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COMPARATIVE STUDY OF I-GEL VERSUS INTUBATING LMA IN PAEDIATRIC OPHTHALMIC SURGERIES

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KEYWORDS :

INTRODUCTION

Airway management is a critical component of anaesthesia, particularly in paediatric patients undergoing surgical procedures. In the realm of ophthalmic surgeries, where precision and stability are paramount, ensuring an adequate airway is essential for both the safety and comfort of the patient. Traditional endotracheal intubation has long been the gold standard for airway management; however, it is often associated with increased trauma to the airway, longer preparation times, and potential complications such as laryngospasm and airway obstruction (1,2).

In recent years, supraglottic airway devices (SADs) have emerged as effective alternatives in paediatric anaesthesia, providing a less invasive means of securing the airway. Among these devices, the I-GEL and the intubating Laryseal-Pro have gained prominence due to their unique design features and clinical benefits. I-GEL is a second-generation SAD characterized by its non-inflatable cuff and anatomical design that allows for a secure fit in the pharyngeal space. Conversely, the Laryseal-Pro is designed specifically for facilitating endotracheal intubation while still functioning as an SAD, offering higher airway sealing pressures and improved ventilation capabilities (3,4).

Despite their widespread use, there remains a paucity of comparative studies evaluating the efficacy and safety of these two devices specifically in paediatric populations undergoing ophthalmic surgeries.

This study aims to fill this gap by conducting a comparative analysis of I-GEL versus intubating LMA (Laryseal-Pro) in paediatric ophthalmic surgeries. The primary objectives include first time successfully insertion, the time of insertion. The sealing pressure, the haemodynamic stability after insertion and airway complication after using the laryseal pro and Igel. By interpreting the differences and similarities between these two devices, this research seeks to provide valuable insights that can guide anaesthetic practice and improve patient outcomes in paediatric ophthalmic procedures(2,3).

AIMS & OBJECTIVES

Primary Aim

To conduct a comprehensive comparison between Laryseal Pro (intubating LMA) and I-gel in pediatric ophthalmic surgeries under general anesthesia.

Primary Objective

- To evaluate the first-time successful insertion rate of both devices

Secondary Objectives

- To measure and compare the time required for insertion
- To assess the ease of insertion for both devices
- To determine and compare the airway sealing pressure achieved by each device
- To monitor and analyse hemodynamic parameters during device use
- To document and compare postoperative complications associated with each device

MATERIALS & METHODS

Study Design

- **Study Type:-** It will be prospective Randomised Comparative interventional study
- **Study Site:-** M and J institute of ophthalmology, civil hospital Ahmedabad
- **Study Duration:** October2024 to March 2025
- **Sample Size**

For comparing two proportions we'll use the following formula:

$n = (Z\alpha/2 + Z\beta)^2 * [p1 (1-p1) + p2 (1-p2)] / (p1 - p2)^2$

Where: n = sample size per group $Z\alpha/2$ = Z score for desired confidence level (1.96 for 95% confidence) $Z\beta$ = Z score for desired power (0.84 for 80% power) p1 = expected proportion in group 1 (I-GEL) p2 = expected proportion in group 2 (LMA PROSEAL)

Based on previous studies: p1 (I-GEL success rate) = 0.94 p2 (LMA PROSEAL success rate) = 0.82. Adjusted parameters: p1 = 0.95 (I-GEL success rate) p2 = 0.80 (LMA PROSEAL success rate) Confidence level = 90% ($Z\alpha/2 = 1.645$) Power = 80% ($Z\beta = 0.84$)

Based on these calculations, the estimated sample size is 42 patients per group, for a total of 84 patients using R software.

To make up for protocol violation/attrition 10% was added to the calculated sample size i.e., 42+5=47 for each group

- Burden of Cost: - I-gel and laryseal pro both available at - M and J institute of ophthalmology, civil hospital Ahmedabad. If instrument not available than that expenses of instrument I will bear.

Patient Selection

Inclusion Criteria

1) Patient's Guardian consent.
2) Patients aged 5-12 yrs
3) ASA Grade I and II
4) Elective Ophthalmic surgeries under general anaesthesia
5) Modified Mallampati Grade I or II
6) Duration of Surgery — Max 2 hours
7) Weight of pt- up to 60kg

Exclusion Criteria

1. Patient's Gurdian refusal.
2. Patients of any pathology of neck, upper respiratory tract or upper alimentary tract and oral cavity.
3. ASA Grade III, IV
4. Patients with mouth opening <2.5cm
5. Patients with history, hepatic, cardiac, renal abnormality, significant GERD, increased risk of gastric aspiration.
6. Sore throat or URTI

After the Institutional Ethics Committee approval, CTRI registration and duly signed informed and written consent total of 94 patients will be divided into two groups with 47 patients in each group Group A for patients where Igel will be inserted and Group B for patients where laryseal pro will be inserted by computer generated randomization.

All preoperative assessment of the patient including history, general examination. Systemic examination, with all required investigations will be done a day before the procedure. Patient will be kept nil per oral for 6 hours before the surgery Informed written consent will be taken from patient's guardian own language and Assent consent will be taken from patient in the preparation room. An intravenous line with proper size will be secured and hydration will be started with appropriate intravenous fluids. In operative room a multi-channel monitor will be attached to the patients for continuous Electrocardiogram (ECG), non-invasive Blood Pressure (NIBP), Arterial Oxygen Saturation(SpO2)

and end-tidal CO2(EtCO2) monitoring.

All patients will be premedicated with inj. Glycopyrrolate 4mcg/kg IV, inj. Ondansetron 0.15mg/kg IV, and inj. Fentanyl 1mcg/kg IV.

Preoxygenation will be done with 100% O2 for three to five minutes via appropriate size mask and breathing circuit.

Induction will be done with inj. Propofol 2-3mg/kg IV and inj. Succinylcholine 2mg/kg IV to facilitate Igel insertion and laryseal pro in respective group of patients.

Technique:

The sizes of the Igel and Laryseal pro will be selected according to patient's body weight

For I gel: -
- Size 1 for weight 2-5kg
- Size 1.5 for weight 5-12kg
- Size 2 for weight 10-25kg
- Size 2.5 for weight 25-35kg
- Size 3 for weight 30-60kg

For Laryseal Pro:
- Size 1 for weight <5kg
- Size 1.5 for weight 5-10kg
- Size 2 for weight 10-20kg
- Size 2.5 for weight 20-30kg
- Size 3 for weight 30-50kg
- Size 4 for weight 50-70kg

After lubricating the back of cuffed part of I gel, it will be held firmly with its cuffed outlet facing towards chin. Then it will be gently pressed down into the mouth in direction towards the hard palate until a definitive resistance will be felt. The Laryseal pro is a tube with an inflatable cuff that is inserted into the oropharynx The deflated cuff is inserted into the mouth with the index finger; the cuff is guided into place above the larynx. Once in place, the cuff is inflated. The haemodynamic (HR, SBP, DBP, MAP) and respiratory data (SPO2, ETCO>) will be recorded immediately after insertion of the device.

Appropriate placement of the supraglottic airway device and ventilation will be determined after connecting the supraglottic airway to the breathing circuit and checked for chest wall movement, a square wave capnograph, lack of gastric insufflation and no audible leak with peak airway pressure >=10cmH20.

If there is leak with peak airway pressure <=10cm H, O, manipulations like gentle advancement, chin lift, jaw thrust, head flexion or extension will be applied. Even after these manipulations if audible air leak persists, the attempt will be considered as a failure and the supraglottic airway device gently removed and reinserted.An additional attempt will be counted when device will be removed from the oral cavity fully and reinserted again. Insertion time, that is the time from the moment the device was taken up by the operator until successful ventilation was achieved, will be noted. No more than 3 attempts will be permitted for each device.

Following failure to place the supraglottic device in three attempts, those patients that will be intubated and then excluded from the study

Sealing pressure will be measured once an effective airway is achieved, by using a fresh gas flow rate of 5L/min, closing of the Adjustable Pressure Limiting Valve of the anaesthetic circuit to 70cmHO and recording the pressure when gas is heard leaking around the device.

DISCUSSION

Our prospective randomized comparative study of I-GEL versus intubating LMA (Laryseal Pro) in pediatric ophthalmic surgeries yielded several significant findings regarding insertion success rates, insertion time, airway sealing pressure, hemodynamic stability, and postoperative complications. This discussion contextualizes our results within the existing literature and explores their clinical implications.

Demographic Characteristics

The demographic profiles between our I-GEL and Laryseal Pro groups were comparable, with no significant differences in age, weight, or gender distribution. This homogeneity provides a solid foundation for evaluating the differences in device performance without demographic confounders.

First-Time Insertion Success Rate

Our study found that the Laryseal Pro demonstrated a 100% first-attempt success rate compared to 91.5% for the I-GEL, though this difference did not reach statistical significance (p=0.117). This finding contrasts with several previous studies. For instance, Ashraf et al. reported a higher first-attempt success rate with I-GEL (95%) compared to ProSeal LMA (77.5%) in pediatric patients [1]. Similarly, Goyal et al. observed first-attempt success rates of 90% with I-GEL versus 82% with ProSeal LMA in children [5].

First-Time Insertion Success Rate

The primary outcome measure of this study was the first-time insertion success rate of both supraglottic airway devices (Table 4).

Table 4: First-Time Insertion Success Rate

Success Rate	I-GEL (n=47)	Laryseal Pro (n=47)	p-value	Statistical Test
First attempt	43 (91.5%)	47 (100.0%)	0.117	Fisher's exact test
Failed first attempt	4 (8.5%)	0 (0.0%)	-	-

Values are Presented as Frequency (Percentage).

The high success rate we observed with Laryseal Pro may be attributed to its unique design features, particularly its guide system that facilitates proper positioning and its cuff design that conforms well to the pediatric airway anatomy. As Miller's Anesthesia textbook notes, "The ideal supraglottic airway device should be easy to insert with a high first-pass success rate by both experienced and novice users, provide adequate ventilation, and minimize the risk of aspiration" [10]. Our findings suggest the Laryseal Pro approaches this ideal in pediatric patients. The 8.5% of I-GEL insertions that required a second attempt in our study necessitated manipulations such as jaw thrust (50%), gentle advancement (25%), and chin lift (25%). This is consistent with Kannaujia et al., who reported that I-GEL often requires manipulations to achieve optimal positioning [6].

Insertion Time and Manipulations Required

One of our most significant findings was the considerably shorter insertion time for the Laryseal Pro (11.3 ± 1.3 seconds) compared to the I-GEL (14.7 ± 2.7 seconds, $p<0.0001$). This contradicts multiple previous studies that have reported faster insertion times with I-GEL. For example, Kara and Sarikas documented median insertion times of 7 seconds for I-GEL versus 14 seconds for Baska Mask, another supraglottic airway device [7]. Similarly, Sezen found significantly longer insertion times with Baska Mask compared to I-GEL in paralyzed adult patients [8].

Our analysis revealed that significantly more I-GEL insertions required manipulations (72.3%) compared to Laryseal Pro insertions (25.5%, $p<0.0001$). This is considerably higher than previously reported rates of manipulation for I-GEL. For instance, Peker et al. reported that IGEL required manipulations in only 30% of pediatric patients undergoing ophthalmic surgery [9]. The lower rate of manipulations required with the Laryseal Pro in our study suggests that its design may offer advantages in pediatric patients, particularly for ophthalmic procedures where airway stability is paramount.

As noted in Coté and Lerman's A Practice of Anesthesia for Infants and Children, "The ease of insertion of a supraglottic airway device is influenced by multiple factors including the device's design, the patient's anatomy, and the operator's experience" [40]. Our findings suggest that the Laryseal Pro's design may be particularly well-suited to the pediatric airway anatomy encountered in ophthalmic surgeries.

Airway Sealing Pressure

Table 6: Insertion Time and Airway Sealing Pressure

Parameter	I-GEL (n=47)	Laryseal Pro (n=47)	p-value	Statistical Test
Insertion Time (seconds)	14.7 ± 2.7	11.3 ± 1.3	<0.0001	Independent t-test
Sealing Pressure (cmH_2O)	23.4 ± 1.8	28.4 ± 3.1	<0.0001	Independent t-test

Values are Presented as Mean ± Standard Deviation.

The Laryseal Pro demonstrated significantly higher airway sealing pressure (28.4 ± 3.1 cmH_2O) compared to the I-GEL (23.4 ± 1.8 cmH_2O, $p<0.0001$) in our study. This superior sealing capacity aligns with findings from several comparable studies. Chaudhary et al. reported that the Baska Mask achieved higher oropharyngeal leak pressures than I-GEL (29.54 ± 1.41 cmH_2O vs. 23.16 ± 3.07 cmH_2O) [33]. Similarly, Shiveshi and Anandaswamy found that ProSeal LMA provided significantly higher oropharyngeal leak pressures than I-GEL in pediatric patients (27.4 ± 2.8 cmH_2O vs. 24.2 ± 2.4 cmH_2O) [11]. A

systematic review and meta-analysis by Maitra et al. concluded that "Laryngeal mask airway ProSeal provides higher oropharyngeal leak pressure than I-gel in adult patients" [12]. Our findings extend this observation to pediatric patients undergoing ophthalmic procedures.

The higher sealing pressure observed with Laryseal Pro can be attributed to its cuff design, which creates a more effective seal around the laryngeal inlet. As explained in Miller's Anesthesia, "The efficacy of a supraglottic airway device is largely determined by its ability to form an effective seal with the upper airway structures, allowing for positive pressure ventilation while minimizing gas leak" [10]. The superior sealing pressure of the Laryseal Pro may be particularly advantageous in ophthalmic surgeries, where stable ventilation without leaks is essential for maintaining intraocular pressure stability.

Hemodynamic Parameters

Our study found no significant differences in hemodynamic responses between the two devices. Both groups showed minimal changes in heart rate after device insertion (I-GEL: 1.5 ± 6.2 beats/min; Laryseal Pro: 1.9 ± 6.8 beats/min, p=0.752). This hemodynamic stability is consistent with findings by Jindal et al., who reported that I-GEL causes minimal hemodynamic changes compared to other supraglottic airway devices [13].Although baseline blood pressure values differed between our study groups, the mean changes in systolic and diastolic blood pressure following device insertion were comparable. This suggests that both devices provide similar hemodynamic stability during insertion, which is particularly important in pediatric patients undergoing ophthalmic procedures where significant hemodynamic fluctuations can affect intraocular pressure. Ismail et al. specifically investigated the effects of I-GEL on intraocular pressure and hemodynamic parameters and found that I-GEL insertion was associated with minimal hemodynamic changes [14]. Our findings with the Laryseal Pro suggest that it offers comparable hemodynamic stability to the I-GEL, which is reassuring for its use in ophthalmic procedures.

Postoperative Complications

Table 9: Postoperative Complications

Complication	I-GEL (n=47)	Laryseal Pro (n=47)	p- value	Statistical Test
Blood Staining	1 (2.1%)	45 (95.7%)	<0.0001	Fisher's exact test
Sore Throat	34 (72.3%)	46 (97.9%)	0.0008	Fisher's exact test
Dysphonia	27 (57.4%)	44 (93.6%)	0.0001	Fisher's exact test

Values are Presented as Frequency (Percentage).

Perhaps the most clinically significant finding in our study was the markedly different complication profiles between the two devices. The Laryseal Pro was associated with substantially higher rates of blood staining (95.7% vs. 2.1%, p<0.0001), sore throat (97.9% vs. 72.3%, p=0.0008), and dysphonia (93.6% vs. 57.4%, p=0.0001) compared to the I-GEL.

Clinical Implications & It's Meaning

The findings of our study have several important clinical implications for paediatric anaesthesia practice, particularly in the context of ophthalmic surgeries:

1. The Laryseal Pro offers advantages in terms of insertion success, insertion time, and airway sealing pressure, making it potentially suitable for cases where these parameters are critical, such as procedures requiring very stable ventilation.
2. However, the I-GEL's superior safety profile, with significantly lower rates of postoperative complications, may make it preferable for day-case procedures and patients at increased risk of pharyngolaryngeal morbidity.
3. The choice between these devices should be guided by individual patient characteristics, procedural requirements, and the anesthesiologist's assessment of which performance parameters are most critical for each specific case.
4. As noted by Jagannathan et al. in their update on pediatric supraglottic airways, "The ideal supraglottic airway for a specific patient depends on various factors including the patient's airway anatomy, the surgical procedure, and the anticipated ventilation requirements" [49]. Our findings provide valuable data to inform this decision-making process.

CONCLUSIONS

This prospective randomized study comparing I-GEL and Laryseal Pro in paediatric ophthalmic surgeries demonstrates that both devices offer effective airway management but with distinct performance profiles and clinical implications.

The Laryseal Pro demonstrated technical advantages in terms of insertion characteristics, with a perfect first-attempt success rate (100%), significantly shorter insertion time, reduced need for manipulations, and superior airway sealing pressure. These attributes suggest potential benefits in scenarios where rapid, reliable airway establishment and high-quality seal are prioritized.

However, the I-GEL exhibited a markedly superior safety profile, with significantly lower rates of postoperative complications, particularly blood staining (2.1% vs. 95.7%), sore throat (72.3% vs. 97.9%), and dysphonia (57.4% vs. 93.6%). This substantial difference in complication rates represents a major clinical consideration, particularly for pediatric day-case procedures where postoperative discomfort may delay discharge and reduce patient satisfaction.

Both devices provided comparable hemodynamic stability and ventilation efficacy, confirming their suitability for pediatric ophthalmic procedures where stable intraocular pressure is essential. Neither device demonstrated superiority in maintaining optimal physiological parameters during anesthesia.

The clinical decision between these devices should be guided by a thoughtful assessment of individual patient factors, specific procedural requirements, and the relative importance of technical performance versus postoperative comfort in each case. For brief procedures in which rapid recovery with minimal pharyngolaryngeal morbidity is prioritized, the I-GEL may be preferable despite its slightly lower technical performance metrics. Conversely, in cases where higher sealing pressures and faster insertion times are critical, the Laryseal Pro may offer advantages if appropriate measures are implemented to mitigate postoperative complications.

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