

# Comparative study of supraglottic airway device proseal versus I-gel in mechanically ventilated patients

Kalyani Venkatrao Malshetwar<sup>1</sup>, Sachin R Totawar<sup>2\*</sup>

<sup>1</sup>Assistant Professor, Department of Anaesthesiology, Government Medical College, Aurangabad, Maharashtra, INDIA.

<sup>2</sup>Associate Professor, Swami Ramanand Teerth Rural Government Medical College, Ambajogai, Maharashtra, INDIA.

Email: [sachin.totawar@gmail.com](mailto:sachin.totawar@gmail.com)

## Abstract

**Background:** Laryngeal mask airways (LMA) represent a good alternative to endotracheal intubation in suitable cases. I-gel is more frequently used in patients under general anesthesia and receiving positive pressure ventilation. Another supraglottic airway device that enables gastric aspiration is the LMA ProSeal. In this study, we compared supraglottic airway device proseal versus I-gel with respect to ease of insertion, duration, number of attempts required and complications in surgeries under general anaesthesia and controlled ventilation. **Material and Methods:** A total of 80 patients were randomly assigned in two groups: Group I (n- 40) in which I-gel was used and in Group P (n- 40) Proseal was used for airway management. In both groups, the insertion time of the devices, difficulty during insertion, difficulty during gastric tube insertion, coverage of airway pressure, and complications were recorded. **Results:** In 85% (34/40) patients I gel was inserted in first attempt, whereas in 80% (32/40) patients Proseal was inserted in first attempt. I gel required lesser time (10.78±2.10 seconds) for insertion compared to the PLMA (12.30 ± 2.54 seconds). Placement of nasogastric tube was 100% successful in both the groups. Hemodynamic response for insertion between two groups did not show any statistically significant differences. The incidence of post-operative complaints of cough and sore throat were similar in both the groups. It was minimal with both groups.

**Key Words:** Proseal LMA, I-gel, ventilation, insertion, attempts, complications.

## \*Address for Correspondence:

Dr. Sachin R Totawar, Associate Professor, Swami Ramanand Teerth Rural Government Medical College, Ambajogai, Maharashtra, INDIA.

Email: [sachin.totawar@gmail.com](mailto:sachin.totawar@gmail.com)

Received Date: 12/05/2017 Revised Date: 09/06/2017 Accepted Date: 19/07/2017

DOI: <https://doi.org/10.26611/1015322>

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Accessed Date:  
04 August 2017

## INTRODUCTION

Patency of the airway is the fundamental concern in anaesthesia. In 1981, Archie Brain developed the laryngeal mask airway (LMA), which resolved the problems of position instability and epiglottic obstruction, while at the same time producing no greater gastric insufflation than endotracheal tubes (ETTs)<sup>1</sup>. LMA represent a good alternative to endotracheal intubation in suitable cases. New modifications were done in Classic

LMA (cLMA) model to incorporate second tube placed lateral to the airway channel to facilitate passage of nasogastric tube, separate respiratory and oesophageal pathways and permit escape of gastric contents to reduce risk of gastric insufflation, regurgitation and pulmonary aspiration. Various such models are LMA- Proseal, LMA Supreme<sup>2</sup>. Other use of successful nasogastric tube placement was to confirm correct position of the mask. The ProSeal laryngeal mask airway (PLMA; Intravent Orthofix, Maidenhead, UK), designed by Dr. Archie Brain, is based on the Clma<sup>3</sup>. A new variant of supraglottic airway device "I-gel" (Inter surgical Ltd., Wokingham, Berkshire, UK) is designed to anatomically fit the perilaryngeal and hypopharyngeal structures without an inflatable cuff. It also has a port for gastric tube placement, which is placed lateral to airway channel intended to separate the alimentary and respiratory tracts. It is a latex free supraglottic device providing good vertical stability upon insertion which is an advantage over LMA with inflatable cuffs where mechanical inflation can cause movement of the device because the

distal wedge shape of the mask is forced out of the upper oesophagus<sup>4</sup>. It is not necessary to insert fingers into the mouth of the patient for full insertion<sup>5</sup>. I-gel is designed to achieve a mirrored impression of the pharyngeal and laryngeal structures and to provide a perilaryngeal seal without cuff inflation<sup>6</sup>. In this prospective randomized study, we compared supraglottic airway device proseal versus I-gel with respect to ease of insertion, duration, number of attempts required and complications in surgeries under general anaesthesia and controlled ventilation.

## MATERIAL AND METHODS

This randomized prospective study involved randomized comparison between the I-gel and the Proseal LMA for surgery, under general anaesthesia and controlled ventilation. A total of 80 patients were randomly assigned in two groups: Group I (n- 40) - use of I-gel for airway management and Group P (n- 40) - use of Proseal for airway management. Patients aged between 20-40 years with ASA grade I and II, inter incisor gap > 2.5 cms, Mallampatti classes I and II and surgery duration of less than 2 hrs were included in the study and patient refused to enroll, with upper respiratory tract infection, non-fasting status, mouth opening < 2.5cm, lung diseases, head neck surgeries, medical disorders (Hypertension, DM, Coronary heart diseases) and patients with increased risk of aspiration like (GE reflux, Hiatus Hernia, Pregnancy) were excluded from the study. A complete pre-anaesthetic evaluation was done a day prior to surgery. Routine preoperative investigations were carried out. Patients were explained about the nature of the study and written informed valid consent was taken. Adequate starvation was confirmed. On arrival in the operation theatre patients were monitored with electrocardiography, pulse oximeter, and non-invasive blood pressure measurement. Patients in both the groups were given premedication in the form of inj. Midazolam 0.03 mg/kg, Inj. Fentanyl 2 mcg/kg, inj. Ondansetron 0.1 mg/kg intravenously. Heart rate, systolic and diastolic blood pressure and oxygen saturation were noted 5 minutes after premedication (Pre-induction). Patients were pre-oxygenated for 3 minutes with 100% oxygen. General anaesthesia was induced with inj. Propofol 2 mg/kg, the endpoint being loss of eyelash reflex. Ventilation was checked. After confirming ventilation inj. Vecuronium 0.1 mg/kg was given intravenously. Patients were mask ventilated for 3 minutes with 50:50, Nitrous oxide and Oxygen. The dorsal surface of the I-gel / Proseal was lubricated with Lignocaine 2% jelly. Appropriate size I-gel/ Proseal, as per manufacturer's recommendation, i.e. size 3 for 30-50Kg, Size 4 for >60Kg, Nasogastric tube number 12 was selected for both groups. Both I-gel and

Proseal LMA were lubricated with water soluble jelly. The airway device was inserted by Anaesthesiologist by gentle pushing until resistance felt. The insertion technique included neck flexion, head extension, and midline approach along the hard palate downwards and backwards. Correct placement was confirmed by auscultation on chest. In cases of Proseal, introducer was removed after insertion and cuff inflated. The time of insertion was defined as time taken for holding the prelubricated suraglottic device to the first square shaped capnograph tracing. Number of attempts required for obtaining an effective airway was noted. Three attempts were allowed before insertion of I-gel / Proseal was considered as failure. Ease of insertion of device also recorded. Ease was defined as no resistance to insertion in single manoeuvre. In difficult insertion, there was resistance to insertion or more than one manoeuvre is required. An effective airway was defined as normal thoraco-abdominal movement and a square wave capnograph trace. All parameters i.e. pulse, systolic blood pressure, oxygen saturation, end tidal carbon dioxide were recorded at 0 minute (immediately after insertion of airway device), 1 minute, 5 minute, and 10 minutes after insertion of airway device. The nasogastric tube (NGT) was inserted 2 minutes after the placement of airway device. The placement was confirmed by synchronous injection of air and epigastric auscultation during apnoea. In case of difficulty in introducing NGT, two attempts were allowed and more than two were considered as failure. Inability to insert the gastric tube (if any) was recorded. Intraoperatively any complications like gastric distension (as seen on the monitor and enquired with the surgeons), regurgitation visible from the NGT and pulmonary aspiration (signs such as visualization of the gastric contents in the airway device and crepitations on chest auscultation) were noted. In both groups airway sealing pressure was noted at 10 min of insertion and 10 min before completion of surgery this is measured by closing expiratory valve of circle system at a fixed gas flow of 5 lit/min and airway pressure at which equilibrium was reached was recorded (maximum pressure allowed was 40 cm of H<sub>2</sub>O). Gas leakage was noted at this time by placing stethoscope lateral to thyroid cartilage. Anaesthesia was maintained on O<sub>2</sub> (50%), N<sub>2</sub>O (50%), Isoflurane and inj. Vecuronium (1/5<sup>th</sup> of the loading dose). IPPV was given. After completion of the procedure, the neuromuscular blockade was reversed with inj. Glycopyrrolate 8 mcg/kg and inj. Neostigmine 0.05 mg/kg after cessation of N<sub>2</sub>O. Nasogastric tube suctioning was done and any visible secretions noted. The device was removed after the return of adequate spontaneous respiratory efforts and when the patient was able to open the mouth on command. Auscultation of

chest was done after removal of device for any evidence of aspiration. Any incidence of trauma and blood on the airway device was noted. Post operatively, the patients were monitored for pulse, systolic blood pressure, Oxygen saturation at 0 minute, 15 minutes, 30 minutes, and 60 minutes in recovery room. Any incidence of nausea and vomiting was noted. Patients were questioned directly about sore throat half an hour after admission to recovery room. Sore throat incidence was evaluated by asking continuous throat pain, throat discomfort, or no complaints at all. Enquiry for the same was done 24 hrs later.

### Statistical Analysis

Data analysis was done with the help of Graph Pad Prism. Quantitative data was presented with the help of mean, standard deviation. Comparison between two variables was done with the help of unpaired 't' test. Changes in the various parameters within same group were analysed with the help of Paired 't' test. Qualitative data was analysed using Chi- Square test. 'p' value less than 0.05 was considered statistically significant.

## RESULTS

In present study, 80 patients within a range of 20 to 40 years, of ASA I and II were randomly divided into two groups as - Group I: (n= 40) where I-gel was inserted and Group P (n= 40) where Proseal was inserted.

**Table 1:** Age distribution of patients in both the groups

Age(years)	Number of patients			
	Group I	(%)	Group P	(%)
20-24	04	10	05	12.5
25-30	21	52.5	18	45
31-35	11	27.5	15	37.5
36-40	04	10	02	5

The average age in Group I was  $29.97 \pm 3.75$  years, and in Group P it was  $29.53 \pm 3.63$  years. 'p' value was found to be 0.587 ( $p > 0.05$ ). Thus, the difference of age distribution in both the groups was not statistically significant. Weight of the patients ranged from 38-60 kgs. The average weight in Group I was  $48.25 \pm 5.40$  kgs, whereas in Group P was  $49.90 \pm 4.94$  kgs. The 'p' value was found to be 0.158 ( $p > 0.05$ ). Thus, the difference of weight distribution between the two groups was not statistically significant. Patients of both sexes were included in the study. In Group I, 21 (31.5%) patients were male and 19 (47.5%) females. While in Group P, males were 18 (45%) and females were 22 (55%). Thus, both the groups were comparable in distribution of sex.

**Table 2:** Operations performed in between both groups

Type of surgery	Number of patients			
	Group I	Percentage	Group P	Percentage
Hernioplasty	6	15%	6	15%
Tibial Plating	7	17.5%	8	20%
Upper limb	10	25%	8	20%
Skin grafting	6	15%	8	20%
Mastectomy	6	15%	6	15%
MTP And TL	5	12.5%	4	10%

Both groups were comparable when compared for distribution of operations performed in both groups (Table 2).

**Table 3:** Variables studied between two groups

Variable	Group I	Group P	p value
Mean duration of anaesthesia (min)	82.25±23.42	82.75±27.36	0.661
No. of attempts			
One	34(85%)	32 (80%)	
Two	4(10%)	4 (10%)	0.346
Three	2 (5%)	4 (10%)	
Mean SD	1.2+0.52	1.32+0.65	
Time required for insertion (seconds)	10.78±2.10	2.30 ± 2.54	0.0046
Airway seal pressure achieved			
After insertion	26.85±6.29	26.10 ± 4.87	0.552
Before extubation	26.93±5.85	26.50 ± 5.01	0.728
Ease of nasogastric tube placements	40 (100%)	40 (100%)	

Duration of anaesthesia were comparable. Applying unpaired 't' test which shows there is no any significant statistical difference between these two groups as p value is 0.661. ( $p > 0.05$ ). The duration of the operation did not last for more than 120 minutes in any of the cases. There was no any significant statistical difference in number of attempts taken ( $p > 0.05$ ). We found statistically

significant difference between two groups with respect to time taken for effective airway establishment. Thus, I-gel required less time than Proseal LMA for effective airway establishment. Airway seal pressure was recorded at two times, 10 minutes after insertion and 10 minutes before extubation. Mean of the airway seal pressure recorded 10 minutes after insertion (ASP1) of I-gel was  $26.85 \pm 6.29$

cm of H<sub>2</sub>O. Whereas in group P, airway seal pressure was 26.10 ± 4.87cm of H<sub>2</sub>O. Also we recorded Airway seal pressure 10 minutes before extubation (ASP2). For group I it was 26.50 ± 5.01 cm of H<sub>2</sub>O and for group P, 26.10 ± 4.87 cm of H<sub>2</sub>O. ‘p’ value 10 minutes after insertion was 0.552 and 10 minutes before completion of surgery was 0.728.(p>0.005). Pressure recorded between two groups

does not show any significant statistical difference as calculated by unpaired ‘t’ test. We found 100% success rate of insertion of nasogastric tube in both I-gel as well Proseal LMA group. In all patients of both the groups there was no any statistical difference. We were able to pass nasogastric tube in 1st attempt of both groups (Table 3).

**Table 4:** Comparisons of heart rate changes at various intervals in study groups

Time Interval	Heart Rate ( beats/min)				Unpaired t test	p value
	Group I		Group P			
	Mean	SD	Mean	SD		
Pre Op	83.30	11	81.60	6.93	1.05	0.87
00 Min	84.20	57	82.35	6.27	1.09	0.77
05 Min	84.50	55	82.60	6.50	1.015	0.96
10 Min	84.30	33	82.60	6.34	1.003	0.99
20 Min	84.05	5.82	82.80	6.28	1.16	0.63
Before Extubation	84.25	6.26	81.7	6.41	1.04	0.88
After Extubation 00 Min	84.9	5.92	82.35	6.38	1.16	0.64
05 Min	84.03	6.11	82.3	6.58	1.15	0.64
10 Min	83.7	6.00	82.2	6.14	1.04	0.88

4 out of 40 cases in group I required various maneuvers to aid insertion while group P had 5 cases which required different maneuvers including flexion, extension flexion withdrawal, jaw elevation. Whereas in group I, 36 patients did not require any maneuvers and in group P, 35 patients didn’t require any maneuvers. We compared mean of heart rate at different interval i.e. at pre op, immediately after insertion, at 5 minute, 10 minutes, 20

minutes after insertion, and just after extubation, 5 and 10 minutes after extubation in both groups. Thus, we found that changes in mean heart rate at various time intervals were comparable in both groups. As ‘p’ value for all intervals in both groups were more than 0.05, difference between changes in heart rate in both the groups were found to be statistically insignificant as calculated by unpaired ‘t’ test (Table 4).

**Table 5:** Changes in systolic blood pressure at various intervals in study groups

Time Interval	Systolic Blood Pressure (mm of Hg)				Unpaired t test	p value
	Group I		Group P			
	Mean	SD	Mean	SD		
Pre Op	114.7	7.87	111.90	8.20	1.08	0.79
00 Min	114.8	8.08	112.67	7.41	1.18	0.59
05 Min	113.9	7.63	112.6	7.27	1.10	0.76
10 Min	113.8	6.97	111.7	6.67	1.09	0.78
20 Min	113.9	7.37	112.4	6.41	1.32	0.38
Before Extubation	115.6	6.53	112.35	8.16	1.56	0.16
After Extubation 00 Min	114.75	6.99	112.9	6.97	1.005	0.98
05 Min	115.5	6.30	112.8	7.27	1.33	0.37
10 Min	114.4	6.69	112.15	7.61	1.29	0.42

We compared mean of systolic blood pressure at different interval i.e. at pre op, immediately after insertion, at 5 minute, 10 minutes, 20 minutes after insertion, and just after extubation, 5 and 10 minutes after extubation in both groups. Thus, we found that changes in mean systolic blood pressure at various time intervals were comparable Postoperative complications like sore throat was found in 3 cases in group I-gel and 4 cases in Proseal group, whereas cough occurred in 1 patient of group I, and 1 patient of group I. Incidence of post op complications between the two groups was not statistically significant as p value of 0.92 (p>0.005).

in both groups. As ‘p’ value for all intervals in both groups were more than 0.05, difference between changes in systolic blood pressure in both the groups were found to be statistically insignificant as calculated by unpaired ‘t’ test. (p> 0.05) (Table 5).

**DISCUSSION**

All the patients in the two groups were compared with each other with regards to confounding factors such as age, sex, weight i.e. group I with group P and there was no statistically significant difference and patients in the

two groups were comparable as far as demographic profile was concerned. We included age group of 20 to 40 years in our study. Different problems like cervical spondylitis, obesity, hemodynamic instability goes on increasing as age advances which can affect final result. Referring to studies done by Ishwar Singh *et al*<sup>5</sup> and Bimla Sharma *et al*<sup>7</sup>, mean age group was around 40. In this study, mean duration of anaesthesia in group I was 82.25±23.42 minutes, whereas group P was 82.75±27.36 minutes. Maltby JR *et al*[8] found mean duration of surgery in Proseal group was 95±36 minutes and 104±52 minutes in ETT group which is similar to present study. Although, I-gel was easier to insert with higher success rate 85% (34/40) in first attempt than Proseal 80% (32/40). But this difference was not statistically significant ( $p=0.346$ ). The device could not be inserted successfully in two patients of group I and three patients of group P within stipulated time and attempts. These cases were excluded from further analysis. An endotracheal tube was used to secure the airways in these patients. We did not encounter any episodes of hypoxemia ( $SpO_2 < 90\%$ ) or any other adverse events during entire course of our study. Cook TM *et al*<sup>3</sup> reviewed literature of Proseal, and found that in different 33 studies for insertion of Proseal 1st attempt success rate was 76 to 100%. Wharton NM *et al*<sup>9</sup> found that incidence of I gel insertion in 1st attempt was 82.5% (33/40), and in 2nd attempt it was 15% (6/40). Ishwar Singh *et al*<sup>5</sup> found that 30/30 patients of I gel group and 28/30 patients of Proseal group required only one attempt for insertion of LMA. Bimla Sharma *et al*<sup>7</sup> found that in 28 patients I gel was inserted in 1st attempt, whereas, in Proseal group 24 patients required one attempt. But there was no statistically significant difference found in two groups. Our result was consistent with above studies. The time from picking up the device to first square shaped capnograph tracing following clinically adequate ventilation of lungs was recorded as the time taken for insertion. In our study, we found that the time taken for insertion of I gel (10.78±2.10sec) was less than that for Proseal LMA (12.30±2.54sec) and this difference was statistically significant ( $p=0.0046$ ). While, Wharton NM *et al*<sup>9</sup> reported median insertion time 17.5 sec (range 7–19) for I gel. Bimla Sharma *et al*<sup>7</sup> found that time required for insertion of I gel was less than Proseal, although, it was statistically insignificant. Saraswat N *et al* [10] compared Proseal versus ETT. In this study time required for insertion of Proseal was 15 seconds which was less than that of ETT. However, the exact definition of insertion time in these studies remains unclear. The time taken for insertion showed statistical difference indicating that the I-gel took lesser time for securing airway than the PLMA. Regardless of differences in

defining the insertion time in our and earlier studies, it is obvious that the two devices take similar time. Thus, although the I-gel is a relatively new device with limited literature available (as compared to PLMA), we could insert I-gel as quickly as that of the PLMA. This indicates that the learning curve for I gel is quite short, which may be attributable to its novel, non-inflatable, anatomically shaped cuff, mounted on a rigid airway shaft aiding insertion. Overall, both PLMA and I gel were comparable with respect to their insertion characteristics in our study and comparable with earlier studies as well. We evaluated the correct placement of the device looking for the smooth passage of NGT. In our study, both devices were comparable with respect to their placement characteristics. Nasogastric tube was successfully inserted in all patients of Group I and Group P. Brain AJ *et al*<sup>11</sup> found 100% success rate for nasogastric tube insertion. Maltby JR<sup>8</sup> also found similar success rate in case of Proseal LMA as compared to ETT. Bimla Sharma *et al*<sup>7</sup> found 100% success rate of nasogastric tube insertion with I gel and Proseal LMA. Our results are consistent with above mentioned studies. Thus, both devices are similar with respect to its placement characteristics as evaluated clinically by inserting NGT. The airway seal pressure for both the devices, PLMA and I gel was found to be similar. In the study done by Maltby JR *et al*<sup>8</sup> achieved similar airway pressure in patients using Proseal LMA which was 34 cm of H<sub>2</sub>O. Ishwar Singh *et al*<sup>5</sup> compared clinical performance of I-gel with LMA Proseal in elective surgeries. Although the airway sealing pressure was higher in group P (29.6 cm of H<sub>2</sub>O) than with group I (25.27 cm of H<sub>2</sub>O) ( $p < 0.05$ ), but the airway sealing pressure of group I was very well within the normal limit to prevent aspiration, without clinically significant gastric distension or regurgitation. In a study by Uppal V *et al*<sup>12</sup> none of the cases had gastric regurgitation or aspiration. I-gel provided equally effective pulmonary ventilation despite high airway pressures without gastric distension. Bimla Sharma *et al*<sup>7</sup> found comparable airway seal pressure in both groups. I-gel achieved similar glottic seal pressures to those of PLMA. Hence, our study projects the fact that the I gel achieved similar glottis seal pressures to those of PLMA. Hence, present study projects the fact that I-gel is also a reliable airway device similar to its prototype PLMA that can give an effective leak free glottis seal. In present study, both the groups were hemodynamically (Blood Pressure and pulse rate) similar at base line and after insertion. The trend of increase in heart rate and blood pressure after insertion compared to baseline values were not statistically significant ( $p > 0.05$ ) and comparable between groups. Thus, both devices might elicit a response to the same degree when all parameters are kept

constant. Wood ML *et al*<sup>13</sup> found that there were minimal hemodynamic changes after insertion of LMA as compared to endotracheal tube. These results were similar to study done by Halaseh BK *et al*<sup>14</sup> where they found that there were no hemodynamic variations after insertion of Proseal LMA. By comparing our results with above mentioned studies, we concluded that minimal hemodynamic changes occur after insertion of Proseal and I gel LMA. The major cause of the sympathoadrenal response to tracheal intubation arises from stimulation of the supraglottic region by tissue irritation induced by direct laryngoscopy. Insertion of the tube through the vocal cords and inflation of the cuff in the infraglottic region should contribute additional stimulation. Also, by activating proprioceptors, direct laryngoscopy induces arterial hypertension, tachycardia, and increased catecholamine concentrations proportional to the intensity of the stimulus exerted against the base of the tongue. However, subsequent tracheal intubation should stimulate additional receptors in the larynx and the trachea, thus enhancing the hemodynamic and epinephrine response. Use of the LMA avoids the need for laryngoscopy and tracheal intubation, so that the marked haemodynamic response to these procedures may be circumvented. There was no any intra operative complication occurred. None of the device in study caused trauma (blood staining on device or trauma to teeth) during insertion. Contradictory to our results Ishwar Singh *et al*<sup>5</sup> found blood staining of Proseal LMA in 6 out of 30 patients and 1 out of 30 patients in I gel group. Better acquaintance with devices, prior training on mannequins, keeping number of attempts to only three, and close attention to details like positioning of the patient and device movement inside the airway probably allowed us to bring down the incidence of airway trauma to zero. Post-operative complications (cough and sore throat) were found in 4 cases in group I and in group P. Maltby JR *et al*<sup>8</sup> found cough in two patients and laryngeal stridor in two patients out of 50 patients after insertion of Proseal LMA in patients undergoing laparoscopic surgery. Giuseppe Natalini *et al*<sup>2</sup> compared standard LMA and the PLMA and frequency of sore throat was scored as mild in 13% and 10% of patients with the standard LMA and the PLMA, respectively, and was absent in the remaining patients ( $p = 0.99$ , between groups). Richez B *et al*<sup>6</sup> found only one case of coughing and one case of mild sore throat following use of I-gel. In a study by Ishwar Singh *et al*<sup>5</sup>, there was no incidence of hoarseness of voice or airway morbidity during their study. A large sample size may be required to substantiate the incidence and severity of post-operative complications between these 2 devices. Occurrence of sore throat is less because it is a supraglottic device, which achieves mucosal pressure

below pharyngeal perfusion pressure. LMA is associated with a lower incidence of laryngospasm during emergence, postoperative hoarse voice, and coughing than the ETT. Because the ETT is placed in the trachea beyond the vocal cords, it can irritate the airway and result in a greater incidence of laryngospasm, postoperative hoarse voice, and coughing. From this study, we can conclude that I gel proved to be equally efficient as the PLMA with regards to the ease of insertion as evidenced by similar number of attempts required and the manoeuvres required. The time taken for insertion was considerably less for I gel highlighting its efficacy in controlled ventilation as well as resuscitative scenarios. The nasogastric channel of I gel like in the PLMA provided a conduit to gastric chamber with similar success rates. Hemodynamic responses elicited by each device were comparable. Post-operative complications were minimal as with the PLMA. Thus, the I-gel and PLMA can be used interchangeably for airway maintenance during general anaesthesia under mechanical ventilation.

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Source of Support: None Declared  
Conflict of Interest: None Declared

