



A COMPARATIVE STUDY OF PROSEAL LARYNGEAL MASK AIRWAY VERSUS THE I-GEL ON HEMODYNAMIC AND RESPIRATORY MECHANICS IN PATIENTS UNDERGOING LAPAROSCOPIC CHOLECYSTECTOMY.

Anaesthesiology

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ABSTRACT

Background: The Proseal laryngeal mask airway (PLMA)[3] is a reusable SGA with a modified cuff made of silicone and a double tube arrangement. The I-GEL[4] is a disposable SGA made of a soft, gel-like thermoplastic elastomer with a noninflatable cuff and is easier and faster to insert than other SGAs. The aim of study was to compare the respiratory mechanics, hemodynamic changes, attempts taken for insertion, oxygenation, intraoperative and post-operative laryngopharyngeal morbidity using either P-LMA or I-GEL in adult patient undergoing laparoscopic cholecystectomy.

Patients And Methods: this prospective randomized comparative study was conducted on 60 adult patients of either sex, of ASA physical status I-II, scheduled to undergo elective laparoscopic cholecystectomy under general anaesthesia. Group P (n=30): Patients received P-LMA. Group I (n=30): Patients received I-GEL. Sample size were estimated based on an alpha error of 0.05 and a power of 80%.

Conclusion: On intra group comparison peak airway pressure increases significantly after insufflation of CO₂ for laparoscopic surgery. There was no evidence of gastric insufflation, aspiration and regurgitation in either of group I or group P.

KEYWORDS

LMA, Supraglottic Airway Device, PLMA, I-GEL, clonidine, pregabalin, spinal anaesthesia.

INTRODUCTION:

Endotracheal intubation is considered to be safest way to safeguard the airway, but it involves rigid laryngoscope that can cause trauma to teeth and soft tissues. The immediate life threatening situation like 'cannot intubate, cannot ventilate' situation may occur to anyone, anywhere and anytime due to glottis view obstruction. Good oropharyngeal sealing pressures (OSP) are necessary for adequacy of ventilation and prevention of aspiration. In an effort to deal with these dangerous situations, Dr. Archie Brain pioneered the Laryngeal mask airway [LMA].

Supraglottic airways (SGAs) offer distinct advantages including an increased speed and ease of placement, maintenance of haemodynamic stability during induction and emergence,^[1] better oxygenation during emergence and lesser postoperative sore throat and voice alteration.^[2] The second-generation SGAs have additional features to reduce the risk of aspiration and provide an improved pharyngeal seal making them more efficient and reliable in their performance. The Proseal laryngeal mask airway (PLMA)^[3] is a reusable SGA with a modified cuff made of silicone and a double tube arrangement. The I-GEL^[4] is a disposable SGA made of a soft, gel-like thermoplastic elastomer with a noninflatable cuff and is easier and faster to insert than other SGAs.

Doubts still remain concerning the use of SADs with positive pressure ventilation (PPV) especially in laparoscopic procedures.^[5,6] Changes in respiratory mechanics following capnoperitoneum may result in increased airway pressures that may exceed the oropharyngeal seal pressure (OSP) of the used device, leading to inadequate ventilation, gastric insufflation and increased risk of regurgitation and subsequent pulmonary aspiration. The aim of study was to compare the respiratory mechanics, hemodynamic changes, attempts taken for insertion, oxygenation, intraoperative and post-operative laryngopharyngeal morbidity using either P-LMA or I-GEL in adult patient undergoing laparoscopic cholecystectomy.

MATERIALS AND METHODS

After taking approval from the institutional ethics committee vide letter no. IGIMS/2016/1222/Acad. dated 24.11.2016 & registration with clinical Trial Registry-India (CTRI/2018/06/014676) and written informed consent from the patients, this prospective randomized comparative study was conducted on 60 adult patients of either sex, of ASA physical status I-II, scheduled to undergo elective laparoscopic

cholecystectomy under general anaesthesia. Patient refusal, ASA grade III and IV, upper respiratory tract infections, anticipated difficult airway, mouth opening less than 2.5 cm, patients with acute cholecystitis, morbid obesity (BMI > 30 Kg/m²), gastro-oesophageal reflux disease, lung disease and in whom procedure has to be converted to open cholecystectomy were excluded from the study. The patients were randomly allocated two different groups (Group P & Group I) using computer generated code in random way to 30 patients in each group so that each patient was assigned to a group by chance not by choice.

Group P (n=30): Patients received P-LMA.

Group I (n=30): Patients received I-GEL

Sample size were estimated based on an alpha error of 0.05 and a power of 80%.

Taking overnight fasting history, patients were taken in the operation theatre, intravenous (iv) access was secured and standard monitoring like electrocardiogram, capnogram (ETCO₂), pulse oximeter (SpO₂), non-invasive blood pressure (NIBP) and neuromuscular monitoring (NMB) were applied. The patients were placed supine with the head in sniffing position using a 7-cm high firm pillow and administered IV fentanyl 2µg/kg, 10 minutes before induction. After preoxygenation for 3 minutes, general anaesthesia was induced with IV Propofol 2mg/kg and muscle relaxation facilitated by IV Vecuronium 0.1 mg/kg. The lungs were manually ventilated with a facemask with 1-1.5% isoflurane in oxygen and nitrous oxide (1:2) for 3 minutes, neuromuscular blockade was confirmed using train-of-four (TOF) stimulation and the airway device inserted once TOF count was zero in order to ensure comparable conditions for device insertion in the study groups.

PLMA and I-GEL were checked, prepared, inserted and secured according to the corresponding manufacturer's recommendations. Size 3 I-GEL and PLMA were checked and water soluble lubricant was placed on the posterior surface of I-GEL and PLMA. After achieving paralysis and "sniffing" position of the patient, the I-GEL and PLMA were held in the right hand and inserted by firmly holding the device such that cuff outlet were facing towards the chin of the patient, and guided along hard palate using digital technique until definitive resistance were felt. Both devices were fixed in this position and connected to the anaesthesia machine via a breathing circuit and

ventilation of lung commenced. Orogastric tubes (size 14) were passed through gastric outlet port of I- GEL and PLMA in all cases and the posterior folding of the mask tip was ruled out. Assessment of adequate depth of insertion by examining the relation of the bite block to the incisors confirmed the correct position of devices. Ideally the bite block lies between the teeth. Adequacy of ventilation was assessed by Leak pressure, Observing chest bilateral movement, chest auscultation, ETCO₂ waveform and SpO₂. Following successful insertion of the device, the patient was maintained ventilation with Oxygen plus N₂O in 50% ratio and Isoflurane with closed circle system at 14-16 breaths per minute and tidal volume 10ml/kg in both groups.

Parameters recorded for study was Quality of insertion, Time taken for successful placement, Ease of passage of Orogastric tube, Hemodynamic parameters, Quality of ventilation and complications if any. Quality of insertion was depends on Number of attempts, maximum three attempts were allowed. A failed attempt was declared after 3 unsuccessful attempts and in such situation intubation was done with an endotracheal tube. Time taken for successful placement was calculated as that from the removal of the facemask used for preoxygenation to placement of device and achieving effective ventilation. Insertion of Orogastric tube (size 14) was done and confirmed by injection of air and auscultation over epigastrium and or aspiration of gastric fluid. Hemodynamic parameters such as pulse rate and systolic and diastolic blood pressure were recorded immediately prior to induction (control) and subsequently at 1min (carboperitoneum), 5min, 10min, 20min and 30 min following successful device placement. Ventilation was considered adequate if there were no leak with pre-set tidal volume of 10ml/kg, achieves good chest movement, square shaped EtCO₂ and a SpO₂ >95%. Respiratory parameters like dynamic compliance, peak airway pressure, the minute volume also measured at same time interval and compared in both group.

ETCO₂ & Spo₂ recorded just after insertion, 1min, 5min, 10 min, 20min, 30min, and 45min and just before removal. Complication like sore throat, aspiration, hoarseness or dysphagia was recorded postoperatively. Residual neuromuscular block was reversed after completion of surgery with inj. Neostigmine methyl sulphate (0.05 mg/kg wt.) and inj. Glycopyrrolate (0.01 mg/kg wt.) intravenously.

RESULT

In this study 100 patients were enrolled according to study protocol out of which 60 patients were selected which met all the inclusion criteria and divided into two groups of 30 each. The data were analysed using SPSS version software for window 10. For categorized parameter chi-square test was used, while for numerical data student t-test was used to compare two groups. Percentage of relative changes were also determined and compared between groups. Microsoft excels and words have been used to generate, tables etc. Power analysis was also done for exact difference between the two groups for all the variables. p-value >0.05(not significant), <0.05(significant), <0.01(highly significant), <0.001(very highly significant).

The demographic data were comparable in both groups [Table 1]

Parameter (Mean±SD)	Group P	Group I	p
Age (years)	35.65±14.09	35.28±10.97	0.91
Weight (kg)	55.27±8.03	55.72±8.40	0.56
Sex			
Male	6	24	> 0.05
Female	7	23	
ASA Grade			
I	26	27	> 0.05
II	4	3	
MMP Class I / II	26/4	27/3	> 0.05

The success rate in first attempt in group I was 83.3% and in group P was 76.7%. The P value was 0.503 which is not significant. The success rate in second attempt was 6.67% in group I and 20% in group P. Failed insertion was recorded in 6.67% (2 patient) in Group I and 3.33% in Group P (1 patient). From the above analysis, it can be seen that first attempt success rate was higher in Group I but it was statistically insignificant.

The mean time to place the airway device in group I was 20.78sec and 21.64 second in group P but the difference was statistically insignificant. It was found that OGT could be successfully placed in 71% patient in group-I and 76% in group-P. However this difference

was statistically not significant [Table 2].

Table 2: Insertion Characteristic

	Group P	Group I	p
Number of attempts 1 st / 2 nd / 3 rd / Failed	23/ 6/ 0/ 1	25/ 2/ 1/ 2	0.503
Insertion time device (seconds) (Mean±SD)	21.64±3.14	20.78±3.19	>0.05
Insertion of Orogastric tube attempts 1 st / 2 nd / 3 rd / Failed	22/ 3/ 2/ 3	20/ 4/ 2/ 4	

The heart rate was observed to be statistically significant for a period of 1 min following insertion of PLMA and for 5 min following placement of I-GEL, after which the heart rate returned to near pre-insertion values in both the groups. The heart rate variation at 1min and 5mins were not statistically significant between both the groups but it was significant at pre-insertion, 10mins, 20mins and 30mins. The systolic blood pressure was significantly increased in both groups at 1 minute after placement of device. This increase in SBP was statistically significant for a period 1min following placement of PLMA and for 5 min following placement of I-GEL, but it was insignificant at pre-insertion, 10min, 20min and 30mins in both groups. It was observed that there was extremely significant increase in the diastolic blood pressure compared to the pre-insertion values and 1min after placement of the device in both groups. The DBP was statistically significant for a period of 1 min for PLMA and for 5min for I-GEL but it was insignificant at 10min, 20min and 30mins in both groups [Table 3].

Table 3: Haemodynamic Response To Insertion

Time	Parameters	Group P	Group I	p
T ₀	HR	77.689± 7.226	73.214± 5.202	0.010
	SBP	115.241± 4.256	115.285± 8.644	0.981
	DBP	75.310± 2.578	76.071± 4.090	0.407
T1	HR	84.689±6.964	86.464±6.909	0.338
	SBP	125.793±4.451	130.214±8.799	0.022
	DBP	84.069±2.298	89.428±5.159	0.000
T5	HR	77.344±7.301	79.321±6.018	0.269
	SBP	115.862±5.152	124.071±7.128	0.000
	DBP	76.206±4.546	81.571±3.862	0.000
T10	HR	77.310±7.275	72.178±4.876	0.003
	SBP	115.931±4.358	115.785±6.402	0.921
	DBP	75.655±2.676	75.500±3.986	0.864
T20	HR	77.689±7.297	72.857±5.488	0.007
	SBP	115.172±3.274	115.642±7.813	0.770
	DBP	75.241±4.256	76.142±3.728	0.398
T30	HR	77.379±7.208	73.821±5.368	0.039
	SBP	115.655±2.781	115.571±7.704	0.957
	DBP	75.103±4.126	75.642±3.851	0.612

There was no statistically significant difference between the two groups regarding oxygen saturation throughout the study interval [Table 4].

Table 4: SpO₂ Variation With Time.

Time	Group P	Group I	p-value
T0	99.172±0.889	99.071±0.899	0.672
T1	98.896±0.859	99.000±0.666	0.615
T5	98.551±1.616	98.785±1.066	0.523
T10	98.793±1.048	98.714±1.013	0.774
T20	98.896±0.724	98.785±0.629	0.541
T30	98.896±0.772	98.678±0.772	0.276
After removal	99.034±0.421	98.785±0.498	0.051

ETCO₂ was well maintained throughout the procedure and significant changes were noted at 20 minutes which were clinically acceptable [Table 5].

Table 5: ETCO₂ Variation With Time.

Time	Group P	Group I	p-value
T0 (After placement)	33.965±1.972	34.214±1.969	0.636
T1	34.724±2.185	34.535±1.855	0.727
T5	35.413±1.936	35.035±2.531	0.528
T10	36.172±2.841	35.607±3.107	0.476
T20	37.069±3.093	34.607±2.793	0.003
T30	36.172±3.252	34.714±2.813	0.076
Before removal	35.000±1.752	36.523±2.960	0.289

Quality of ventilation in terms of leak, peak airway pressure, chest movement and compliance and found that peak airway pressure was significantly higher in I-GEL at just after insertion and 10 min after insertion. On intra group comparison peak airway pressure increases significantly after insufflation of CO_2 for laparoscopic surgery [Table 6].

Table 6: Quality Of Ventilation

Parameters	Group P	Group I	p-value
Leak- present	2	3	0.195
-Not Present	27	25	
Peak airway pressure (cm H_2O)			
- After placement	15.206 \pm 1.145	16.285 \pm 1.08	0.001
- 10 min	21.931 \pm 0.961	22.821 \pm 0.863	0.001
- 30 min	23.000 \pm 0.886	23.464 \pm 0.922	0.058
Chest movement			
- Good	27	24	0.633
-Not good	2	4	
Compliance			
- Good	28	25	0.572
-Not good	1	3	

Complication-

Sore throat was most common complication and it was found in 3 cases (10.3%) in group P and 2 cases (7%) in group I. Gastric insufflation, regurgitation, aspiration and Hoarseness absent in both the groups [Table 7].

Sore throat	Group I	Group P	p-value
Present	2	3	>0.05
Absent	26	26	

DISCUSSION

After introduction of LMA by **Dr. Archie J. Brain** in 1981 changed the scenario from 'cannot intubate, cannot ventilate' to 'cannot intubate can ventilate'. We compared the p-LMA with i-GEL in terms of quality of insertion, ease of passage of Orogastric tube, variation of haemodynamic parameters after insertion, quality of ventilation & any complication following their use. In the present study, 60 patients of ASA status I and II of either sex, weigh 40-70kg undergoing Laparoscopic cholecystectomy under general anaesthesia were randomly selected and divided into two groups. Group I (n=30):received i-GEL Group P (n=30): received p-LMA. From table (1) shows that the overall mean age with standard deviation (SD) was 35.285 \pm 10.97 (years), mean weight with SD was 55.714 \pm 8.401 (kg) in the group I. In the P-LMA group, mean age of patient with SD was 35.655 \pm 14.049 (years), mean weight with SD was 55.275 \pm 8.030 (kg) which was statistically insignificant (p = 0.913 for age and p = 0.841 for weight). In the present study, there was no significant difference (p > 0.05) in the sex distribution between the two groups. However the female population was significantly more than the male population in both the groups.

Quality of insertion in terms of number of attempts and time taken for successful placement was 83.3% in group I and 76.7% in group P in first attempt while 6.67% in group I and 20% in group P in second attempt. The total mean time for I-GEL insertion in this study was 20.78 \pm 3.19 seconds, and for PLMA insertion was 21.64 \pm 3.14 seconds. The difference was clinically as well as statistically insignificant. There are many study comparing LMA-Proseal with classic LMA in which they observed lower first attempt insertion success with LMA-proseal **Brimacombe et al**; **Cook et al.**^[7,8] **Levitan and Kinkle**^[9] presumed that on insertion of LMA with inflatable mask the deflated leading edge of mask can catch the edge of the epiglottis and cause it to down fold or impede proper placement beneath the tongue. Higher first attempt success rate slightly less time required for I-GEL insertion because I-GEL can be inserted without introducer. As no cuff inflation is required in the I-GEL shorter time was required to achieve an effective airway by many investigator **Singh et al**; **Kanauji et al.**^[10,11] **Saran et al.**^[12] found that time taken for successful insertion were comparable in both group as in our study. This might be attributed be due to similar technique of insertion of PLMA as **Saran et al** also used digital technique.

In this study success rate of OGT insertion were 85% in I-GEL and 90% in P-LMA. There were 4 failed insertions in group-I and 3 failed insertions in group-P.

Nirupa R, et al.^[13] found that ease of insertion of Orogastric tube and pulmonary mechanics were similar in both the groups.

In the present study we observed that there was a significant rise in the Heart rate (HR), Systolic blood pressure (SBP) and Diastolic blood pressure (DBP) in both the groups following insertion of the respective devices. This rise, peaked at 1 minute (carboperitoneum) in both the groups but duration of raised heart rate and blood pressure was longer in group I in contrast to group P (5 minutes and 1 minute respectively). Moreover, the peak rise in heart rate and blood pressure was significantly more in Group I than Group P. The above haemodynamic changes following airway device insertion can be explained by the fact that the larger, softer wedge shaped PLMA adapt the shape of the pharynx better and there was less requirement of manipulation and patient remains more stable hemodynamically.

Rukhsana Najeeb et al.^[14] observed that there is significant increase in heart rate and blood pressure just after insertion of I-GEL as well as LMA-PROSEAL. **Sebastian G et al.**^[15] observed the increase in heart by 9.3 \pm 2.3 after insertion of PLMA, which was significantly lower than the ETT group. In the present study also increase in HR was similar to their study after insertion of p-LMA. **Uday Ambi et al.**^[16] - compared CLMA and PLMA for airway management in patients undergoing non abdominal surgeries under general anaesthesia. They observed that heart rate increased significantly after insertion of both the devices and remained significant till 5 min after the insertion LMA. **Sharma et al, Bennett S.R et al, Won-Jung Shin et al.**^[17,18] - They also observed the minimal changes in hemodynamic responses after insertion of these devices in their study.

In the present study we observed that in some cases despite of a steady maintenance of $\text{SpO}_2 > 95\%$, there was leak which was detected from an audible sound by listening over the mouth by stethoscope. In Group I leak was detected in 17.9% than the Group P 6.9% which was statistically insignificant (p=0.195). In all these cases there were requirement of manipulation along with an increase in the cuff volume (p-LMA). Chest movement was sufficient in 85% in case of Group I and 93% in Group P but was statistically insignificant. On comparison of quality of ventilation in terms of compliance it was found that compliance was good in most of the cases in both the groups but it was insignificantly higher in GROUP P. Compliance was good in 93.3% in GROUP P and 83.3% in GROUP I. Peak airway pressure significantly high in Group I, just after insertion and 10 min after insertion. It was not significant after 30 min. On intra group comparison peak airway pressure increases significantly after insufflation of CO_2 for laparoscopic surgery. **ETCO2** and **SPO2** remained satisfactory in both groups and were of no significance clinically. By considering all these parameters mentioned above, ventilation was considered adequate in 93% of patient in Group-P and 84% of patient in Group I which was statistically insignificant. Laparoscopic surgery has been shown to adversely affect intraoperative pulmonary mechanics, thus providing the most severe test of the efficacy of an airway device. Pulmonary compliance is decreased and the resistance is increased leading to high airway pressures. Therefore, higher inspiratory pressures are required to provide adequate tidal volume and minute ventilation. Intra-abdominal pressure of 15 - 20 mm Hg is associated with increase in the peak airway pressure of about 50 per cent, decrease in lung compliance by 25 per cent and an increase in PaCO_2 by 10 mmHg^[19,20]. Consistent with these results, we observed that following carboperitoneum, compliance decreased and the peak airway pressure, resistance, work of breathing increased in both groups. **Sharma et al.**^[21] found that respiratory mechanics parameters using the two devices (I-GEL VS PROSEAL LMA) were comparable apart from the dynamic compliance, which was significantly higher with i-gel (P < 0.05). Malrotation was higher with i-gel than with PLMA (15 vs. 5, P = 0.006). **W J Shin et al.**^[22] conclude that I-gel may have a similar airway sealing to that of p-LMA, higher than that of cLMA, and is not associated with adverse events. The I-gel might be an effective alternative as a supraglottic airway device. **W J Jeon et al.**^[23] conclude that I-gel is a reasonable alternative to the PLMA for controlled ventilation during laparoscopic gynaecologic surgery. **Brimacombe et al.**^[24] described one case of gastric insufflation with LMA-proseal where in the tip of the LMA-proseal had folded posteriorly after insertion resulting in the failure of the drainage tube to perform its intended function. **S. Saini et al** observed that during laparoscopic surgery passive regurgitation of fluid can occur during procedure but PLMA is able to protect the airway during such event. **N.R. Evans et al.**^[25] studied the ability of PLMA to isolate the airway in 103 anaesthetized adults by filling the hypo pharynx with methylene blue dyed saline introduced down the drainage tube. They conclude that the PLMA isolate the airway from fluid in hypo pharynx and can prevent

aspiration and regurgitation.

In the present study, it was found that sore throat was most common postoperative laryngopharyngeal morbidity recorded in both groups. However incidence of sore throat in p-LMA was more than the I-GEL (10.7% and 6.9 % respectively). The incidence of hoarseness was zero for both groups. These findings are comparable in both groups. The incidence is slightly more with p-LMA because the presence of an inflatable cuff of the p-LMA compresses microvascular structure and terminal nerve endings. In contrast i-GEL has a non-inflatable cuff designed to provide an anatomical fit over these perilaryngeal structures^[26]. Soliveres et al^[27] found that the use of PLMA produced more sore throat as compared to i-GEL. Various studies have reported similar findings, wherein the incidence of sore throat is minimal with i-GEL in comparison to other supraglottic airway devices.

CONCLUSION

In our study, quality of ventilation in terms of leak, peak airway pressure, chest movement and compliance was found that peak airway pressure was significantly higher in I-GEL at just after insertion and 10 min after insertion. On intra-group comparison, peak airway pressure increases significantly after insufflation of CO₂ for laparoscopic surgery. There was no evidence of gastric insufflation, aspiration and regurgitation in either of group I or group P. Majority of the patients from our study did not have post-operative sore throat, which could be due to a high success rate in the first attempt in both groups.

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