, 3 attempts in 1 (1.27%) patient and 4 attempts in 1(1.27%) patient. Out of 22 patients in whom Ambu Aura was used, it was successfully inserted in one attempt in 20 (90.91%) patients and two attempts in 2(9.09%) patients. Out of 22 patients in whom Proseal was used it was successfully inserted in one attempt in all 22(100%) patients. Out of 27 patients in whom i-gel was used it was successfully inserted in all 27 (100%) patients in one attempt. Chi Square test was applied which showed a value of 9.480 with corresponding p value of above association is insignificant (p=0.401) i.e., there was no difference among the four airway devices in the number of attempts required for successful insertion in infants.

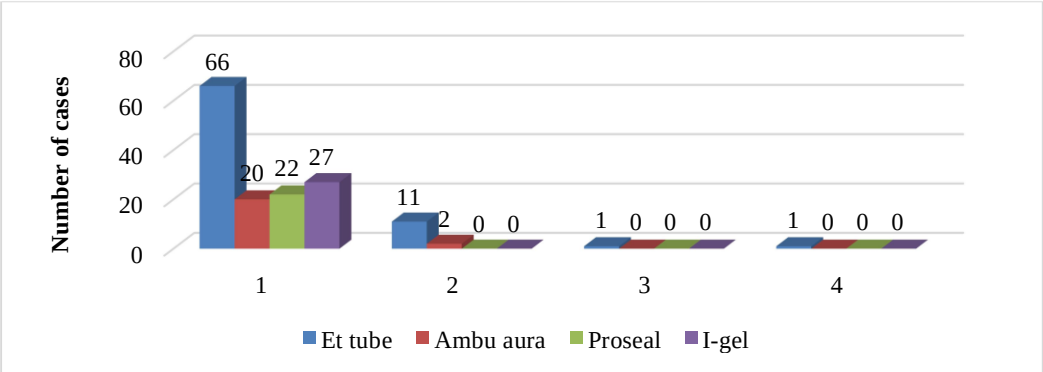

Figure 13: Number of attempts for successful insertion airway device

Table 9: Proportion of change of airway device between the study groups

Change of airway device	ET tube n (%)	Ambu aura n (%)	Proseal n (%)	i-gel n (%)	P, X^2
No	78(98.73%)	20(90.91%)	20(90.91%)	23(85.19%)	0.071,7.604
Yes	1(1.27%)	2(9.09%)	2(9.09%)	4(14.81%)	
Total	79(100%)	22(100%)	22(100%)	27(100%)	

The above table shows proportion of change of airway device between the study groups .in ET tube group, it was changed in 1(1.27%) patient and not changed in 78(98.73%) patients, in Ambu Aura group, it was changed in 2(9.09%) patients and not changed in 20(90.91%) patients, in Proseal group it was changed in 2(9.09%) patients and not changed in 20(90.91%) patients and in i-gel group it was changed in 4(14.81%) patients and not changed in 23(85.19%) patients. Chi square test was applied which showed a value of 7.604 with corresponding p-value of above association as insignificant (p>0.05) i.e., there was no difference in the incidence of change of device during induction between the four airway devices in infants.

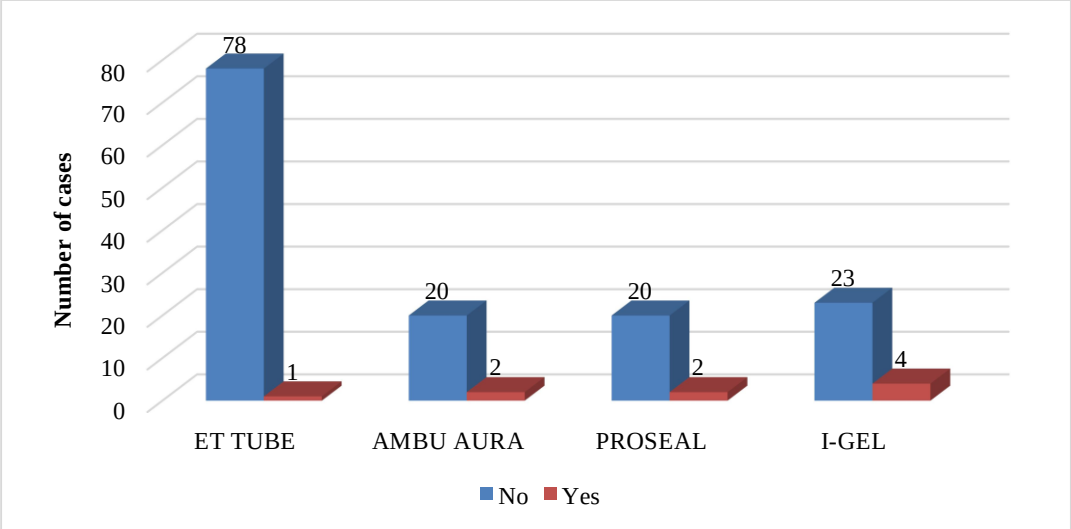

Figure 14: Proportion of change of airway device during induction

Table 10: Proportion of airway devices used in different patient positions.

Patient position	ET tube n (%)	Ambu Aura n (%)	Proseal n (%)	i-gel n (%)
Supine	50(63.29%)	11(50.00%)	6(27.27%)	12(44.44%)
Lateral	3(3.80%)	0(0.00%)	0(0.00%)	0(0.00%)
Prone	19(24.05%)	0(0.00%)	0(0.00%)	0(0.00%)
Lithotomy	7(8.86%)	11(50.00%)	16(72.73%)	15(55.56%)
Total	79(100%)	22(100%)	22(100%)	27(100%)

The above table shows proportion of airway devices used in different patient position's during surgeries. ET tube was the most commonly airway device in supine position 50(63.29%) cases, and in prone position 19(24.05%) cases and in lateral position 3(3.80%) cases it was also used in lithotomy position 7 (8.86%) cases. Ambu Aura was used in supine position 11(50.00%) cases and in lithotomy position 11(50.00%) cases. Proseal was the most commonly used device in lithotomy position 16(72.73%) and also used in supine position 6(27.27%). i-gel was used in supine position 12(44.44%) cases and in lithotomy position 15(55.56%) cases.

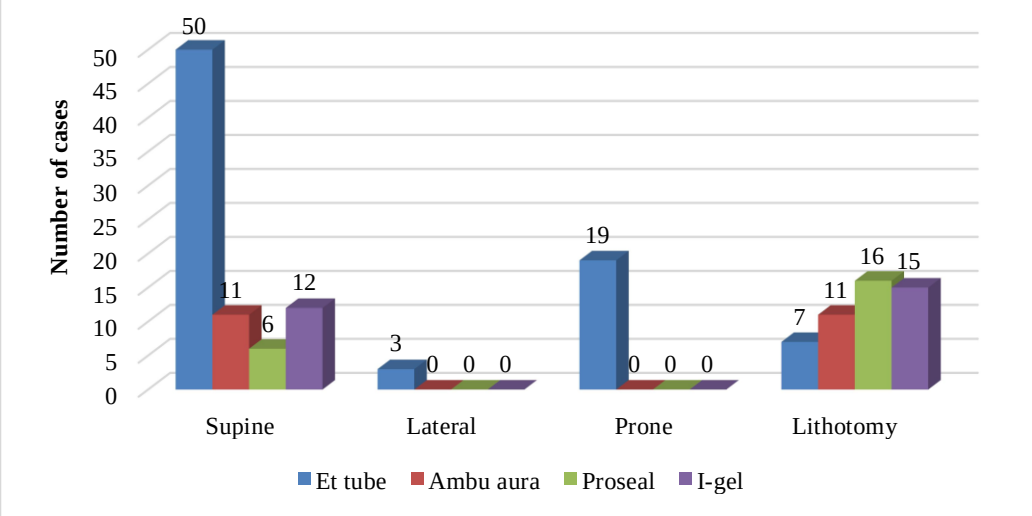

Figure 15: Proportion of airway devices used in different patient positions

Table 11: Proportion of patient's position during Surgery

Position	Number of cases (%)
Supine	79(52.67%)
Lateral	3(2.00%)
Prone	19(12.67%)
Lithotomy	49(32.67%)
Total	150(100.00%)

The above table shows proportion of position during surgeries. Most surgeries were in supine position 79(52.67%) cases, followed by lithotomy position 49(32.67%) cases, prone position 19(32.67%) cases and lateral position 3(2.00%) cases.

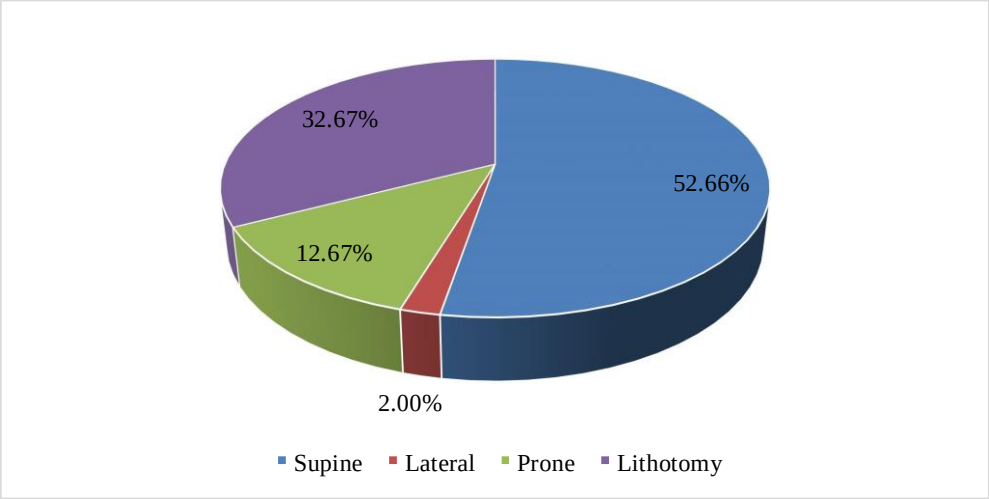

Figure 16: Proportion of patient's positions during surgery.

Table 12: Proportion of airway devices used in different types of surgeries

Type of surgery	ET tube n (%)	Ambu Aura n (%)	Proseal n (%)	i-gel n (%)
Laparoscopic	14(17.72%)	4(18.18%)	3(13.64%)	3(11.11%)
Open	56(70.89%)	6(27.27%)	3(13.64%)	10(37.04%)
Cystoscopic	4(5.06%)	12(54.55%)	16(72.73%)	13(48.15%)
Thoracoscopic	5(6.33%)	0(0.00%)	0(0.00%)	0(0.00%)
Bronchoscopy	0(0.00%)	0(0.00%)	0(0.00%)	1(3.70%)
Total	79(100%)	22(100%)	22(100%)	27(100%)

The above table shows proportion of airway devices used in infants in different types of surgeries. ETT was used most commonly in open 56(70.89%) surgeries, laproscopic 14(17.72%) surgeries and in thorascopic 5(6.33%) surgeries, and also used in cystoscopic 4(5.06%) surgeries. Ambu Aura was used in laparoscopic 4(17.72%) surgeries, open 6(27.27%) surgeries and cystoscopic 4(5.06%) surgeries. Proseal was most commonly used in cystoscopic 16(72.73%) surgeries and also used in laparoscopic 3(13.64%) surgeries , open 3(13.64%) surgerie's. i-gel was used in laparoscopic 3(11/11%) surgeries ,open 10 (37.04%) surgeries and in 1 (3.70%) bronchoscopy procedure.

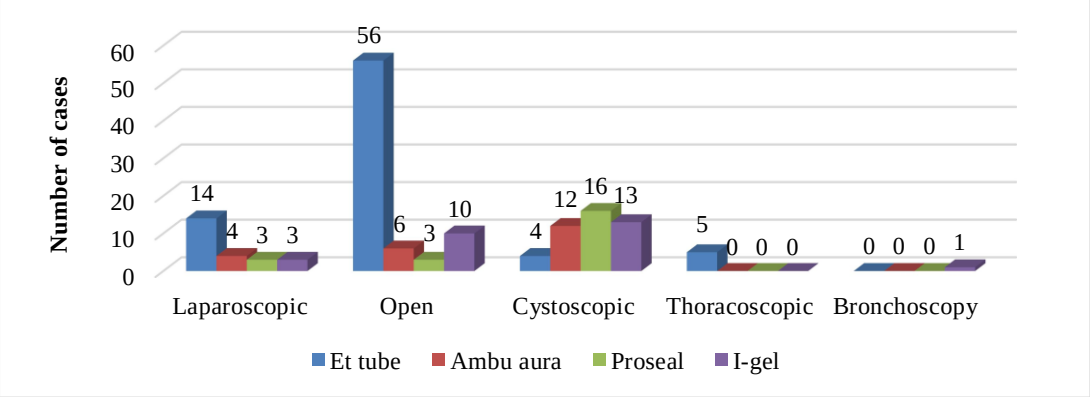

Figure 17: Proportion of airway devices used in different types of surgeries.

INTRAOPERATIVE

Table 13: Proportion of complications intraoperatively between the study groups

Complications	ET tube n (%)	Ambu Aura n (%)	Proseal n (%)	i-gel n (%)	P, X^2
No	72(91.14%)	20(90.91%)	21(95.45%)	22(81.48%)	0.324,4.193
Yes	7(8.86%)	2(9.09%)	1(4.55%)	5(18.52%)	
Total	79(100%)	22(100%)	22(100%)	27(100%)	

The above table shows proportion of complications intraoperatively in four different study groups. In ET tube group complications occurred in 7(8.86%)patients and did not occur in 72(91.14%) patients , in Ambu Aura group complications occurred in 2(9.09%) patients and did not occur in 20(90.91%) patients , in Proseal group complications occurred in 1 (4.55%) patient and did not occur in 21(95.45%) patients and in i-gel group complications occurred in 5(18.52%) patients and did not occur in 22(81.48%) patients. Chi square test was applied which showed a value of 4.193 with corresponding p-value of above association is insignificant (p>0.05) i.e., there was no difference in the incidence of intraoperative respiratory complications between the ET tube, Ambu Aura, Proseal and i-gel in infants.

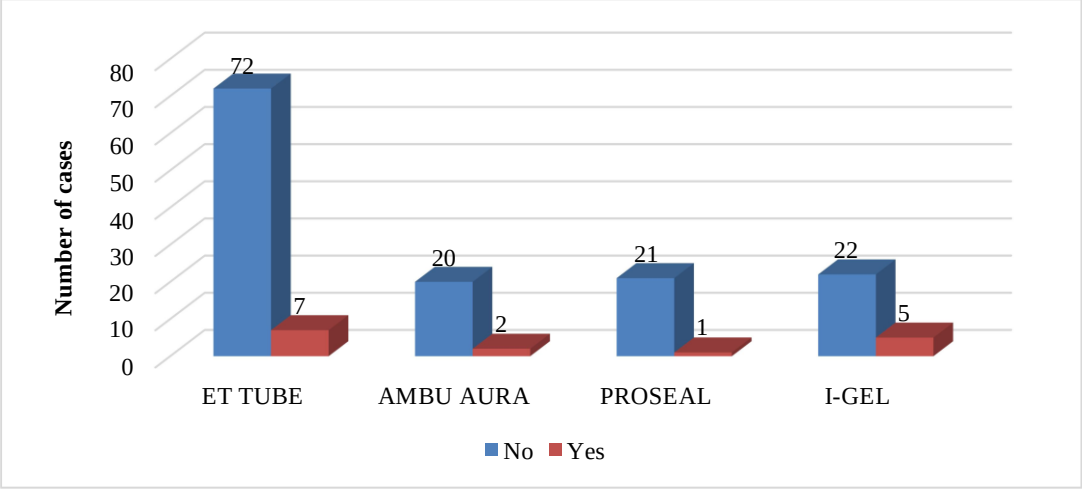

Figure 18: Proportion of complications intraoperatively

Table 14: Proportion of laryngospasm intraoperatively between study groups

Laryngospasm	ET tube n (%)	Ambu Aura n (%)	Proseal n (%)	i-gel n (%)
No	79(100%)	22(100%)	22(100%)	27(100%)
Yes	0(0.00%)	0(0.00%)	0(0.00%)	0(0.00%)
Total	79(100%)	22(100%)	22(100%)	27(100%)

The above table shows proportion of laryngospasm intraoperatively in four different study groups. Laryngospasm did not occur in any patient enrolled in the study.

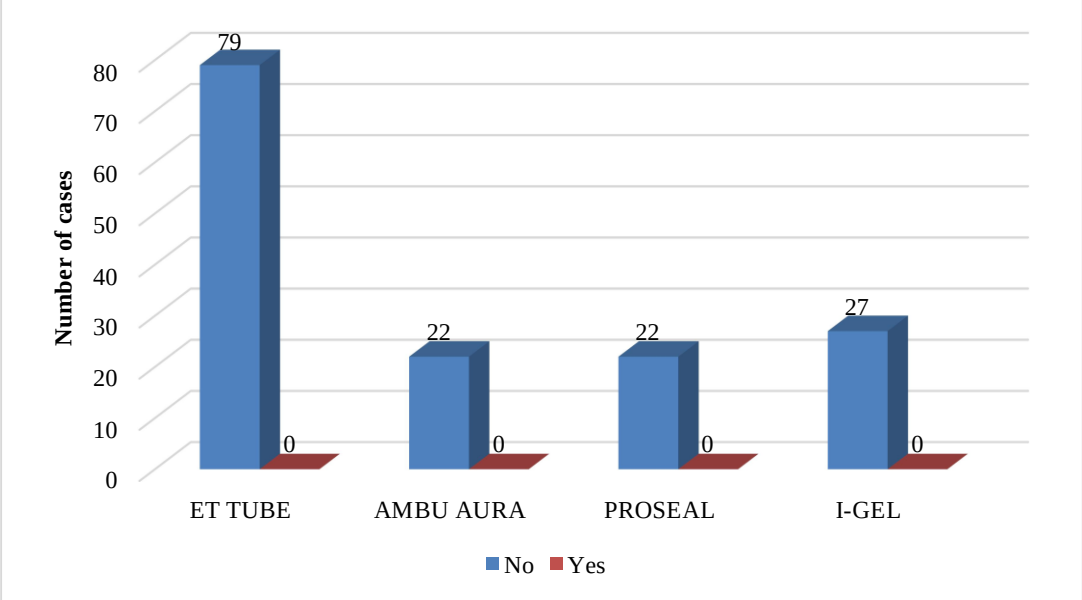

Figure 19: proportion of larngospasm intraoperatively.

Table 15: Proportion of bronchospasm intraoperatively between study groups

Bronchospasm	ET tube n (%)	Ambu Aura n (%)	Proseal n (%)	i-gel n (%)	P, X^2
No	76(96.20%)	22(100%)	22(100%)	27(100%)	0.587,2.751
Yes	3(3.80%)	0(0.00%)	0(0.00%)	0(0.00%)	
Total	79(100%)	22(100%)	22(100%)	27(100%)	

The above table shows proportion of bronchospasm intraoperatively in four different study groups. In ET tube group, bronchospasm occurred in 3(3.80%) patients and did not occur in 76(96.20%) patients. Bronchospasm was not observed in patients in other study groups. Chi square test was applied which showed a value of 2.751 with corresponding p value of above association is insignificant (p>0.05) i.e., there was no difference in the incidence of intraoperative bronchospasm between the four airway devices in infants.

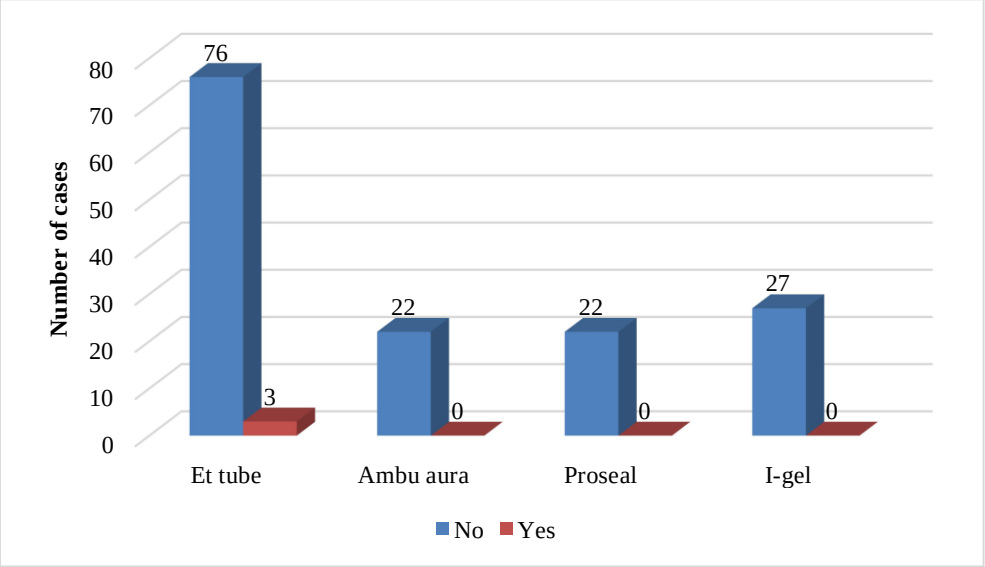

Figure 20: Proportion of bronchospasm intraoperatively

Table 16: Proportion of desaturation intraoperatively between the study groups

Desaturation	ET tube n (%)	Ambu Aura n (%)	Proseal n (%)	i-gel n (%)	P, X^2
No	75(94.94%)	22(100%)	22(100%)	27(100%)	0.400,3.693
Yes	4(5.06%)	0(0.00%)	0(0.00%)	0(0.00%)	
Total	79(100%)	22(100%)	22(100%)	27(100%)	

The above table shows proportion of desaturation intraoperatively in four different study groups. In ET tube group desaturation occurred in 4(5.06%) patients and did not occur in 75(94.94%) patients. Desaturation was not observed in patients in other study groups. Chi square test was applied which showed a value of 3.693 with corresponding p value of above association is insignificant (p>0.05) i.e., there was no difference in the incidence of intraoperative desaturation between the four airway devices in infants.

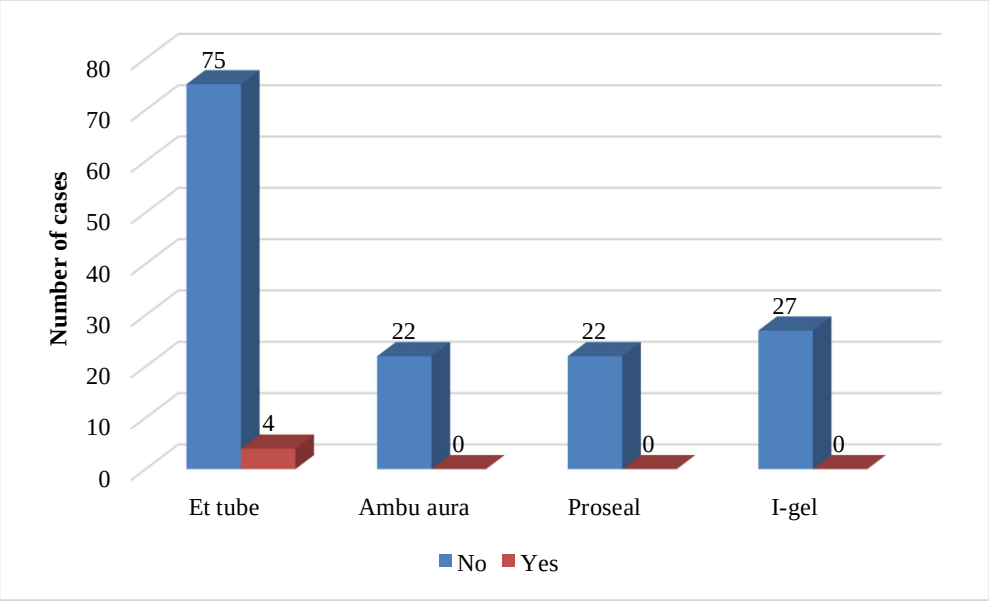

Figure 21: proportion of desaturation intraoperatively

Table 17: Proportion of change in airway device intraoperatively between the study groups

Change of airway device	ET tube n (%)	Ambu Aura n (%)	Proseal n (%)	i-gel n (%)	P, X^2
No	78(98.73%)	21(95.45%)	22(100%)	26(96.30%)	0.844,1.793
Yes	1(1.27%)	1(4.55%)	0(0.00%)	1(3.70%)	
Total	79(100%)	22(100%)	22(100%)	27(100%)	

The above table shows proportion of change in airway device intraoperatively in four different study groups. In ET tube group airway device was changed in 1(1.27%) patient and not changed in 78(98.73%) patients ,where as in Ambu Aura group airway device was changed in 1(4.55%) patient and not changed in 21(95.45%) patients, in Proseal group airway device was not changed in 22(100.00%) patients and in i-gel group aiway device was changed in 1(3.70%) patient not changed in 26(96.30%) patients .chi square test was applied which showed a value of 1.793 with corresponding p value of above association is insignificant (p>0.05) i.e., there was no difference in the incidence of intraoperative change of device between the four airway devices in infants .

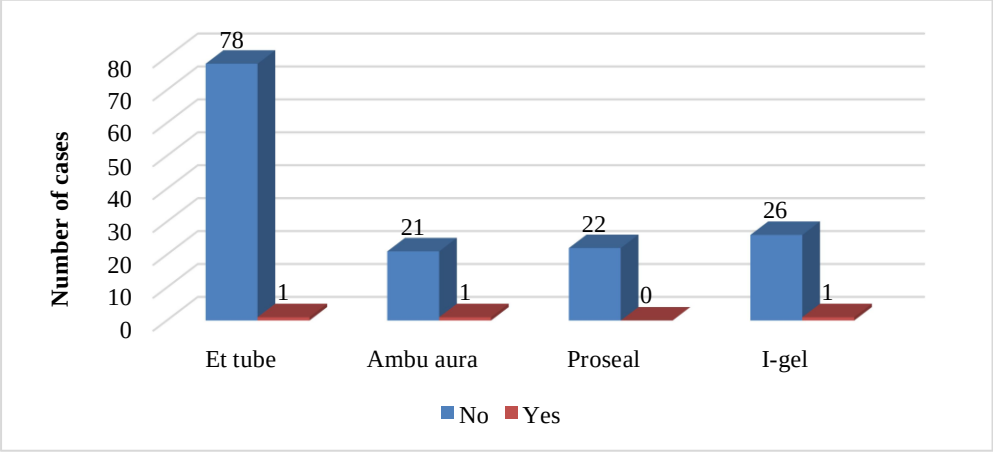

Figure 22: Proportion of change in airway device intraoperatively

Table 18: Proportion of displacement of airway device intraoperatively between the study groups

Displacement	ET tube n (%)	Ambu Aura n (%)	Proseal n (%)	i-gel n (%)	P, X^2
No	78(98.73%)	21(95.45%)	22(100%)	24(88.89%)	0.095,6.976
Yes	1(1.27%)	1(4.55%)	0(0.00%)	3(11.11%)	
Total	79(100%)	22(100%)	22(100%)	27(100%)	

The above table shows proportion of displacement of airway device intraoperatively in four different study groups. In ET tube group airway device was displaced in 1(1.27%) patient and not displaced in 78(98.73%) patients ,where as in Ambu Aura group airway device was displaced in 1(4.55%) patient and not displaced in 21(95.45%) patients and in Proseal group airway device was not displaced in 22(100.00%) patients and in i-gel group aiway device was displaced in 3(11.11%) patients and not displaced in 24(88.89%) patients .Chi square test was applied which showed a value of 6.976 with corresponding p value of above association is insignificant (p>0.05) i.e., there was no difference in the incidence of intraoperative displacement of device between the four airway devices in infants.

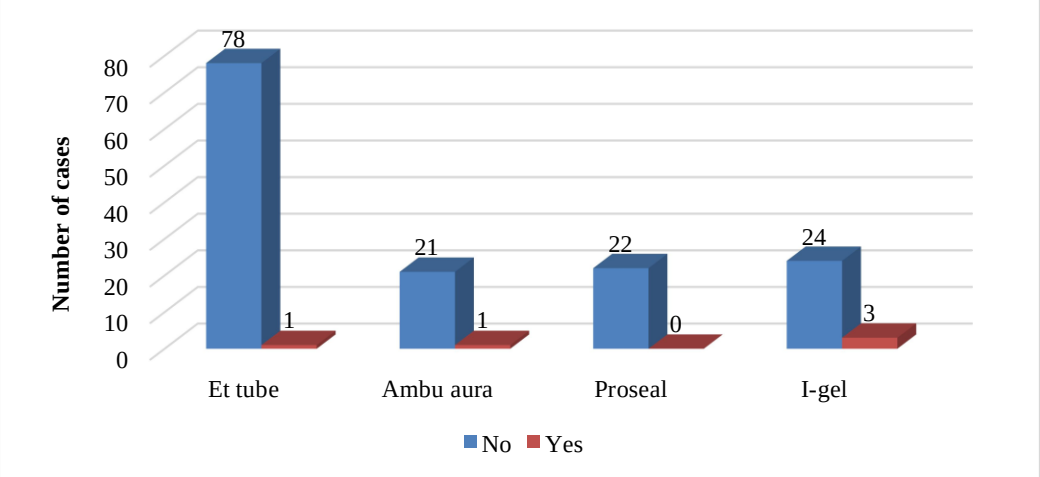

Figure 23: Proportion of displacement of airway device intraoperatively

Table 19: Proportion of repositioning of airway device intraoperatively between the study groups

	ET tube n (%)	Ambu Aura n (%)	Proseal n (%)	i-gel n (%)	P, X^2
Repositioning	1(1.26%)	1(4.54%)	1(4.54%)	3(11.11%)	0.140,6.107
Total	79(100%)	22(100%)	22(100%)	27(100%)	

The above table shows proportion of repositioning of airway device intraoperatively in four different study groups. In ET tube group repositioning was done in 1(1.26%) patient ,in Ambu Aura group repositioning was done in 1(4.54%) patient and in Proseal group repositioning was done in 1(4.54%) patient and in i-gel group repositioning was done in 3(11.11%) patients . Chi square test was applied which showed a value of 6.107 with corresponding p value of above association is insignificant (p>0.05) i.e., there was no difference in the incidence of intraoperative repositioning of airway between the four airway devices in infants.

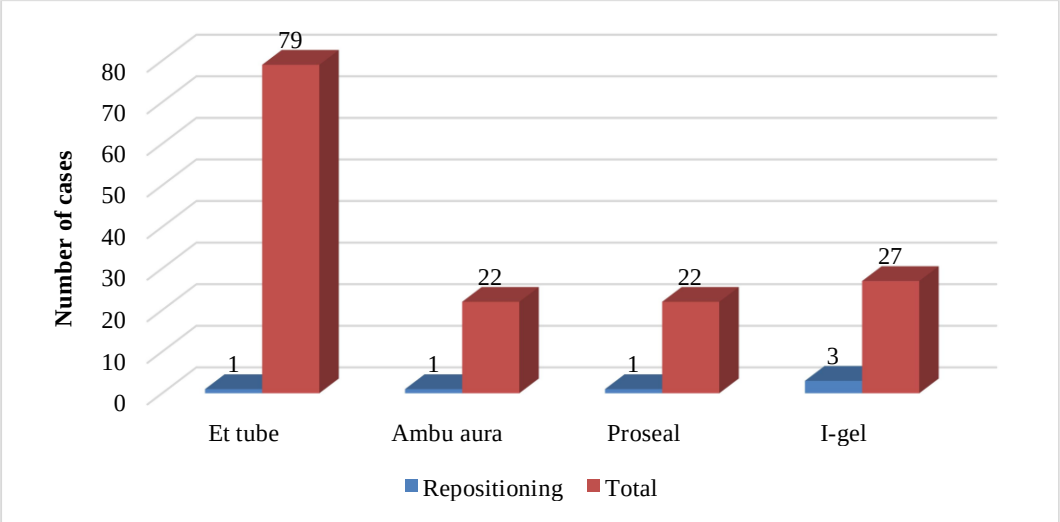

Figure 24: Proportion of repositioning of airway device intraoperatively

Table 20: Proportion of accidental extubation intraoperatively between the study groups

Accidental extubation	ET tube n (%)	Ambu Aura n (%)	Proseal n (%)	i-gel n (%)
No	79(100%)	22(100%)	22 (100%)	27(100%)
Yes	0(0.00%)	0(0.00%)	0 (0.00%)	0(0.00%)
Total	79(100%)	22(100%)	22(100%)	27(100%)

The above table shows proportion of accidental extubation intraoperatively in four different study groups. Accidental extubation did not occur in any of the four study groups.

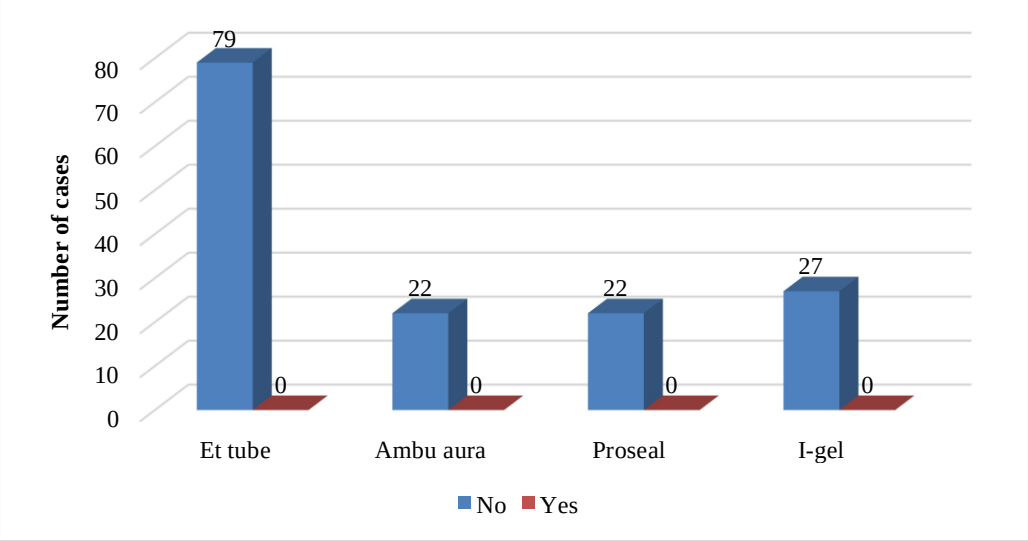

Figure 25: Proportion of accidental extubation intraoperatively

POST OPERATIVE

Table 21: Proportion of complications post operatively between the study groups

Complications	ET tube n (%)	Ambu Aura n (%)	Proseal n (%)	i-gel n (%)	P, X^2
No	62(78.48%)	21(95.45%)	22(100%)	27(100%)	0.003,14.618
Yes	17(21.52%)	1(4.55%)	0(0.00%)	0(0.00%)	
Total	79(100%)	22(100%)	22(100%)	27(100%)	

The above table shows proportion of post operative complications in four different study groups. In ET tube group complications occurred in 17(21.52%) patients and did not occur in 62(78.48%) patients, where as in Ambu Aura group complications occurred in 1(4.55%) patient and did not occur in 21(95.45%) patients, post operative complications did not occur in any patient in Proseal and i-gel group. Chi square test was applied which showed a value of 14.618 with corresponding p value of above association is significant ($p<0.05$) i.e., there is higher incidence of postoperative respiratory complication in infants who received ET tube when compared to Ambu Aura, Proseal and i-gel.

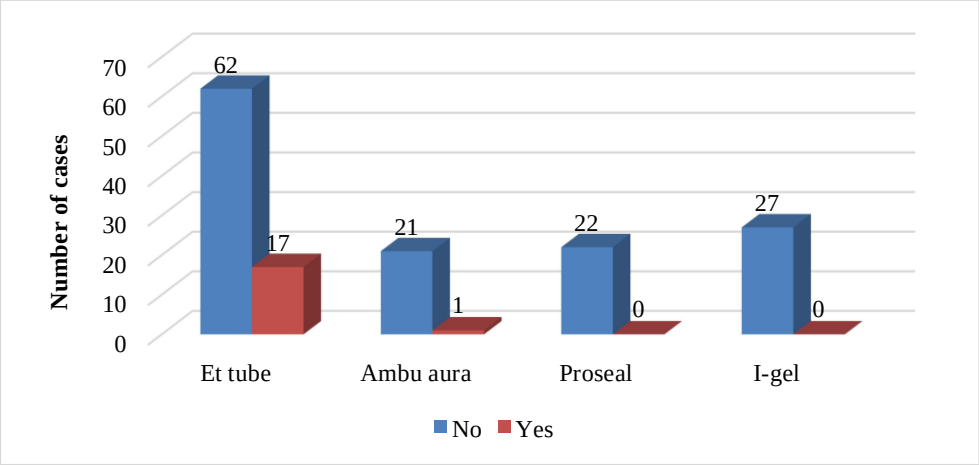

Figure 26: Proportion of complications post operatively

Table 22: Proportion of laryngospasm post operatively between the study groups

Laryngospasm	ET tube n (%)	Ambu Aura n (%)	Proseal n (%)	i-gel n (%)	P, X^2
No	71(89.87%)	22(100%)	22(100%)	27(100%)	0.072,7.595
Yes	8(10.13%)	0(0.00)	0(0.00%)	0(0.00%)	
Total	79(100%)	22(100%)	22(100%)	27(100%)	

The above table shows proportion of post operative laryngospasm in four different study groups. In ET tube group, laryngospasm occurred in 8(10.13%) patients and did not occur in 71(89.87%) patients. Laryngospasm was not observed in any of the other study groups. Chi square test was applied which showed a value of 7.595 with corresponding p value of above association is insignificant (p>0.05) i.e., there was no difference in the incidence of postoperative laryngospasm between the four airway devices in infants.

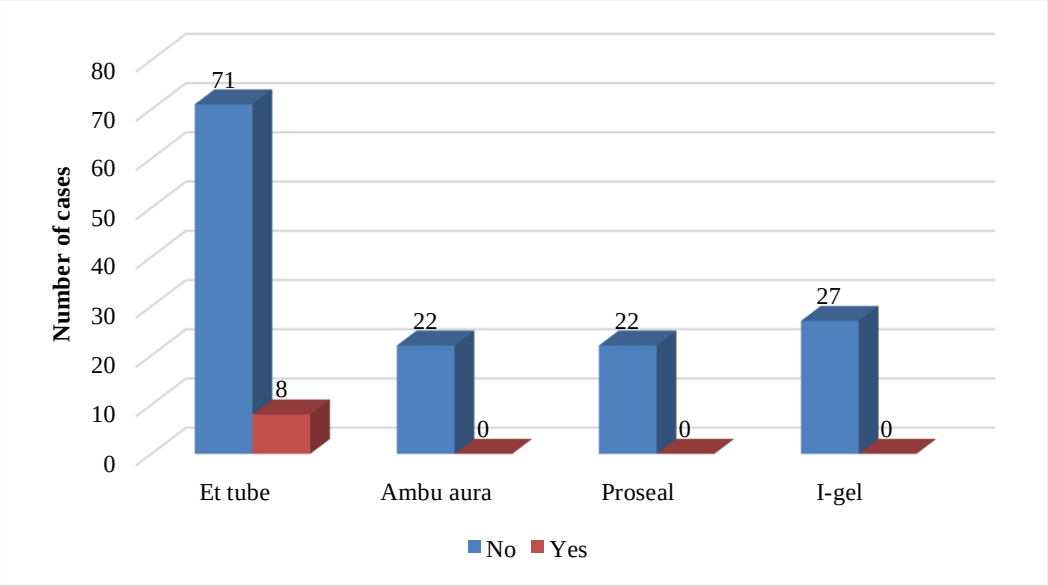

Figure 27: Proportion of laryngospasm post operatively

Table 23: Proportion of bronchospasm post operatively between the study groups

Bronchospasm	ET tube n (%)	Ambu Aura n (%)	Proseal n (%)	i-gel n (%)	P, X^2
No	77(97.47%)	21(95.45%)	22(100%)	27(100%)	0.829,1.841
Yes	2(2.53%)	1(4.55%)	0(0.00%)	0(0.00%)	
Total	79(100%)	22(100%)	22(100%)	27(100%)	

The above table shows proportion of bronchospasm post operatively in four different study groups. In ET tube group, bronchospasm occurred in 2(2.53%) patients and did not occur in 77(97.47%) patients, where as in Ambu Aura group, bronchospasm occurred in 1(4.55%) patient and did not occur in 21(95.45%) patients. Bronchospasm did not occur in any patient in Proseal group and i-gel group. Chi square test was applied which showed a value of 1.841 with corresponding p value of above association is insignificant (p>0.05) i.e., there was no difference in the incidence of postoperative bronchospasm between the four airway devices in infants.

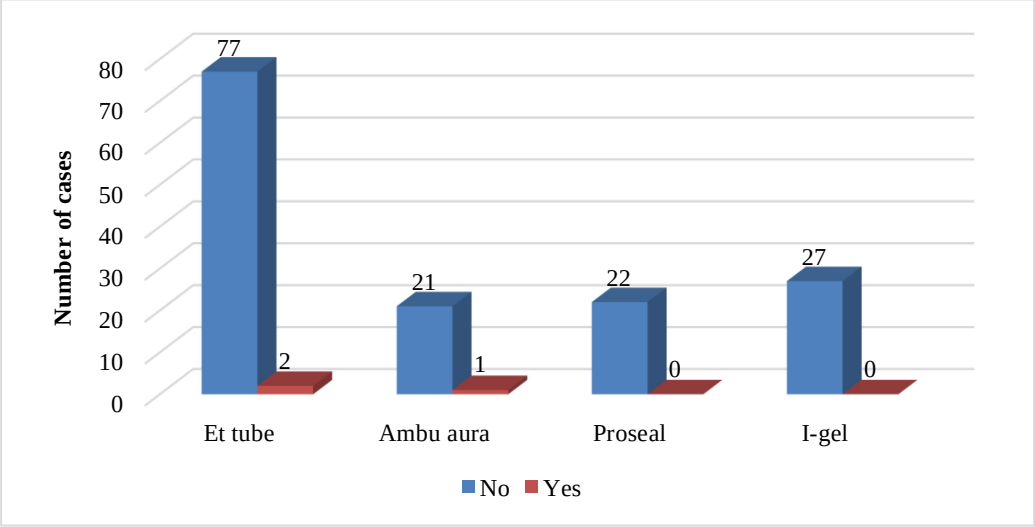

Figure 28: Proportion of bronchospasm post operatively

Table 24: Proportion of aspiration post operatively between the study groups

Aspiration	ET tube n (%)	Ambu Aura n (%)	Proseal n (%)	i-gel n (%)
No	79(100%)	22(100%)	22(100%)	27(100%)
Yes	0(0.00%)	0(0.00%)	0(0.00%)	0(0.00%)
Total	79(100%)	22(100%)	22(100%)	27(100%)

The above table shows proportion of aspiration post operatively in four different study groups. Post operatively aspiration did not occur in any study group.

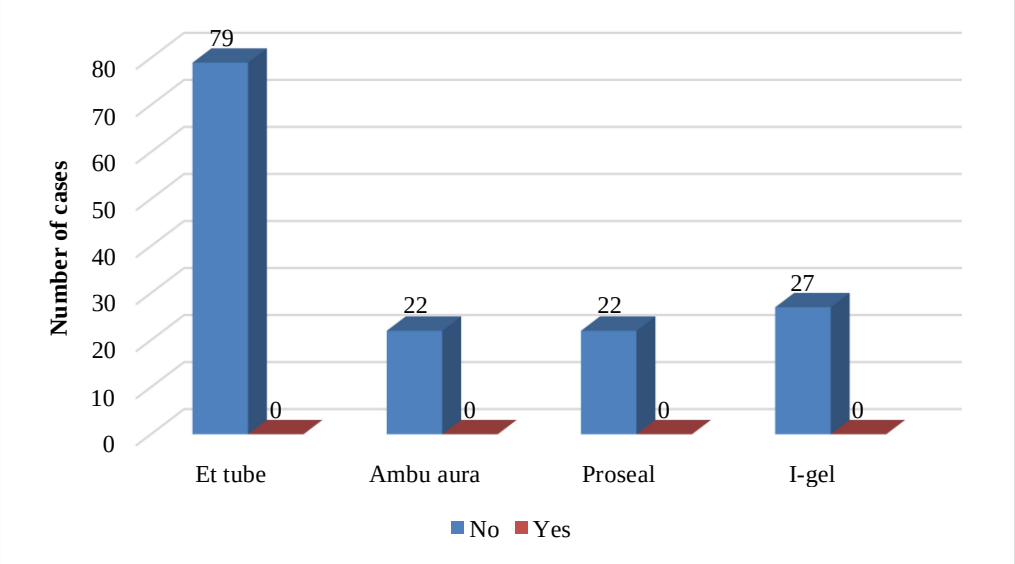

Figure 29: Proportion of aspiration post operatively

Table 25: Proportion of post extubation croup post operatively between the study groups

Post extubation croup	ET tube n (%)	Ambu Aura n (%)	Proseal n (%)	i-gel n (%)
No	79(100%)	22(100%)	22(100%)	27(100)
Yes	0(0.00%)	0(0.00%)	0(0.00%)	0(0.00%)
Total	79(100%)	22(100%)	22(100%)	27(100%)

The above table shows proportion of post extubation croup post operatively in four different study groups. Post extubation croup did not occur in any patient in any study group.

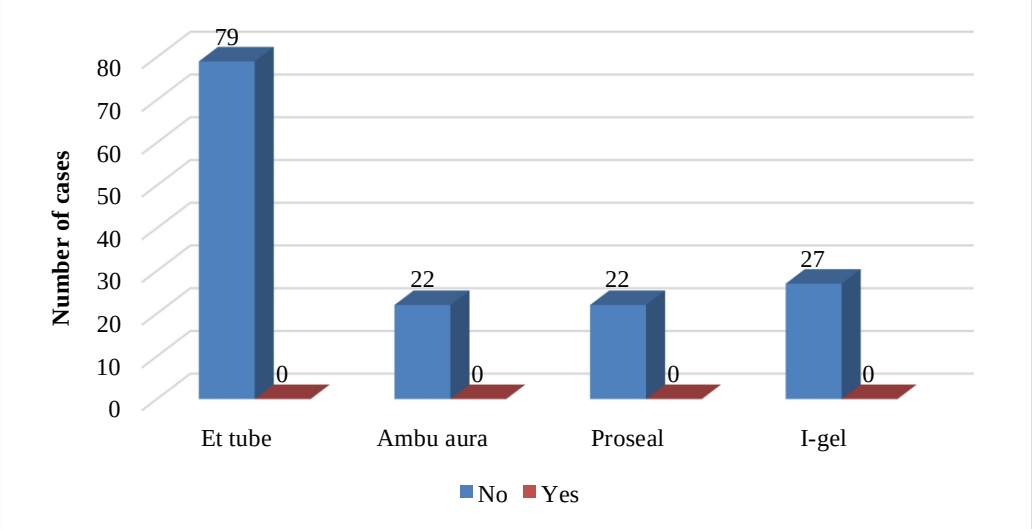

Figure 30: Proportion of post extubation croup post operatively

Table 26: Proportion of cough post operatively between the study groups

Cough	ET tube n (%)	Ambu Aura n (%)	Proseal n (%)	i-gel n (%)
No	79(100%)	22(100%)	22(100%)	27(100%)
Yes	0(0.00%)	0(0.00%)	0(0.00%)	0(0.00%)
Total	79(100%)	22(100%)	22(100%)	27(100%)

The above table shows proportion of cough post operatively in four different study groups. Post operatively cough did not occur in any patient in any study group.

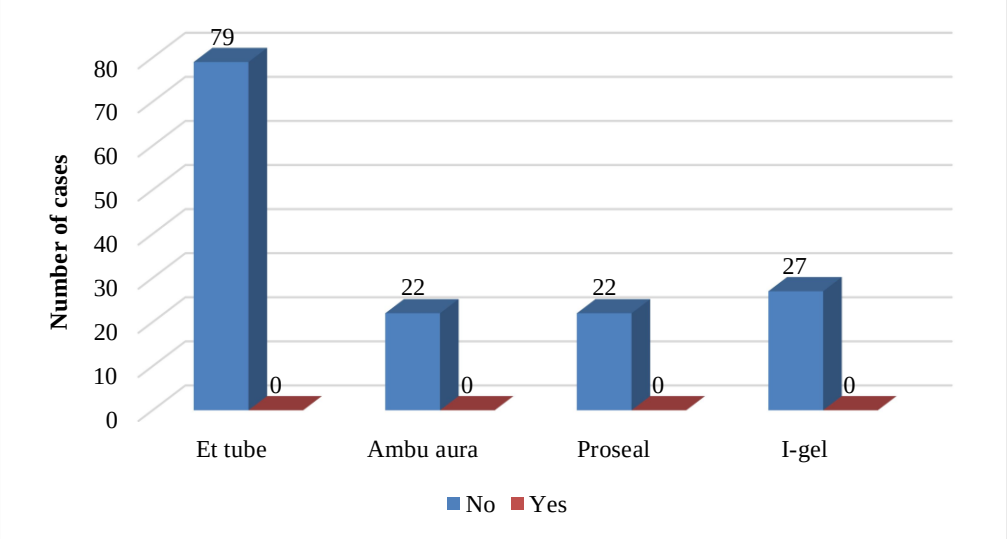

Figure 31: Proportion of cough post operatively

Table 27: Proportion of reintubation post operatively between the study groups

Re intubation	ET tube n (%)	Ambu Aura n (%)	Proseal n (%)	i-gel n (%)	P, X^2
No	77(97.47%)	22(100%)	22(100%)	27(100%)	0.835,1.822
Yes	2(2.53%)	0(0.00%)	0(0.00%)	0(0.00%)	
Total	79(100%)	22(100%)	22(100%)	27(100%)	

The above table shows proportion of re intubation post operatively in four different study groups. In ET tube group, 2 patients (2.53%) were re-intubated after extubation. Patients in other study group didn't need to be re-intubated after extubation. Chi square test was applied which showed a value of 1.822 with corresponding p value of above association is insignificant (p>0.05) i.e., there was no difference in the incidence of re intubation between the study groups in infants.

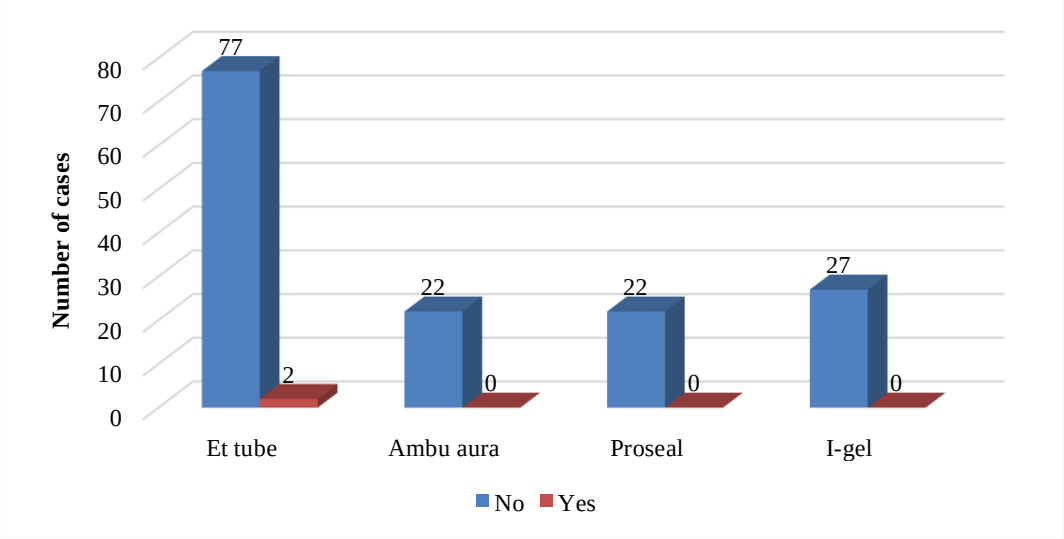

Figure 32: Proportion of reintubation post operatively

Table 28: Proportion of oxygen requirement post operatively between the study groups

Oxygen requirement	ET tube n (%)	Ambu Aura n (%)	Proseal n (%)	i-gel n (%)	P, X^2
No	59(74.68%)	21(95.45%)	22(100%)	25(92.59%)	0.005,13.328
Yes	20(25.32%)	1(4.55%)	0(0.00%)	2(7.41%)	
Total	79(100%)	22(100%)	22(100%)	27(100%)	

The above table shows proportion of oxygen requirement post operatively in four different study groups. In ET tube group oxygen was required in 20(25.32%) patients and not required in 59(74.68%) patients , in Ambu Aura group oxygen was required in 1(4.55%) patient, in Proseal group oxygen was not required in 22(100.0%) patients and in i-gel group oxygen was required in 2(7.41%) patients and not required in 25(92.59%)patients . Chi square test was applied which showed a value of 13.328 with corresponding p value of above association is significant ($p<0.05$) i.e., there was higher incidence of postoperative oxygen requirement in infants who received ET tube when compared to other study groups.

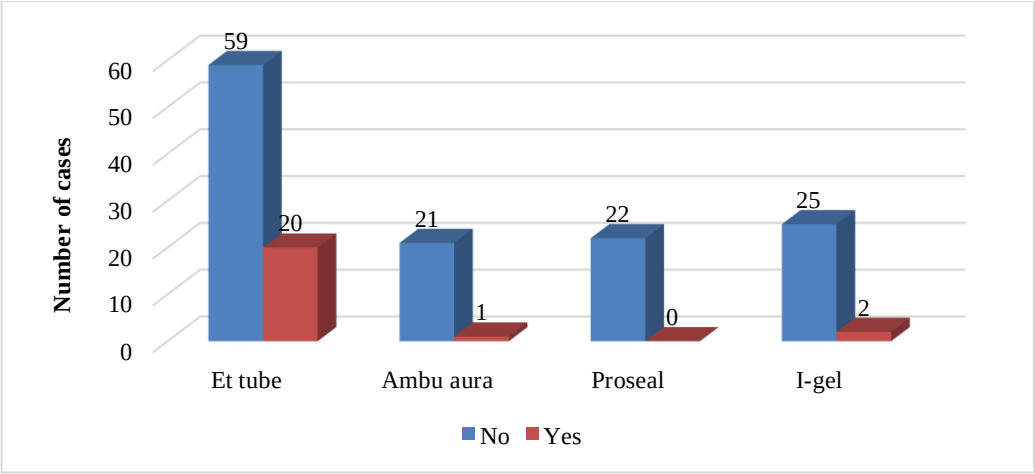

Figure 33: Proportion of oxygen requirement post operatively

Table 29: Proportion of type of analgesia used perioperatively between the study groups

Type of analgesia	ET tube n (%)	Ambu Aura n (%)	Proseal n (%)	i-gel n (%)
Iv	57(72.15%)	20(90.91%)	19(86.36%)	24(88.89%)
CNB	19(24.05%)	0(0.00%)	2(9.09%)	2(7.41%)
Local infiltration	3(3.80%)	2(9.09%)	1(4.55%)	1(3.70%)
Total	79(100%)	22(100%)	22(100%)	27(100%)

The above table shows proportion of type of analgesia used perioperatively in four different study groups. In ET tube group iv analgesia was used in 57(72.15%) patients ,and CNB was used in 19(24.05%)patients and local infiltration was used in 3(3.08%) patients , in Ambu Aura group iv analgesia was used in 20(90.91%) patients and local infiltration was used in 1(4.55%) patient, in Proseal group iv analgesia was used in 19(86.36%)patients and CNB was used in 2(9.09%) patients and local infiltration was used in 1(4.55%) patients where as in i-gel group iv analgesia was used in 24(88.89%) patients and CNB was used in 2(7.41%) patients and local infiltration was used in 1(3.70%) patient.

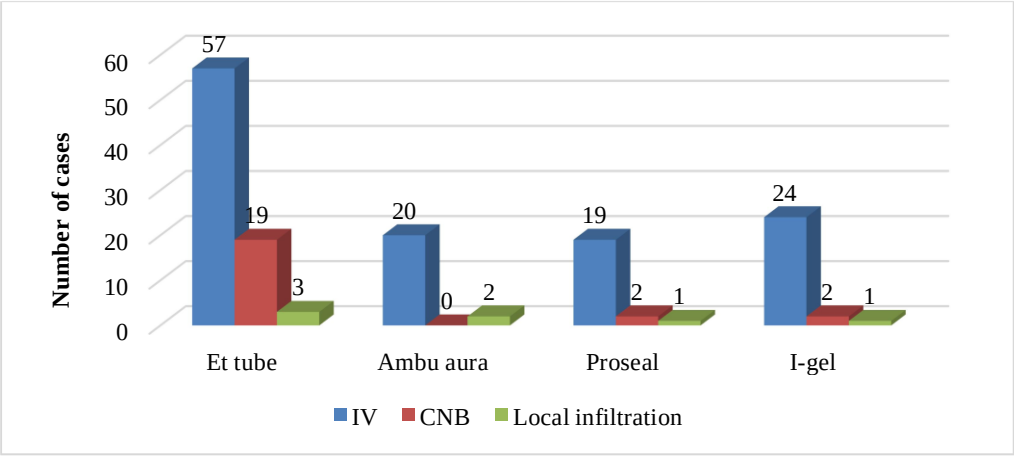

Figure 34: Proportion of type of analgesia used perioperatively

Table 30: Proportion of type of surgeries

Type of surgery	n (%)
Laparoscopy	24(16.00%)
Open	75(50.00%)
Cystoscopy	45(30.005)
Thoracoscopy	5(3.33%)
Bronchoscopy	1(0.67%)
Total	150(100%)

The above table shows proportion of type of surgeries occurred in infants ,in which majority are open 75(50.00%) surgeries, followed by cystoscopic 45(30.00%) surgeries, laparoscopic 24(16.00%) surgeries, thorascopic 5(3.33%) surgeries and 1(0.67%) bronchoscopy.

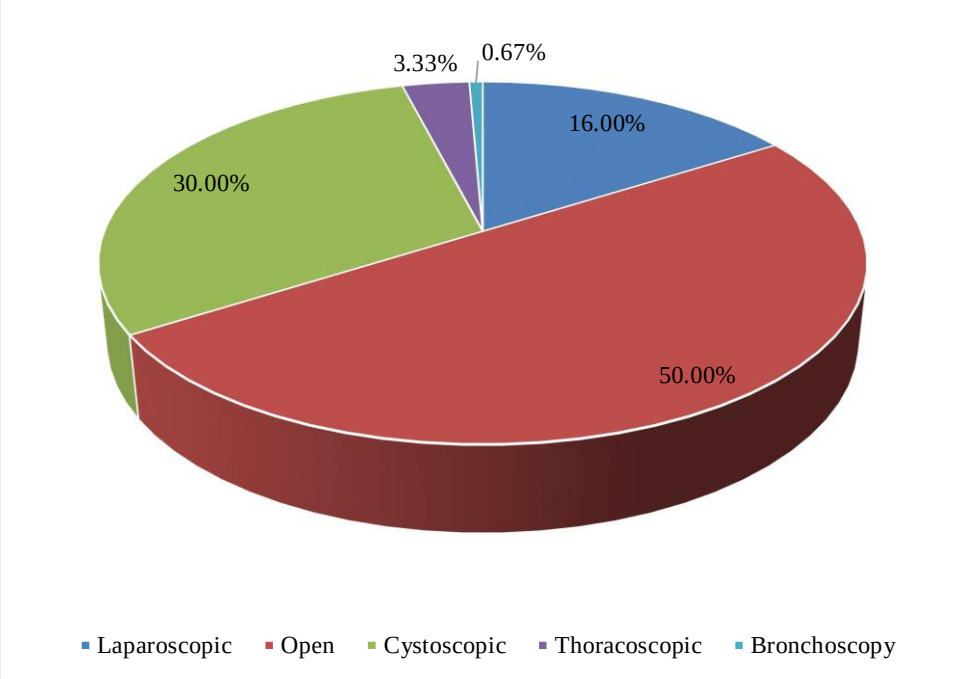

Figure 35: Proportion of type of surgeries

Table 31: Proportion of complications in neonates (<1month)

Complications	Yes/ No	ET tube n (%)	Ambu Aura n (%)	Proseal n (%)	i-gel n (%)	P value, X^2
Induction						
Change of airway device due to leak	Yes	1(8.33%)	0(0%)	1(33.33%)	0(0%)	0.417, 1.747
	No	11(91.67%)	0(0%)	2(66.67%)	2(100%)	
Intraoperative						
Overall complications	Yes	3(25%)	0(0%)	0(0%)	0(0%)	0.468, 1.518
	No	9(75%)	0(0%)	3(100%)	2(100%)	
Bronchospasm	Yes	1(8.33%)	0(0%)	0(0%)	0(0%)	0.801, 0.443
	No	11(91.67%)	0(0%)	3(100%)	2(100%)	
Desaturation	Yes	2(16.67%)	0(0%)	0(0%)	0(0%)	0.624, 0.944
	No	10(83.33%)	0(0%)	3(100%)	2(100%)	
Change of device	Yes	0(0%)	0(0%)	0(0%)	0(0%)	
	No	12(100%)	0(0%)	3(100%)	2(100%)	
Displacement of device	Yes	0(0%)	0(0%)	0(0%)	0(0%)	
	No	12(100%)	0(0%)	3(100%)	2(100%)	
Postoperative						
Over all Complications	Yes	2(16.67%)	0(0%)	0(0%)	0(0%)	0.624, 0.944
	No	10(83.33%)	0(0%)	3(100%)	2(100%)	
Laryngospasm	Yes	0(0%)	0(0%)	0(0%)	0(0%)	
	No	12(100%)	0(0%)	3(100%)	2(100%)	
Bronchospasm	Yes	1(8.33%)	0(0%)	0(0%)	0(0%)	0.801, 0.443
	No	11(91.67%)	0(0%)	3(100%)	2(100%)	
Reintubation	Yes	0(0%)	0(0%)	0(0%)	0(0%)	
	No	12(100%)	0(0%)	3(100%)	2(100%)	
Oxygen requirement	Yes	5(41.67%)	0(0%)	0(0%)	0(0%)	0.229, 2.951
	No	7(58.33%)	0(0%)	3(100%)	2(100%)	

The above table shows proportion of perioperative respiratory complications in neonates (<1 month). Airway device was changed during induction due to leak in 1(8.33%) neonate in ET tube group, 1(33.33%) neonate in Proseal group and airway device was not changed in other study groups. Chi square test was applied which showed a value of 1.747 with corresponding p value of (0.417) which is statistically insignificant i.e., there was no difference in the incidence of airway device change due to leak between the four airway devices in neonates.

Intraoperatively bronchospasm occurred in 1(8.33%) neonate in ET tube group and did not occur in other study groups. Chi square test was applied which showed a value of 0.443 with corresponding p value of (0.801) which is statistically insignificant i.e., there was no difference in the incidence of intraoperative bronchospasm between the four airway devices in neonates. Desaturation occurred in 2(16.67%) neonates in ET tube group and did not occur in other study groups. Chi square test was applied which showed a value of 0.944 with corresponding p value of (0.624) which is statistically insignificant i.e., there was no difference in the incidence of intraoperative desaturation between the four airway devices in neonates. Over all intraoperative complications occurred in 3(25%) neonates in ET tube group and in 1(33.33%) neonate in Proseal group. Chi square test was applied which showed a value of 1.518 with corresponding p value of (0.468) which is statistically insignificant i.e., there was no difference in the intraoperative incidence of respiratory complication between the ET tube, Ambu Aura, Proseal and i-gel in neonates.

Postoperatively bronchospasm occurred in 1(8.33%) neonate in ET tube group and did not occur in other study groups. Chi square test was applied which showed a value of 0.443 with corresponding p value of (0.801) which is statistically

insignificant i.e., there was no difference in the incidence of postoperative bronchospasm between the four airway devices in neonates. Postoperative oxygen requirement was there in 5(41.67%) neonates in ET tube group and not required in other study groups. Chi square test was applied which showed a value of 2.951 with corresponding p value of (0.229) which is statistically insignificant i.e., there was no difference in the incidence of postoperative oxygen requirement between the four airway devices in neonates.

DISCUSSION

There are numerous studies that compared the perioperative respiratory complications experienced by the paediatric patients when using endotracheal tubes and laryngeal mask airways, but none that specifically looked at the perioperative respiratory complications experienced by infants and neonates when using ETT, Ambu Aura, Proseal, and i-gel. To our knowledge, this study is the first to examine the effect of Ambu Aura, Proseal, i-gel and endotracheal tubes on the incidence of perioperative respiratory adverse events in infants and neonates.

Because of its ease of insertion and potential lower risk of tracheal trauma, the LMA has gained widespread acceptance as an alternative to traditional ETT intubation. A higher cuff pressure can be used to achieve PPV with an LMA, but this does not provide an airtight seal and increases the risk of regurgitation and pulmonary aspiration. Second-generation supraglottic airway devices have been introduced, allowing for higher positive pressure and lowering the risk of aspiration and respiratory complications. **Seung H.YuBS** et.al conducted a meta analysis and found that the LMA is associated with a decreased risk of several postoperative airway complications when compared to the ETT [(22)] which is comparable to our study where the post operative respiratory complications are significant in infants who received ETT when compared to Ambu Aura , proseal and i-gel which is statistically significant (p=0.003)

Luce et al[(16)] in a meta-analysis, compared the laryngeal mask airway with tracheal intubation for perioperative respiratory problems in paediatric patients and concluded that fewer common postoperative respiratory problems when laryngeal mask airways are used for paediatric anaesthesia , which is comparable to our study

where the post operative respiratory complications are fewer in infants who received Ambu Aura 1(4.55%), Proseal 0(0.00) and i-gel 0(0.00) with statistically significant value of p=0.003, when compared to ETT(21%). Post operative oxygen requirement is the most common respiratory complication in infants 20(25.32%) who received ETT which is statistically significant (p=0.005) when compared to other study groups. This difference is likely due to intubation and use of muscle relaxant leading to fall in FRC and atelectasis.

Lingzhi Li et al[8] in a meta analysis compared perioperative respiratory complications in children who received laryngeal mask airways and other airways, concluded that LMA's considerably reduced the perioperative adverse events in comparison to endotracheal tubes which is similar to our study where the perioperative respiratory complications are considerably low in infants who received Ambu Aura, Proseal and i-gel when compared to ETT which is statistically significant ($p<0.05$).

In our study, intraoperative respiratory complications were not significant (p=0.324) in infants who received ETT, Ambu Aura, Proseal and i-gel. There are no episodes of intra operative laryngospasm in infants who received ETT, Ambu Aura, Proseal and i-gel intraoperatively and post operatively laryngospasm was occurred in infants who received ETT in 8(10.13%) patients and not occurred in other study groups, but this proportion of laryngospasm was not statistically significant among the study groups (p=0.072). Intraoperatively, there were episodes of bronchospasm in infants who received ETT 3(3.80%) patients and not occurred in infants who received Ambu Aura, Proseal and i-gel but the episodes of bronchospasm were not statistically significant among the study groups (p=0.587) . Post operatively bronchospasm was

occurred in infants who received ETT 2(2.53%) patients, and Ambu Aura 1(4.55%) patient and not occurred in other study groups. In the study conducted by **Thomas F. Edrake-Brockman et al**[11] concluded that in infants LMAs were associated with clinically significant fewer perioperative respiratory adverse events than endotracheal tubes which is comparable to our study.

Subgroup analysis on perioperative respiratory complications in neonates due to ET tube, Ambu Aura, Proseal, and i-gel was performed in our study. In neonates, the incidence of intraoperative respiratory complications due to ET tube, Ambu Aura, Proseal, and i-gel was not statistically significant (p=0.468), and the incidence of postoperative respiratory complications was also not statistically significant (p=0.624). There were no studies available to compare our findings in neonates. It was found that supraglottic airway devices such as Ambu Aura, Proseal, and i-gel are safe to use in neonates and infants undergoing surgical and diagnostic procedures under general anaesthesia.

The current study found that for infants and neonates receiving general anaesthesia for surgery, Ambu Aura, Proseal, and i-gel were associated with a lower incidence of laryngospasm and bronchospasm during emergence, as well as a lower incidence of postoperative oxygen requirement, than the ETT. Because the ETT is placed in the trachea beyond the vocal cords, it can irritate the airway and alter the airway physiology, resulting in a higher incidence of respiratory complications.

In our study ETT was the most commonly used airway device in open surgeries in 56(70.89%) patients, in laparoscopic surgeries 14(17.72%) patients and in thoracoscopic surgeries 5(6.33%) patients where the majority of cases involved bowel handling in 26(35.14%) patients and in head and neck surgeries 10(13.51%) patients.

Proseal was the most commonly used airway device in cystoscopic procedures in 16 (72.73%) patients. Use of ETT in laparoscopic surgeries especially in surgeries involved bowel handling was due to the personal preference of the attending anaesthetist in view of increased risk of regurgitation with LMA which is comparable to the study conducted by **Seung H. Yu et al**[22] where the incidence of regurgitation in the LMA group was (20.0%) compared with the ETT group (18.8%), and risk of aspiration in high risk patients when LMA was used but pulmonary aspiration with the LMA is uncommon according to the meta analysis conducted by **Joseph R.Brimacombe et al**[23]. Preference for using Proseal in cystoscopic procedures may be due to low risk of regurgitation and adequate oro pharyngeal leak pressure.

In our study ETT was the most commonly used airway device in lateral position in 3(3.80%) patients and in prone position in 19(24.05%) patients while Proseal was the most commonly used airway device in lithotomy position in 16(72.73%) patients.

According to the current study, using the Ambu Aura, Proseal, and i-gel instead of the ETT reduces the risk of postoperative bronchospasm, laryngospasm, and oxygen requirement. The SGA devices can be used to maintain airways in neonates and infants undergoing elective surgery who do not have airway compromise according to the consistent results of all the examined studies.

Study Strength

1. This was the first study to conduct in neonates and infants to find out and compare the incidence of perioperative respiratory complications due to ET tube, Ambu Aura, Proseal and i-gel.

Study Limitations

1. Due to the observational nature of our study, the inherent bias in trial design could not be entirely excluded.

2. The outcomes of this study cannot be generalised because it was only conducted at one centre.

3. The fact that the anaesthetic management was left up to the anesthesiologist in charge, which could differ from person to person, was a drawback of this study.

4. However, the majority of our study population consisted of patients who were deemed fit by their attending anaesthetist for care with either an SGA or an endotracheal tube. As a result, generalising our findings to all infants is not possible.

5. The sample size may be small because this was a time-limited study. To replicate our findings, similar studies with a large enough sample size are required.

CONCLUSION

It was found that ETT has a greater incidence of post-operative respiratory complications than Ambu Aura, i-gel, and Proseal. In comparison to other study groups, oxygen supplementation was required in more number of patients in ETT group. There was no statistically significant difference in other complications between the study groups. The proseal was the most frequently used airway device in cystoscopic procedures, whereas the ETT was most frequently used in laparoscopic surgeries, thoracotomies, head and neck surgeries, as well as in prone and lateral positions. Supraglottic airway devices such as Ambu Aura, Proseal, and i-gel are safe to use in neonates and infants undergoing surgical and diagnostic procedures under general anaesthesia.

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ANNEXURE I

अखिल भारतीय आयुर्विज्ञान संस्थान, जोधपुर
All India Institute of Medical Sciences, Jodhpur
संस्थागत नैतिकता समिति
Institutional Ethics Committee

No. AIIMS/IEC/2021/ 3479 Date: 12/03/2021

ETHICAL CLEARANCE CERTIFICATE

Certificate Reference Number: **AIIMS/IEC/2021/3314**

Project title: **"Impact of various airway devices used in infants under General anaesthesia on perioperative respiratory complications- A prospective observational study"**

Nature of Project:	**Research Project Submitted for Expedited Review**
Submitted as:	**M.D. Dissertation**
Student Name:	**Dr. Pilli Sachith Raju**
Guide:	**Dr. Pradeep Kumar Bhatia**
Co-Guide:	**Dr. Shilpa Goyal, Dr. Rakesh Kumar & Dr. Swati Chhabra**

Institutional Ethics Committee after thorough consideration accorded its approval on above project.

The investigator may therefore commence the research from the date of this certificate, using the reference number indicated above.

Please note that the AIIMS IEC must be informed immediately of:

- Any material change in the conditions or undertakings mentioned in the document.
- Any material breaches of ethical undertakings or events that impact upon the ethical conduct of the research.

The Principal Investigator must report to the AIIMS IEC in the prescribed format, where applicable, bi-annually, and at the end of the project, in respect of ethical compliance.

AIIMS IEC retains the right to withdraw or amend this if:

- Any unethical principle or practices are revealed or suspected
- Relevant information has been withheld or misrepresented

AIIMS IEC shall have an access to any information or data at any time during the course or after completion of the project.

Please Note that this approval will be rectified whenever it is possible to hold a meeting in person of the Institutional Ethics Committee. It is possible that the PI may be asked to give more clarifications or the Institutional Ethics Committee may withhold the project. The Institutional Ethics Committee is adopting this procedure due to COVID-19 (Corona Virus) situation.

If the Institutional Ethics Committee does not get back to you, this means your project has been cleared by the IEC.

On behalf of Ethics Committee, I wish you success in your research.

Dr. Praveen Sharma
Member Secretary
Member secretary
Institutional Ethics Committee
AIIMS,Jodhpur

asni Phase-2, Jodhpur, Rajasthan-342005; **Website:** www.aiimsjodhpur.edu.in; **Phone:** 0291-2740741 Extn. 3109
E-mail : ethicscommittee@aiimsjodhpur.edu.in; ethicscommitteeaiimsjdh@gmail.com

ANNEXURE II

All India Institute of Medical Sciences, Jodhpur, Rajasthan

Informed Consent Form

Title: Impact of various airway devices (ETT, Ambu Aura, Proseal, I gel) used in infants under general anaesthesia on perioperative respiratory complications - a prospective observational study.

Name of PG Student: Dr P Sachith Raju

Telephone no: 8978861056 Patient Identification No: _____

I_____M/o or F/o or G/o_____R/o _____give my full, free, voluntary consent for my patient to be a part of the study "**impact of various airway devices (ETT, Ambu Aura, Proseal, i-gel) used in infants under general anaesthesia on perioperative respiratory complications- a prospective observational study.**" The procedure and nature of which has been explained to me in my own language to my full satisfaction. I confirm that i have had the opportunity to ask questions. I understand that my patient's participation is voluntary, and i am aware of my right to opt out of the study at any time without giving any reason.

I understand that the information collected about my patient and any of my patient's medical records may be looked at by responsible individuals from Aiims Jodhpur or from regulatory authorities. I give permission for these individuals to have access to my patient's records. I also give my consent for publication of my medical data for scientific and academic purposes.

Date: _____

Place:_____ _____
Signature/Left thumb impression

This to certify that the above consent has been obtained in my presence.

Date: _____ _____

Place: _____ Signature of Principal Investigator

1. Witness 1

Signature

Name: _____

Address: _____

2. Witness 2

Signature

Name: _____

Address: _____

ANNEXURE III

अिखल भारतीय आयुिवFान संथान, जोधपुर, राजथान

सूिचत सहमित ◌ा

शीषक: पेरऑपरेिटव ासन जिटलताओं पर सामाQसंयाहरण के तहत िशशुओं मÓउपयोग

िकए जाने वाले िविभUवायुमाग उपकरणों (ETT, अंबु ऑरा, ोसील, आई जेल) का Ôभाव -

एक संभािवत अवलोकन संबंधी

अोयन।पीजी छाा का नाम: डॉ पी सिचत

राजू

टेलीफोन नंबर: 8978861056 रोगी पहचान सं%ा: _____

I_____M/o या F/o या G/o_____

R/o_____मेरे मरीज को "िविभUवायुमाग उपकरणों (ETT, Ambu Aura, Proseal, i-gel) के Ôभाव" के अÓयन का िह4ा बनने के िलए अपनी पूण, मु4, 4ैिDछ सहमित देता 5ं।) पेरऑपरेिटव ासन जिटलताओं पर सामाQ संयाहरण के तहत िशशुओं मÓ उपयोग िकया जाता है - एक संभािवत अवलोकन संबंधी अÓयन। िजसकी ◌ाियाा और 4Vप मुझे मेरी भाषा मÓपूरी संतुि´ के साथसमझाया गया है। म पुि´ करता 5ं िक मुझे Ô पूछने का अवसर िमला है। म समझता 5ं
िक मेरे मरीज की भागीदारी 4ैिDछ है, और म िबना कोई कारण बताए िकसी भी समय अोयन से बाहर िनकलने के अपने अिधकार से अवगत 5ं।
म समझता 5ं िक मेरे मरीज और मेरे मरीज के िकसी भी मेिडकल रकॉड के बारे मÓएकाकी गई जानकारी को एt जोधपुर के िज◌ेदार Dि4यों या िनयामक अिधकारयों ◌ारा देखा जा सकता है। म इन Dि4यों को मेरे मरीज के रकॉड तक प5ंच की अनुमित देता 5ं। मवैyािनक और शै◌िणक उहे4ों के िलए अपने िचिकTा डेटा के Ôकाशन के िलए भी अपनी सहमित देता/देती 5ं।

तारीख:_____ _____

3थान:_____ ह™ाार/बाएं अंगूठे का िनशान

यह Ôमाणित िकया जाता है िक उपरो4 सहमित मेरी उपि3थित मÓ◌ा™ की गई है।

तारीख:_____ _____

3थान: _____ Ôधान अ◌ेषक के ह™ाार

1. सा□ी 1
ह™ा◌ार
नाम:_____
पता:_____

2. सा□ी 2
ह™ा◌ार
नाम:_____
पता: _____

ANNEXURE IV

All India Institute of Medical Sciences Jodhpur, Rajasthan

All India Institute of Medical Sciences

Jodhpur, Rajasthan

PATIENT INFORMATION SHEET

Patient name:

Patient id:

Title of study: Impact of various airway devices used in infants under general anaesthesia on perioperative respiratory complications- a prospective observational study.

Purpose of study: To find out and compare the incidences of perioperative respiratory complications while use of various airway devices in infants under General anaesthesia**.**

Study design: Observational study.

I have been explained in my own understanding language by the Principal Investigator that they are doing this study and the risk and benefits associated with it.

I have been informed that I can withdraw my patient from the study at any time.

The data obtained from my patient will be used for the purpose of the study only. All records will be kept confidential.

Benefits of the study to the patients:

Any potential risks to the participants: No additional risks

Details of the candidate with phone number: Dr Sachith Raju

Post Graduate, Anaesthesiology & Critical Care

AIIMS Jodhpur

8978861056

ANNEXURE V

अिखल भारतीय आयुिवyान संउथान
जोधपुर, राजउथान अिखल भारतीय
आयुिवyान संउथान
जोधपुर, राजउथान

रोगी सूचना पा

रोगी का नाम:

रोगी आईडी:

अaन का शीषक: पेरीओपरे िटव ास जिटलताओं पर सामाq एनेउथीिसया के तहत

िशशुओं मó उपयोग िकए जाने वाले िविभ वायुमाग उपकरणों का ूभाव - एक संभाियत अवलोकन संबंधी अóयन।

सामाq सं yाहरण के तहत िशशुओं मó िविभ वायुमाग उपकरणों का उपयोग करते समय सन संबंधी जिटलताएँ।

अóयन िडजाइन: अवलोकन संबंधी अóयन।

ूधान अेषक ारा मुझे मेरी अपनी समझ की भाषा मó समझाया गया है िक वे यह अ और इससे जुड़े जोिखम और लाभ कर रहे ह।

मुझे सूिचत िकया गया है िक म अपने रोगी को िकसी भी समय अaन से वापस ले सकता 5ँ। मेरे रोगी से ा™ डेटा का उपयोग के वल अaन के ूयोजन के िलए िकया जाएगा। सभी रकॉड गोपनीय रखे जाएं गे।

रोिगयों को अóयन के लाभ:

ितभािगयों के िलए कोई संभाियत जोिखम: कोई अित4 जोिखम नहीं

फोन नंबर के साथ उीदवार का िववरण: डॉ पी सिचत राजू

पो™ ेजुएट, एनेिउथिसयोलॉजी और ि िटकल
के यरए, जोधपुर
8978861056

ANNEXURE VI

Performa

Name- Age-

Sex - Weight-

ASA 1/11-

Procedure-

Type of surgery-

Position during surgery-

Duration of surgery-

Preoperative –

H/O URI/Asthma/ Allergy atopy/ eczema/ rhinitis/ food allergy/ previous allergic tests/pollens or animal allergy/ passive smoking/obstructive sleep disorders.

Anticipated difficult airway: Yes/No _____

H/O occurrence of asthma/eczema in first-degree relatives

Morbid obesity/pre-existing pulmonary disorder/ pre-existing neurological disorder

Premedication:

Yes/ No :

If yes, specify:

Induction-

Inhalation/ Intravenous / Both

Use of muscle relaxant: Yes / No

Bag Mask Ventilation: Easy/ difficult

Difficult intubation: yes/no

Type of airway devices used: ET tube/i-GEL/Proseal/Ambu Aura

Laryngoscope use Yes/ No (if yes type of laryngoscope) _____

No of attempts:

Change of devices: yes/no

If yes, reason:

Type of surgery- open/laparoscopic

Position of infants during surgery:

INTRAOPERATIVE:

Laryngospasm:

Bronchospasm:

(Include all the intraop complications):

Episodes of desaturation:

Change in devices:

Displacement of device:

Accidental extubation of device:

Extubation: Deep/ awake:

POSTOPERATIVE

Laryngospasm:

Bronchospasm:

Aspiration:

Cough/cyanosis:

Blood stained device:

Postextubation croup:

Re-intubation:

Requirement of postoperative respiratory support (O2 requirement/ mechanical ventilation)-

TYPE OF ANALGESIA TECHNIQUE: CNB/PNB/IV/LIA

REASON FOR SELECTION OF AIRWAY DEVICE: ET tube/i-Gel/ PROSEAL/AMBU AURA

1. Personal preference-
2. Indication /reason (if any)-

EXPERIENCE OF THE ANAESTHETIST IN CHARGE OF AIRWAY MANAGEMENT:

PLAGIARISM CHECK CERTIFICATE