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Original Research Article

Comparison of I-GEL and LMA Proseal for Airway Management in Pediatric Patients under Controlled Mechanical Ventilation

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Abstract:

Background and Aim: I-gel™ and the ProSeal™ laryngeal mask airway (PLMA) are two supraglottic airway devices with gastric channel used for airway maintenance in anesthesia. Present study was designed to compare supraglottic airway devices proseal LMA versus I-gel for evaluation of their effectiveness in pediatric patients under controlled mechanical ventilation for ease of insertion, haemodynamic stability, and changes in ETCO2 and SpO2.

Material and Methods: Present study was done at Department of Anesthesia, B.J. Medical College, Ahmedabad, Gujarat, India from February 2018 to January 2019. A total of 50 patients of ASA grade I &II aged between 2-8 years of either sex scheduled for elective surgical procedures under general anaesthesia lasting less than 60 min were selected. They were randomly divided in to two groups, Group X (pLMA group) &Group Y (I-gel group) of 25 patients each. Patients‟ vitals were measured baseline, after premedication, before induction, immediately after insertion, 5 min, 10 min, 15 min, 20 min, 30 min, 40 min, 50 min and 60 min. after insertion of device/ end of surgery. Intraoperatively patients were watched for any complication like tachycardia/bradycardia, hypotension/hypertension, arrhythmias, hypercarbia, regurgitation/ aspiration, hypoxia, changes in ETCO2.

Results: I gel can be inserted in a significantly shorter time as compared to proseal LMA, the difference in time of insertion is extremely significant. Gastric tube insertion was easy in 84% cases, difficult in 12% cases and in 4% cases gastric tube was not able to pass even after 2 attempts. There is statistically no significant difference in perioperative vital Parameters between two groups.

Conclusion: Both i-gel and LMA ProSeal are useful airway devices for short duration surgeries under general anesthesia in children under controlled mechanical ventilation. Although the LMA ProSeal takes longer to insert, the ease of insertion is comparable to that of i-gel, with minimal occurrence of complications.

Keywords: Children, Gastric tube, I-gel, ProSea.

Introduction

Pediatric patient's airway management during a surgery under general anaesthesia is a challenging task. It is important to secure and maintain a patent airway during the surgery while patient is paralysed. The supraglottic airway device is a novel device that fills the gap in airway management between tracheal intubation and use of face mask.

Supraglottic airway" is a generic description for devices that facilitate ventilation and oxygenation with devices that do not penetrate the vocal cords. Classification of these devices can be constructed based on the laryngeal sealing mechanism of each device or by the evolution of the devices.

Classification for Supraglottic Airways Based on Sealing Mechanisms [1]

1. Perilaryngeal sealers: The LMA family, i-gel and air-Q Intubating Laryngeal Airway (airQ ILA)

2. Pharyngeal sealers: Combitube, the Streamlined Liner of the Pharynx Airway (SLIPA), the Laryngeal Tube

3. Both: The Cobra Perilaryngeal Airway (CobraPLA)

Classification of supraglottic airway based on evolution [1]

1. First-generation devices: Simple airway tubes

The laryngeal mask airway [classic LMA (cLMA)], flexible LMA (fLMA), unique LMA (ULMA) and The Cobra Perilaryngeal Airway (CobraPLA)

2. Second-generation devices: With addition of Drainage tube

Proseal LMA (PLMA), i-gel, Laryngeal tube, LMA Supreme, Streamlined Liner of the Pharyngeal Airway (SLIPA) ProSeal laryngeal mask airway (PLMA), a supraglottic airway device (SAD) with a (gastric) drain tube has been widely used in pediatric and adult patients under both controlled and spontaneous ventilation. [2-4]

Dr Archie Brain, a British anaesthesiologist, for the first time introduced the laryngeal mask airway in 19815 designed to be positioned around the laryngeal inlet that could overcome the complications associated with endotracheal intubation, and yet, be simple and atraumatic to insert. LMA have advantages over the ET tube includes: increased speed and ease of placement by anesthetists, improved haemodynamic stability at induction and during emergence, minimal increase in intraocular pressure following insertion, reduced anesthetic requirements for airway tolerance, lower frequency of coughing during emergence, improved oxygen saturation during emergence, and lower incidence of sore throat(19) in adults cLMA is a simple device that can be used in difficult intubation and for cardiopulmonary resuscitation. [6]

Though, it was shown to have some distinct advantages, like no trauma to vocal cords, avoidance of laryngoscopy and minimal pressure responses, it clearly offered no protection against regurgitation of gastric contents into respiratory tract.

The latest additions to the family of supraglottic airway devices are the second-generation devices namely proseal LMA and I gel. The classic laryngeal mask provides a moderate pharyngeal seal, which causes gastric insufflation associated with an increase in abdominal circumference during positive pressure ventilation. This predisposes to gastric regurgitation and pulmonary aspiration. It also leads to diaphragmatic compression, impeding spontaneous ventilation. The i-gel and the LMA ProSeal, being second - generation devices, have a better safety profile because they have been designed to have a superior esophageal and pharyngeal seal and hence minimal gastric insufflation during positive pressure ventilation. They also have a gastric drain tube to provide protection against aspiration and to aid gastric decompression.

This double lumen, double cuff LMA has some clear advantages over its predecessor. The double tube design separated the respiratory and alimentary tracts, providing a safe escape channel for the regurgitated fluids. The double cuff of the P-LMA gave a better seal around the glottis, hence establishing its superiority in IPPV. These properties increase the suitability of P-LMA in a group of patients who are more prone for aspiration. [7]

I-gel is one of the most recent developments in supraglottic airway devices. I-gel is a new single use non-inflatable supraglottic airway device. It is made of a medical grade thermoplastic elastomer which is soft gel like and transparent. I-gel is designed to create a non-inflatable anatomical seal of the pharyngeal, laryngeal and perilaryngeal structures whilst avoiding the compression trauma that can occur with inflatable supraglottic airway devices. I-gel has several potential advantages including cheaper supraglottic airway device, easier insertion, minimal risk of tissue compression and stability after insertion. I–gel is a truly anatomical device, achieving a mirrored impression of the pharyngeal, laryngeal, and perilaryngel structures, without causing compression or displacement trauma to the tissues and structures in the vicinity. There is an epiglottic rest with a protective ridge which prevents down folding of the epiglottis during insertion. I-gel has easier insertion with minimal risk of tissue compression. [8] Pediatric i-gel is available in different sizes (1, 1.5, 2, and 2.5) according to the weight of the children. [9]

Present study was designed to compare supraglottic airway devices proseal LMA versus I-gel for evaluation of their effectiveness in pediatric patients under controlled mechanical ventilation for ease of insertion, haemodynamic stability, and changes in ETCO2 and SpO2.

Material and Methods

Present study was done at Department of Anesthesia, B.J. Medical College, Ahmedabad, Gujarat, India from February 2018 to January 2019. A total of 50 patients of ASA grade I &II aged between 2-8 years of either sex scheduled for elective surgical procedures under general anaesthesia lasting less than 60 min were selected. They were randomly divided in to two groups, Group X (pLMA group) &Group Y (I-gel group) of 25 patients each.

Inclusion criteria

- Age 2 to 8 years
- Either sex
- ASA grade I , II
- Elective surgery
- Surgery in supine position

Exclusion Criteria

- ASA Grade III, IV and V
- Cervical spine disease

- Patient with known Difficult airway (Mallampati grading III/IV)
- Surgery in prone lateral position
- Full stomach
- Hiatus hernia,
- emergency surgeries

Pre Anaesthetic Assessment:

- Each patient was assessed preoperatively & parents explained about procedures.
- History elicited including past medical and surgical illness. General examination and Systemic examination done including examine for adequate mouth opening and neck extension.
- Airway assessment was done using Modified Mallampati grading.

Class I: Soft palate, fauces, uvula, pillars visible.

Class II: Soft palate, fauces, uvula visible.

Class III: Soft palate, base of uvula visible.

Class IV: Soft palate not visible at all, only hard palate visible.

- Routine investigations done and special investigations like 2D echo, pulmonary function test etc. were advised in special cases.
- Patients were kept nil orally for at least 6 hours pre-operatively & 4 hours post operatively.
- Prior to operation informed and written ASA consent was taken from patient's relative.

In Operation Theatre:

- Intravenous cannula was secured and I.V. fluid started.
- Vitals (Electrocardiograph, NIBP, SpO2) were monitored in all patients.
- Pre-operative baseline readings were recorded.

Premedication:

- Inj. Glycopyrrolate 0.004 mg/kg IV.
- Inj. Ondansetron 0.15 mg/kg IV.
- Inj. Fentanyl 2 µg/kg IV.

Technique of Anaesthesia:

General anaesthesia

All patients were pre-oxygenated for 3 minutes before induction. The size of the device used was decided based on the patient‟s body weight and manufacture‟s recommendation. Vital parameters were recorded just before induction. Induction was done by Inj. Propofol 2.5mg/kg IV. Injscoline 2 mg/kg was used for muscle relaxation.

Adequate depth of anaesthesia was considered when there was loss of eye lash reflex/ loss of verbal command. Both the devices were lubricated with hydrating jelly before insertion as per the manufacturer‟s advice. Once an adequate depth of anaesthesia was achieved, in Group X patients the airway was secured by pLMA using digital method while in Group Y patients the airway was secured by I-gel in "sniffing" position by an anesthesiologist. For pLMA after insertion cuff was inflated with air according to size of pLMA till the absence of audible leak. Both the devices were fixed by taping the tube over the chin.

An effective airway and proper placement of the device was judged by a square wave capnograph trace, normal chest expansion and absence of audible leak. The time taken to insert the device was recorded as the time from picking up the device to the time at first manually ventilation with properly placed device.(1st upstroke of capnogram)

The ease of insertion of device was also recorded. Ease was defined as no resistance to insertion in the pharynx in a single maneuver. Difficult insertion was considered as resistance to insertion or one or more maneuvers like gentle pushing and pulling of the device, chin lift, jaw thrust, head extension and neck flexion. If an effective airway could not be achieved the device was removed and second attempt was done. Total two attempts were permitted before failure of insertion was recorded. The number of insertion attempts was recorded.

Complications during insertion like coughing, gagging, laryngospasm, bronchospasm were noted. The device was connected to a Jackson Rees circuit and anaesthesia was maintained with 50% O2, and sevoflurane on controlled respiration. Atracurium0.5 mg/kg bolus & 0.1 mg/kg incremental was used for muscle relaxation. Appropriate sized nasogastric tube was inserted after proper lubrication. Ease of insetion of nasogastric tube was noted.

Patients‟ vitals were measured baseline, after premedication, before induction, immediately after insertion, 5 min, 10 min, 15 min, 20 min, 30 min, 40 min, 50 min and 60 min. after insertion of device/ end of surgery. Intraoperatively patients were watched for any complication like tachycardia/bradycardia, hypotension/hypertension, arrhythmias, hypercarbia, regurgitation/ aspiration, hypoxia, changes in ETCO2.

After completion of surgery, anaesthetic agents were discontinued and pt reversed with injglycopyrrolate 0.008mg/kg, inj neostigmine 0.05 mg/kg. both the devices were taken out under deeper plane of anaesthesia, after deflating the cuff of pLMA& directly for Igel& suctioning the secretions if present. Postoperative complications like coughing, blood stained device, tongue-lip-dental trauma, sore throat, hoarseness of voice were noted

Statistical Analysis: All observations were recorded and results were analyzed statistically.

Data was expressed as mean and standard deviation. For comparing data between two groups, Unpaired T-Test was used and P value calculated. P value of <0.005 interpreted as clinically significant.

Results

This randomized, prospective study was conducted to comparing supraglottic airway devices proseal LMA and I-gel in fifty pediatric patients.

Fifty patients of ASA grade I & II of age between 2-8 years of either sex were randomly selected &divided into 2 groups, Group X(pLMA) & Group Y(I-gel) of 25 patients each.

Table 1: Demographic Data

Patient Data	Group X (pLMA)	GROUP Y (Igel)	P value
Number of Patients	25	25	
Age (years)	4.88+/- 2.17	3.92+/- 2.935	P value0.194
Male / Female	20/5	17/8	
Weight (kg)	15.04+/- 3.76	13.91+/- 2.71	P value 0.228
ASA grade I/II	16/9	18/7	

Table-1 shows demographic data (age, sex, weight) in patients of both the groups. Both the groups were comparable in view of age, sex and weight distribution. There was no significant difference between the two groups with respect to demographic detail.

Table 2: Duration of Surgery

Duration of Surgery (Minutes)	Group-X (pLMA) n=25	Group-Y (I- Gel) n=25
Minimum duration(min)	25	30
Maximum duration(min)	60	60
Mean ± SD	42+/-8.72	41.2+/-7.52
P value	0.729	

Table 2 shows duration of surgery in two groups. There was no statistically significant difference observed. (P=0.729)

Table 3: Time of Insertion

Time of Insertion (Seconds)	Group-X (pLMA) n=25	Group-Y (I- Gel) n=25
Minimum duration(sec)	24	12
Maximum duration(sec)	33	18
Mean ± SD	26.84+/-2.57	15.4+/-1.62
P value	<0.0001	

Table 3 shows that I gel can be inserted in a significantly shorter time as compared to proseal LMA, the difference in time of insertion is extremely significant statistically as p value is <0.0001.

Table 4: Ease of Insertion

Ease of Insertion	Group-X (pLMA) n=25	Group- Y (I-Gel) n=25	P value
Very easy(no manipulation)	21(84%)	22(88%)	
Easy(1 manipulation)	4(16%)	3(12%)	
Difficult (>1 manipulation)	0	0	0.99

Table 4 shows that pLMA was very easy to insert in 84% cases while Igel was very easy to insert in 88% cases. (p value-1) statistically the difference is not significant. pLMA was inserted successfully in 1st attempt in 84% cases, while igel was inserted successfully in 92% of the cases(1 case required slight manipulation) (p value 0.667- statistically not significant)

Table 5: Gastric Tube Insertion

Gastric Tube Insertion Success	Group-X (pLMA) n=25	Group- Y(I-Gel) n=25	P value
Easy (1 attempt)	21(84%)	23(92%)	
Difficult (2 attempt)	3(12%)	2(8%)	
Unable to insert	1(4%)	0	0.667

Table 5 shows that gastric tube insertion was easy in 84% cases, difficult in 12% cases and in 4% cases gastric tube was not able to pass even after 2 attempts. On the other hand, in case of igel it was easily passed in 92% cases and in 2 attempts in 8% cases. (p value 0.667- not significant statistically)

Table 6: Perioperative Heart Rate Changes

	Group- X(pLMA) Mean+/-SD	Group Y(I- Gel) Mean+/-SD	P Value	NS/S
Baseline	125.64+/-14.73	120+/-8.95	0.108	NS
5 Min	131.6+/-12.15	127+/-7.10	0.1087	NS
10 Min	128.12+/-13.36	128.08+/-5.01	O.989	NS
20 Min	126.16+/-10.86	124.44+/-5.17	0.478	NS

30 Min	122.32+/-12.69	120.92+/-4.19	0.603	NS
40 Min	122.79+/-12.87	117.56+/-4.44	0.061	NS
50 Min	123.88+/-12.268	118+/-6.76	0.050	NS
60 Min	119.34+/-8.85	116.4+/-5.699	0.169	NS

Table 6 show that there is statistically no significant difference in perioperative heart rate changes in both supraglottic airway devices.

Table 7: Perioperative SBP Changes

	Group- X (pLMA) Mean+/ SD	Group Y (I- Gel) Mean+/ SD	P Value
Baseline	116.08+/-5.64	116.44+/-4.88	0.810
5 Min	110.88+/-6.62	112.16+/-5.15	0.449
10 Min	114.44+/-4.46	115.96+/-3.42	0.18
20 Min	116.84+/-3.72	117.96+/-4.25	0.326
30 Min	115.44+/-3.46	114.36+/-3.03	0.246
40 Min	115.8+/-5.38	113.60+/-3.35	0.089
50 Min	116.28+/-4.43	114.6+/-3.87	0.16
60 Min	115.22+/-4.63	114.2+/-3.67	0.39

Table 7 shows that there is statistically no significant difference in perioperative SBP changes in both supraglottic airway devices.

Table 8: Perioperative DBP Changes

	Group X (pLMA) Mean+/- SD	Group Y (I- Gel) Mean+/-SD	P Value
Baseline	75.92+/-4.88	75.2+/-4.23	0.5798
5 Min	72.76+/-5.21	74.8+/-4.08	0.1298
10 Min	74.48+/-5.69	77.52+/-6.42	0.08
20 Min	77.28+/-3.7	78.16+/-3.83	0.4128
30 Min	75.44+/-3.56	76.4+/-4.12	0.3824
40 Min	75.84+/-5.82	74.2+/-4.54	0.272
50 Min	78.36+/-5.175	76.4+/-3.71	0.13
60 Min	76 +/- 4.53	77.44 +/- 3.9	0.23

Table 8 shows that there is statistically no significant difference in perioperative DBP changes in both supraglottic airway devices. Intraoperative SPO2 was maintained in the range of 99-100% with both supraglottic airway devices.

Discussion

Endotracheal intubation has long been considered to be gold standard of care for patients requiring general anaesthesia. But various type of supraglottic devices are good alternative for securing and maintaining a patent airway for surgery requiring general anaesthesia.

There are several advantages of supraglotitc devices include: avoidance of laryngoscopy and avoidance of laryngoscopy associated tachycardia & hypertension, less invasion of respiratory tract, better tolerated by patients, useful in difficult intubation, easier insertion by inexperienced personnel, haemodynamic stability, less coughing, less sore throat,etc.

Thep roseal laryngeal mask airway (pLMA) provides a clear airway without the need for anesthetists' hands to support a face mask. The LMA is inserted blindly into the pharynx, forming a seal around the laryngeal inlet and permitting positive-pressure ventilation. It allows the administration of inhaled anesthetics through a minimally stimulating airway. It has a gastric drain to facilitate gastric drainage reducing chances of aspiration. It is reusable on steam autoclaving, for upto 40 times. The pLMA represents one of the most important revolutions in the management of airway during anaesthesia. [9,10]

I-gel is a relatively new single use non-inflatable supraglottic airway device. It is a truly anatomical device, achieving a mirror impression of the pharyngeal, laryngeal, and perilaryngel structures, without causing compression or displacement trauma to the tissues and structures in the vicinity. Thus supporting the seal by enveloping the laryngeal inlet. The small width and height of I-gel tip is intended to fit into the postcricoid cervical esophagus just proximal to distal tip.

I-gel has potential advantages over other supraglottic airways for use by non-anesthetists during cardiopulmonary resuscitation. It has no cuff to inflate, making it simple to use. Its drain tube allows access to the gastrointestinal tract and it is designed to reduce the risk of gastric inflation and regurgitation. [5] I designed this study to compare pLMA with I-gel for ease of insertion, mean time of insertion, haemodynamic stability, SpO2 changes, in pediatric patients under controlled mechanical ventilation.

The insertion time for the I-gel was significantly shorter than that of PLMA. The mean time of insertion was calculated from the time of picking up SAD to the first upstroke of EtCO2 graph. The mean time of insertion of pLMA in Group-X was 26.84+/-2.57 seconds while I-gel in Group-Y was 15.4+/-1.62 seconds. The difference between both groups regarding insertion time was statistically extremely significant (P=<0.0001) In study by Chauhan et al [11] mean insertion time for the I-gel (11.12 ± 1.814 sec) was significantly lower than that of the PLMA. In study by Chauhan et al [11] mean insertion time for the I-gel (11.12 ± 1.814 sec) was significantly lower than that of the PLMA (15.13 ± 2.91 sec) (P = 0.001) The time of insertion of i-gel in study by Bhargavi S et al [12] was significantly shorter compared with the LMA ProSeal.

In our study 84%% (21/25) patients of group-X (pLMA) and 88% (22/25) patients of group-Y (I-gel), insertion was done easily without any manipulation. The ease of insertion was more with Group-Y (I-gel) (22/25) than Group-X (pLMA) (21/25) which was statistically not significant. (p>0.05). In our study 16% (04/25) patients of group-X (pLMA) and 12% (03/25) patients of group-Y (I-gel) required manipulations while insertion sequentially in the form of, head extension/neck flexion jaw thrust and chin lift respectively, which is higher in group-X (pLMA) as compared to Group-Y(I-gel). Bikramjit das et al [13] had found no failure in insertion of airway in group I-gel and group LMA. Higher number of manipulations was required to insert pLMA than I-gel. This shows insertion of airway device was easy in group I-gel (no difficult insertion) than group pLMA (4 difficult insertions).

In our study 84% (21/25) patients of group-X (pLMA) device was placed in first attempt and 16% (04/25) patients in second attempt. While in group-Y (I-gel) in 92% (23/25) patient's device was placed in first attempt, 8% (02/25) in second attempt. There was no failure rate in both the group. (P-value 0.667) Goyal et al [14] got similar results with size 2, in which 38 of 40 insertions were successful on the first attempt with i-gel, and 36 of 40, with LMA ProSeal. Bikramjit das et al [13] found success rate of insertion in first attempt to be comparable among cLMA, pLMA & Igel.

In our study 84% (21/25) patients of group-X (pLMA) gastric tube was placed in first attempt and 12% (03/25) patients in second attempt, and in 4% cases (1/25) gastric tube could not be placed even after 2 attempts and labelled as failure. While in group-Y (I-gel) in 92% (23/25) patients gastric was placed in first attempt, 8% (02/25) in second attempt. There was no failure rate in I-gel group (p value 0.667) In study by Singh et al [15], ease of gastric tube placement was more with Igel Group (p > 0.05).

In our study at all points of time interval mean heart rates were comparable and there was no statistically significant difference between the two groups with p value >0.05. Systolic and Diastolic Blood pressure at all points of time interval was comparable and there was no statistically significant difference between the two groups with p value >0.05. In our study no significant change in heart rate and blood pressure was observed at baseline between both the groups. There was rise in heart rate and blood pressure seen during insertion and after insertion in both the groups. However, this increase in heart rate and blood pressure was higher in Group-X (pLMA) as compared to the Group-Y (I-gel) though statistically non-significant. Bikramjit das et al [13] in their study they found there were not any significant change occur in heart rate and mean arterial pressure throughout the study. Data from both the group I-gel and group LMA were comparable.

In our study, none of the patient had coughing, gagging or bronchospasm/laryngospasm during insertion of the device in any of the group. Intraoperatively also none of the patients had any complication like hypoxia, nausea, vomiting, pulmonary aspiration, regurgitation or gastric insufflation. Bikramjit das et al [13] found blood staining was observed in two cases in the LMA group and in one case in the I-gel group in sixty patients. There was no incidence of sore throat or hoarse cry in any of the two groups.

Conclusion

Both i-gel and LMA ProSeal are useful airway devices for short duration surgeries under general anesthesia in children under controlled mechanical ventilation.

Although the LMA ProSeal takes longer to insert, the ease of insertion is comparable to that of i-gel, with minimal occurrence of complications Both devices were comparable in view of haemodynamic parameters, SpO2, ETCO2, proper placement of device and failure rate, complications during insertion and intraoperatively.

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