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Proseal Laryngeal Mask Airway: An Alternative to Endotracheal Intubation in Adult Patients for Surgical Procedures Under General Anaesthesia

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Abstract

Introduction: An endotracheal tube always considered to be the gold standard to maintain an airway because of its inherent ability to provide positive pressure ventilation [1,2]. Haemodynamic responses, situations of failed intubation, unable to ventilate and unable to intubate are also a serious concern. With the advent of newer supraglottic airway devices, these drawbacks of tracheal tube are avoided. The Proseal laryngeal mask is a new laryngeal mask device with a cuff modified to improve the seal around glottis and a drainage tube to provide for aspiration of gastric contents. The aim of our study was to compare efficacy and safety of Proseal Laryngeal Mask Airway with portex cuffed endotracheal tube in patients undergoing surgeries under general anaesthesia. *Aim and Objectives:* To compare efficacy and safety of Proseal Laryngeal Mask Airway with Portex cuffed endotracheal intubation in sixty adult patients undergoing surgeries under general anaesthesia. *Results:* Both groups were comparable with respect to their demographic characteristics. Time taken for insertion in group P and group E was similar. The study participants where Proseal LMA was used had a statistically significant lower rates of HR, SBP, DBP and MAP, at 1, 3, 5, 10 mins and after removal of device than participants in whom endotracheal tube was used. Side effects were lower in group P than group E. *Conclusion:* Proseal LMA is suitable and safe alternative to endotracheal tube for airway management.

Keywords: Proseal Laryngeal Mask; Laryngoscopy; Intubation; Endotracheal tube.

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Introduction

An endotracheal tube always considered to be the gold standard to maintain an airway because of its inherent ability to provide positive pressure ventilation [1,2].

The major cause of sympatho-adrenal response to tracheal intubation is due to the stimulation of supraglottic region by tissue irritation induced by direct laryngoscopy.

Haemodynamic responses, situations of failed intubation, unable to ventilate and unable to

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intubate are also a serious concern. This precludes the global utility of the tracheal tube and asks for better alternatives. With the advent of newer supraglottic airway devices, these drawbacks of tracheal tube are avoided. Maintenance of a patent airway remains an important concern of an anaesthesiologist [3].

The first supraglottic airway device The Laryngeal Mask Airway was designed in 1981 by Dr. Archie Brain. Though it was highly satisfactory device in securing airway, its lacunae with positive pressure ventilation, especially in patients with obesity and decreased pulmonary compliance prompted him further to find a better airway device. This led him to design and develop the Proseal LMA. The proseal LMA was introduced by Dr. Archie Brain in 2000 [4].

The Proseal laryngeal mask is a new laryngeal mask device with a cuff modified to improve seal around glottis and a drainage tube to provide for aspiration of regurgitated gastric contents and prevent gastric insufflation. These features are designed to improve the safety of the mask and broaden its scope, especially when used with positive pressure ventilation. Proseal LMA is less invasive device and considered to cause less stress response [2,5,6].

The aim of our study was to compare efficacy and safety of Proseal Laryngeal Mask Airway with portex cuffed endotracheal tube in patients undergoing surgeries under general anaesthesia.

Material and Methods

Type of Study: Prospective randomized comparative study.

Sample size: 60.

Proseal Laryngeal Mask Airway (Group P) – 30.

Endotracheal tube (Group E) – 30.

Method of Randomization: After approval from hospital research and ethics committee, a prospective, randomized, comparative study was conducted on adult patients undergoing surgeries under general anaesthesia. Randomization was done using a computer generated random number table. Sample size was calculated using Winpepi software with confidance interval of 95% and power of study 80%. Minimum sample size calculated was 12, 6 in each group. For detailed study purpose, we took sample size 60, 30 in each group.

The study was conducted on 60 adult patients cases randomly divided into two groups of 30 each.

Group P: Proseal laryngeal mask airway was used.

Group E: Endotracheal tube was used.

Pre Operative Evaluation

All patients were thoroughly evaluated pre-operatively. All the necessary and relevant laboratory and other investigations were carried out. In the pre-operative room, the patient's pulse, blood pressure and heart rate was taken, with the patient lying comfortably in supine position.

Anaesthesia Procedure

During pre-anaesthetic assessment, a detailed history and examination of each patient was carried out to optimize them prior to surgery. All the patients were kept fasting for 8 hours. In the operating room, all monitors were attached to patients, pulse oximeter, ECG and non-invasive blood pressure cuff. A wide bore 20G intravenous line established. Intra-operatively end tidal carbon dioxide ($ETCO_2$) was monitored.

The patients were pre-medicated with intravenous Glycopyrrolate 0.004 mg/kg, Ondansetron 0.1 mg/kg, Midazolam 0.02 mg/kg, Pentazocine 0.3 mg/kg. General anaesthesia was induced with Propofol 2 mg/kg and Vecuronium 0.1 mg/kg. After induction, appropriate size of PLMA was used in P group and appropriate size portex ETT was used in E group. Anaesthesia was maintained with isoflurane in 60% N_2O / 40% O_2 mixture. Controlled mechanical ventilation was applied to maintain end tidal CO_2 between 30-40 mm of Hg.

Correct placement of PLMA or ET tube was indicated by normal thoraco-abdominal movements, bilaterally equal audible breath sounds on auscultation and regular waveform capnograph. Along with this, specific tests for correct placement of PLMA are no audible leak from the drain tube with peak airway pressure less than 20 cm of H_2O, gel displacement test, insertion of nasogastric tube and aspiration of gastric contents. Gastric tube of number 12 or 14 was inserted through a drain tube. Two attempts were allowed before gastric tube insertion was considered a failure and repositioning of PLMA was done. Haemodynamic responses pulse rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure were recorded prior to induction, 1 min, 3 min, 5 min and 10 min after endotracheal intubation or PLMA insertion, and after removal of ETT or PLMA. After procedure reversal was done by using Inj. Neostigmine

0.05 mg/kg and Inj. Glycopyrrolate 0.008 mg/kg. Postoperative observations were done.

Clinical Parameters Monitored

1. Monitoring were done for following parameters:
2. Time taken for insertion of PLMA or ETT.
3. Ease of insertion of PLMA or ETT.
4. Attempts taken for insertion of Ryle's tube.
5. Time taken for insertion of Ryle's tube.
6. Haemodynamic changes after laryngoscopy and intubation or after insertion of PLMA and removal of device:
   - Heart rate monitoring.
   - Blood pressure monitoring (S.B.P, D.B.P, Mean B.P)
   - Oxygen saturation
   - $EtCO_2$
7. Perioperative complications
   - Cough
   - Laryngospasm
   - Bronchospasm
   - Blood on device
   - Aspiration
   - Hoarseness/sore throat

Statistical Analysis

All cases were completed in stipulated time. Data was collected, compiled and tabulated. The statistical analysis was done using parametric test and the final interpretation was based on Z-test [standard normal variate] with 95% level of significance. A p – value < 0.05 was considered statistically significant.

- Results were statistically analyzed,
- Quantitative data was analyzed by paired and unpaired t test.
- Qualitative data was analyzed by chi square test.

Results

Both groups were comparable with respect to their demographic characteristics. Time taken for insertion in group P and group E was similar.

The study participants where Proseal LMA was used had a statistically significant lower rates of heart rate, systolic blood pressure, diastolic blood pressure and mean arterial pressure, at 1, 3, 5, 10 mins than the participants in whom endotracheal tube was used. These rates for group P remained lower than group E after removal of airway device.

There was no significant difference in SpO_2 and $EtCO_2$ in both the groups at 1 min, 3 mins, 5 mins, 10 mins after insertion of device and after removal of device.

Side effects such as cough, sore throat and blood on device were seen in both groups. Group E had more patients with cough and sore throat than group P, difference was statistically significant. Group P had more patients with blood on device than group E, this difference was also statistically significant.

Table 1: Distribution of different procedures

Type of Surgery	No of Cases Group P	No of Cases Group E
Diagnostic Hysterolaparoscopy	5	6
MTP with Tubal ligation	5	5
Fibroadenoma Excision	8	9
Breast abcess Incision and drainage	1	2
CRIF with K wire radius fracture	3	
Contracture release of right little finger	1	1
Dilatation and curettage with polypectomy	1	1
Diagnostic laparoscopy	3	2
Laparoscopic Tubal Ligation	3	3
Excision of lipoma over arm		1
Total	30	30

Table 2: Groups

Group P (n=30)	Proseal LMA
Group E (n=30)	Endotracheal tube

Discussion

Airway management is a fundamental aspect of anaesthetic practice and of emergency and critical care medicine. Traditionally, laryngoscopy and endotracheal intubation has been the mainstay in safeguarding the airway in patients. It is rapid, safe and non-surgical technique that achieves all the goals of airway management. Intubation has its own advantages such as prevention of aspiration and delivery of anaesthetic gases, leak free ventilation during mechanical ventilation and remains the gold standard procedure for airway management. Despite of advantages of endotracheal intubation it has its own complications [7]. Laryngoscopy and endotracheal intubation are noxious stimuli capable of producing a huge spectrum of stress responses such as tachycardia, hypertension, bronchospasm, raised intracranial pressure and intraocular pressure [8].

The haemodynamic changes brought about by laryngoscopy and intubation was first described by Reid and Brace [9]. The haemodynamic response is initiated within seconds of direct laryngoscopy and further increases with the passage of the endotracheal tube. The response is initiated within 5 s of laryngoscopy, peaks in 1–2 min and returns to normal levels by 5 min [10]. These changes are usually short lived and well tolerated by normal patients. In patients with cardiovascular disease, it can incite harmful effects such as myocardial ischaemia, ventricular dysrhythmias, ventricular failure and pulmonary oedema. It can also lead to cerebrovascular accidents in cerebrovascular disease patients [11]. This precludes global utility of the tracheal tube and asks for better alternative. With advent of newer supra-glottic airway devices these drawbacks of tracheal tube are avoided.

The Proseal Laryngeal Mask Airway is a new laryngeal mask device with a cuff modified to improve seal around glottis and a drainage tube to provide a bypass channel for regurgitated gastric contents, prevent gastric insufflation and allow the passage of a gastric tube. The features are designed to improve the safety of the mask and broaden its scope, especially when used with positive pressure ventilation [12].

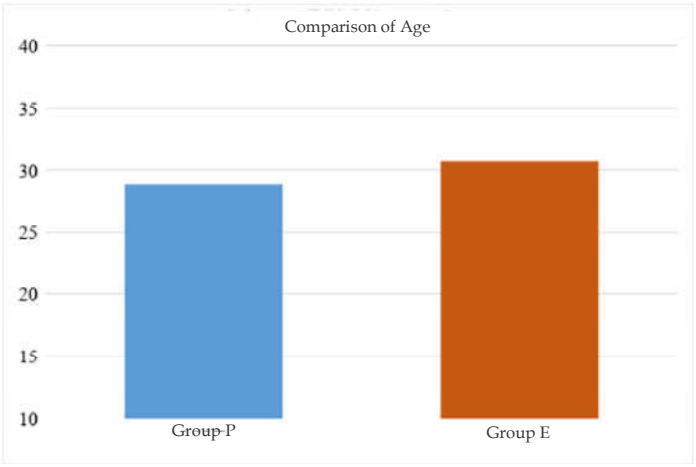
In this study we aimed to compare efficacy and safety of Proseal Laryngeal Mask Airway with Portex cuffed endotracheal intubation in adult patients undergoing surgeries under general anaesthesia.

Table 3: Gender Distribution

	Group P		Group E	
	No of Cases	**Percentage**	**No of Cases**	**Percentage**
Male	8	26.6%	5	16.6%
Female	22	73.3%	25	83.4%
Total	30	100%	30	100%

Table 4: Comparison of Age between two groups

Parameter	**Group P (Mean ± SD)**	**Group E (Mean ± SD)**	**p-value**
Mean Age (years)	28.8 ± 5.07	31.6 ± 6.26	0.08



Graph 1: Comparison of Age between two groups

Patient Characteristics across the groups

Both groups were similar in terms of age, gender, weight, ASA grading as shown in Table 3,4,5 and 6. Average duration of surgery was similar in both the groups, as shown in Table 7.

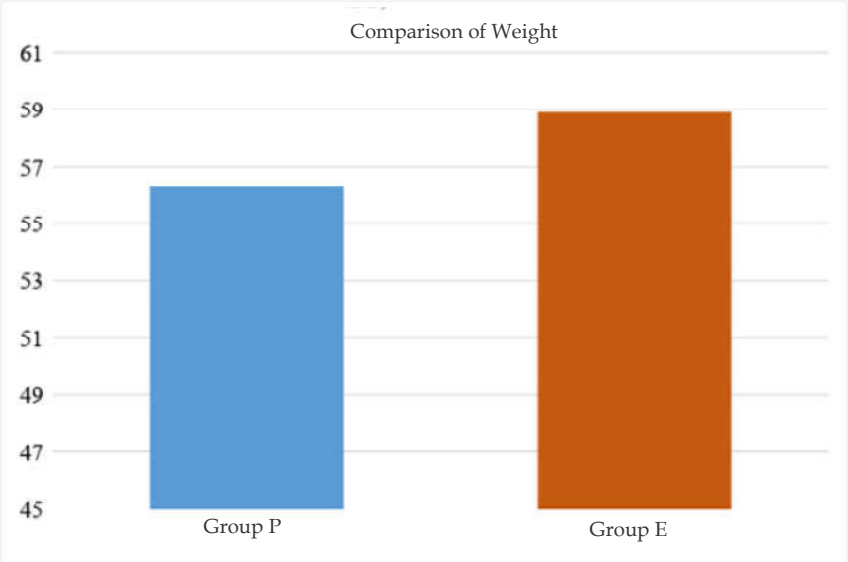
Insertion characteristics of device

Insertion rate was 100% for both groups. P group had 93.33% first attempt success at insertion and eventually 100% at the end of two attempts. In our study in Group P only 2 patients required second attempt for insertion. In Group E, all patients were intubated in first attempt as shown in Table 8.

In 2007, M Misra, B Ramamurthy conducted a study The Pro-seal LMAtm and tracheal tube: A comparison of events at insertion of the airway device. They found similar results as our study.

Table 5: Comparison of weight between two groups.

Parameter	Group P (Mean ± SD)	Group E (Mean ± SD)	p-value
Mean Weight (Kg)	56.3 ± 5.89	58.9 ± 6.20	0.1



Graph 2: Comparison of weight between two groups

Table 6: ASA Grade distribution

No of subjects	Group P	Group E
ASA Grade I	23	25
ASA Grade II	7	5

Table 7: Comparison of duration of surgery between two groups.

	Group P (Mean ± SD)	Group E (Mean ± SD)	p value
Duration of surgery (min)	42.3 ± 12.50	42.6 ± 10.56	0.9

Table 8: Insertion of Device

	Group P	Group E	p value
No. of attempts of insertion	I = 28 patients II = 2 patients	I = 30 patients	-
Time taken for insertion (seconds)	15.4 ± 2.87	15.9 ± 4.68	0.6
Time taken for RT insertion (seconds)	10.16 ± 1.89	12 ± 1.7	0.0001
No. of attempts taken for RT insertion (1/2/3/failed)	27/3/0	20/7/3/0	-

Group P had 88% first attempt success at insertion. This steadily rose to 98% at second attempt and eventually 100% at the end of three attempts [2].

Brimacombe J *et al.* have compared different techniques of PLMA insertion. Though the purpose of their study was different from ours, the observation in terms of first time success rate at insertion of PS-LMA by introducer tool technique and the number of attempts for successful airway attainment coincide with our study [13].

Time taken for insertion of device in Group P was 15.4 ± 2.87 seconds and in group E was 15.9 ± 4.68 seconds as shown in table 8. There were no statistically significant differences between two groups. (p-value > 0.05).

Sharma B, Sahai C *et al.* conducted a study Proseal Laryngeal Mask Airway: A study of 100 consecutive cases of Laparoscopic surgery. They found that mean time taken for the placement of the device was 13.51 seconds and range (5-33) seconds. Results were comparable to our study [14].

Shroff P, Kamath S conducted a study between the Proseal LMA and Endotracheal intubation for laparoscopic surgery and reported mean time for insertion of PLMA and ETT were 15 seconds and ETT 26 seconds respectively. Time taken for insertion of PLMA was comparable, but time taken for ETT insertion in our study was different [5].

Insertion characteristics of Ryle's tube

Mean time taken for insertion of Ryle's tube was 10 seconds in group P while it was 12 seconds group E. Similarly, the success rate of Ryle's tube in the first attempt was higher (90%) via Proseal than via nasal route in intubated patients (66.67%) with endotracheal intubation.

Namazi IJ, Garia N, Kumar RB *et al.* compared Proseal laryngeal mask airway and endotracheal tube in patients undergoing laproscopic surgeries under general anaesthesia. They reported the mean insertion time taken to insert NGT through PLMA was significantly less (9.4 seconds) than via nose (11.3 seconds) in intubated patients. Similarly success rate of NGT in the first attempt was higher via Proseal than via nasal route in intubated patients with endotracheal intubation [15].

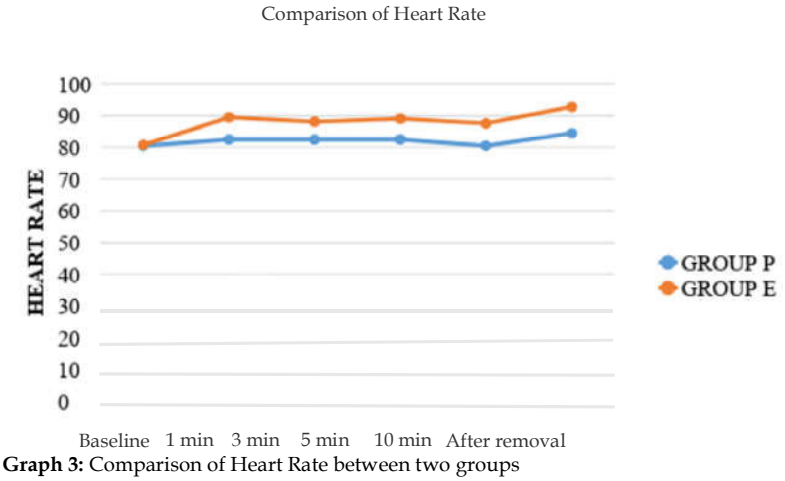
Comparison of Vital Parameters

Comparison of heart rate between two groups

As shown in Table 9 and Graph 3 The mean pulse rate in group P increased from baseline value 80.5 ± 6.13/min to 82.5 ± 5.51/min over five minutes after insertion. At ten minutes after insertion it returned to baseline value and again increased to 84.5 ± 5.51/ min after removal.

Table 9: Comparison of heart rate between two groups

Heart Rate	Group P Mean ± Sd	Group E Mean ± Sd	p Value	Significance
Baseline	80.5 ± 6.13	80.8 ± 6.13	>0.05	Not Significant
1 Min After Insertion	82.5 ± 5.51	89.5 ± 10.83	<0.05	Significant
3 Min After Insertion	82.5 ± 5.51	88.1 ± 12.46	<0.05	Significant
5 Min After Insertion	82.5 ± 5.51	89.0 ± 10.19	<0.05	Significant
10 Min After Insertion	80.5 ± 5.51	87.5 ± 12.02	<0.05	Significant
After Removal	84.5 ± 5.51	92.8 ± 6.13	<0.05	Significant



Graph 3: Comparison of Heart Rate between two groups

In Group E, mean pulse rate increased from baseline value 80.8 ± 6.13/min to 89.0 ± 10.19/min over five minutes after insertion. At ten minutes there was decrease in pulse rate, but it did not reach to baseline value. Pulse rate again increased to 92.8 ± 6.13/min after removal.

There was significant difference between two groups at 1 min, 3 mins, 5 mins and 10 mins and also after removal of device. Values were relatively lower in group P than group E. The difference between two groups was found to be statistically significant (p value <0.05).

Namazi IJ, Garia N, Kumar RB *et al.* compared Proseal Laryngeal Mask Airway and Endotracheal tube in patients undergoing laproscopic surgeries under general anaesthesia. They reported statistically significant ($p < 0.05$) increase in heart rate and mean blood pressure was observed which persisted till 5 minutes after intubation and during the time of extubation in the group E [15].

Mehta K, Sharma S *et al.* compared Proseal LMA with Endotracheal Intubation in Laparoscopic Tubal Ligation. They evaluated hemodynamic responses were lower for placement than ETT. Mean pulse rate increased from baseline value of 91.06 ± 10.22/min to 96.86 ± 9.13/min and 90.26 ± 10.74/min to 108.53 ± 12.04 after the placement of PLMA and ETT intubation respectively. The mean pulse rate was not changed after removal of PLMA in group [16].

These studies suggested that the increase in heart rate was considerably higher with endotracheal intubation as compared to proseal laryngeal mask airway insertion.

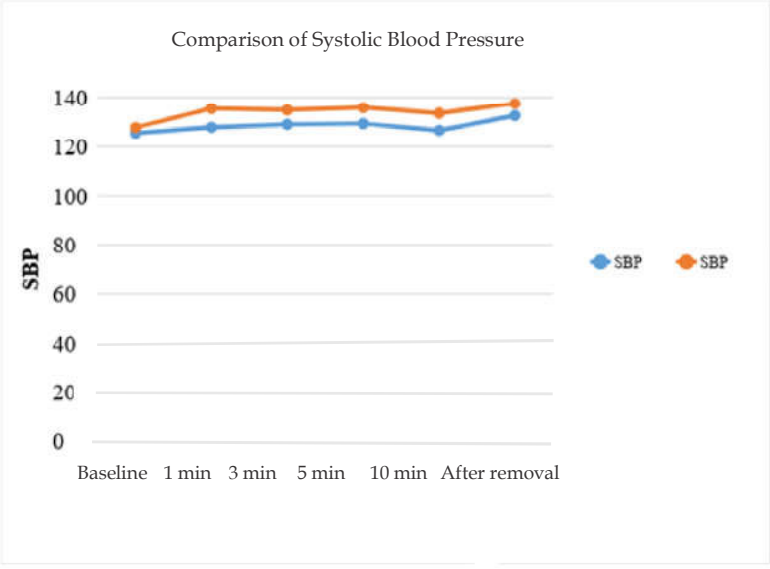
Comparison of Systolic Blood Pressure

As shown in table 10 and graph 4, in group P the systolic blood pressure increased from baseline value of before insertion 125.6 ± 6.08 mm of Hg to 129.4 ± 4.69 mm of Hg over 5 mins after insertion. At 10 mins there was again fall in systolic blood pressure to 126.6 ± 5.73 mm of Hg. And it increased to 132.6 ± 5.15 mm of Hg after removal of device.

In group E the systolic blood pressure increased from baseline value of 127.8 ± 6.67 mm of Hg to 135.8 ± 10.33 mm of Hg over 5 mins after insertion. At 10 mins there was fall in systolic blood pressure

Table 10: Comparison of systolic blood pressure between two groups

Systolic Blood Pressure	Group P Mean ± Sd	Group E Mean ± Sd	p Value	Significance
Baseline	125.6 ± 6.08	127.8 ± 6.67	>0.05	Not Significant
1 Min After Insertion	127.9 ± 5.84	135.46 ± 11.38	<0.05	Significant
3 Min After Insertion	129.1 ± 5.47	134.8 ± 9.04	<0.05	Significant
5 Min After Insertion	129.4 ± 4.69	135.8 ± 10.33	<0.05	Significant
10 Min After Insertion	126.6 ± 5.73	133.5 ± 11.39	<0.05	Significant
After Removal	132.6 ± 5.15	137.4 ± 8.27	<0.05	Significant



Graph 4: Comparison of systolic blood pressure between two groups

to 133.5 ± 11.39 mm of Hg. and it again increased to 137.4 ± 8.27 mm of Hg after extubation.

There was significant difference in systolic blood pressure values after insertion of device at 1 min, 3 mins, 5 mins, 10 mins and after removal of device. Values were relatively lower in group P and difference was found to be statistically significant (p-value <0.05).

Sharma B, Sahai C *et al.*, conducted a study of 100 consecutive cases of laparoscopic surgery. Their results were Pre-induction SBP 125.14 ± 18.89 mm of Hg reached upto 124.56 ± 24.50 mm of Hg at 1 min and 127.11 ± 23.37 mm of Hg at 5 mins after insertion of PLMA (p-value 0.5). They concluded that there were minimum haemodynamic responses to insertion of Proseal Laryngeal Mask Airway [14].

Misra M, Ramamurthy B. compared events at insertion of The Proseal LMA and tracheal tube, they concluded the hemodynamic changes observed were minimal with PLMA while with tracheal tube, significant changes were observed [2].

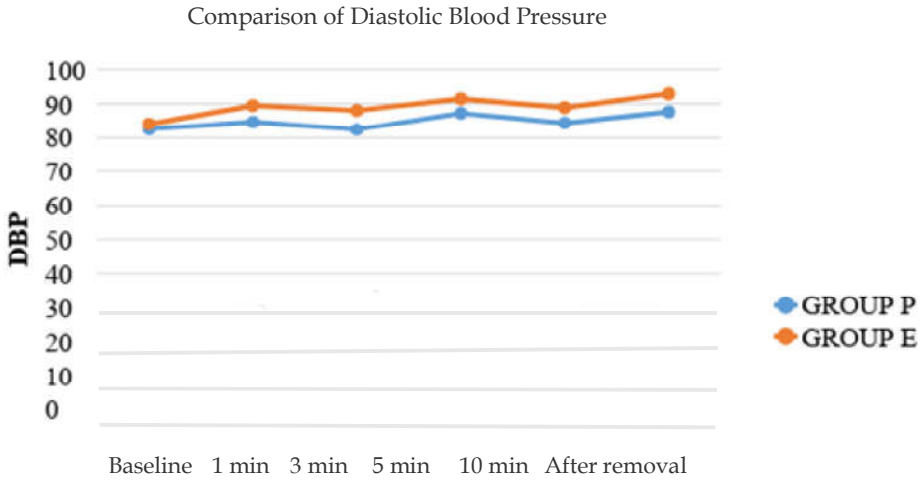
Comparison of Diastolic Blood Pressure

As shown in table 11 and graph 5, the baseline diastolic blood pressure in group P and Group E was 82.6 ± 5.75 mm of Hg and 84.1 ± 6.23 mm of Hg. There was no statistically significant difference. After 1 min of insertion the diastolic BP 84.7 ± 5.64 mm of Hg in group P and 89.5 ± 9.93 mm of Hg in group E. Difference was statistically significant (p-value < 0.05). Similarly there was statistically significant difference in mean diastolic blood pressure between two groups 3 mins, 5 mins and 10 mins after insertion of device. After removal mean diastolic blood pressure in Group P was 87.7 ± 7.53 mm of Hg and in group E 92.9 ± 6.51 mm of Hg. Difference was statistically significant.

Lim Y, Goel S, Brimacombe JR compared PLMA with endotracheal intubation in gynaecological laparoscopy. They concluded haemodynamic responses to placement and removal were lower for PLMA than the TT [17].

Table 11: Comparison of diastolic blood pressure between two groups

Diastolic Blood Pressure	Group P Mean ± Sd	Group E Mean ± Sd	p Value	Significance
Baseline	82.6 ± 5.75	84.1 ± 6.23	>0.05	Not Significant
1 Min After Insertion	84.7 ± 5.64	89.5 ± 9.93	<0.05	Significant
3 Min After Insertion	86.3 ± 5.48	90.1 ± 6.23	<0.05	Significant
5 Min After Insertion	87.3 ± 5.26	91.4 ± 8.20	<0.05	Significant
10 Min After Insertion	84.4 ± 6.02	88.9 ± 9.57	<0.05	Significant
After Removal	87.7 ± 7.53	92.9 ± 6.51	<0.05	Significant



Graph 5: Comparison of Diastolic Blood Pressure between two groups

Comparison of Mean Arterial Pressure

As shown in table 12 and graph 6, the baseline MAP in group P and group E was 82.9 ± 3.86 mm of Hg and 84.5 ± 4.04 mm of Hg. There was statistically significant difference at 1 min, 3 mins, 5 mins and 10 mins after insertion of device. After removal MAP was 87.9 ± 4.97 mm of Hg in group P and 92.4 ± 4.47 mm of Hg in group E. Difference was statistically significant.

Saraswat N, Kumar A *et al.* compared Proseal LMA and Endotracheal tube in patients undergoing laparoscopic surgeries under general anaesthesia. They concluded statistically significant increase in heart rate and mean blood pressure was observed 10 seconds after intubation and persisted till 3 mins after intubation and also during extubation in the ETT group. However statistically significant increase in PLMA group was seen only 10 seconds after insertion [18].

Mehta K, Sharma S *et al.* compared Proseal LMA with Endotracheal Intubation in Laparoscopic Tubal Ligation. They evaluated hemodynamic responses were lower for placement of PLMA than ETT. MAP increased from a baseline value of before insertion 91.02 ± 7.78 to 94.77 ± 8.49 and 90.94 ± 5.67 to 105.72 ± 10.19 after placement of PLMA and ETT and 89.55 ± 6.23 to 90.86 ± 5.86 and 94.08 ± 6.22 to 103.73 ± 6.16 after removal of PLMA and ETT. The increase in MAP was statistically significant in both groups after insertion 5, 10 mins and after removal [16].

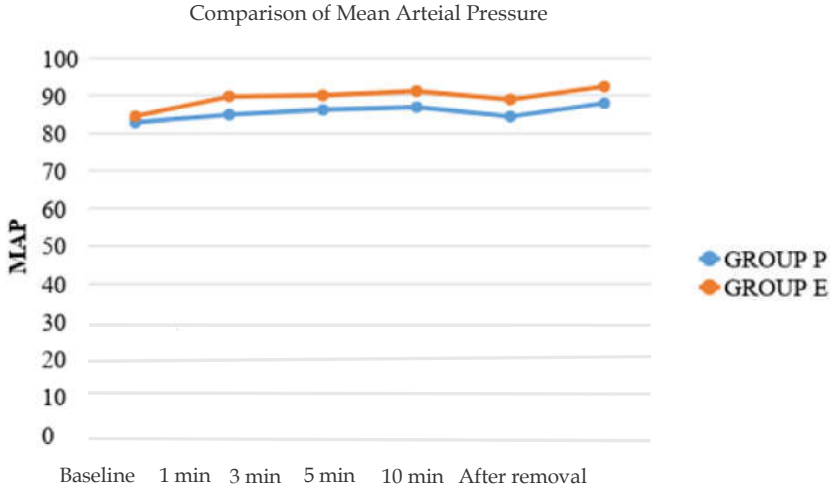
Comparison of End Tidal Carbon Dioxide

As shown in table 13 and graph 7, baseline EtCO2 in group P was 33.3 ± 1.03 and that in group E was 32.2 ± 1.33, there was no statistically significant difference between two groups (p-value > 0.05).

There was no significant difference in $EtCO_2$

Table 12: Comparison of Mean Arterial Pressures between Two Groups

Mean Arterial Pressure	Group P Mean ± Sd	Group E Mean ± Sd	p Value	Significance
Baseline	82.9 ± 3.86	84.5 ± 4.04	>0.05	Not Significant
1 Min After Insertion	84.9 ± 3.86	89.7 ± 6.76	<0.05	Significant
3 Min After Insertion	86.2 ± 3.78	90.0 ± 4.13	<0.05	Significant
5 Min After Insertion	86.9 ± 3.54	91.1 ± 5.69	<0.05	Significant
10 Min After Insertion	84.4 ± 3.96	88.9 ± 6.17	<0.05	Significant
After Removal	87.9 ± 4.97	92.4 ± 4.47	<0.05	Significant



Graph 6: Comparison of Mean Arterial Pressures between Two Groups

Table 13: Comparison of $EtCO_2$ between two groups

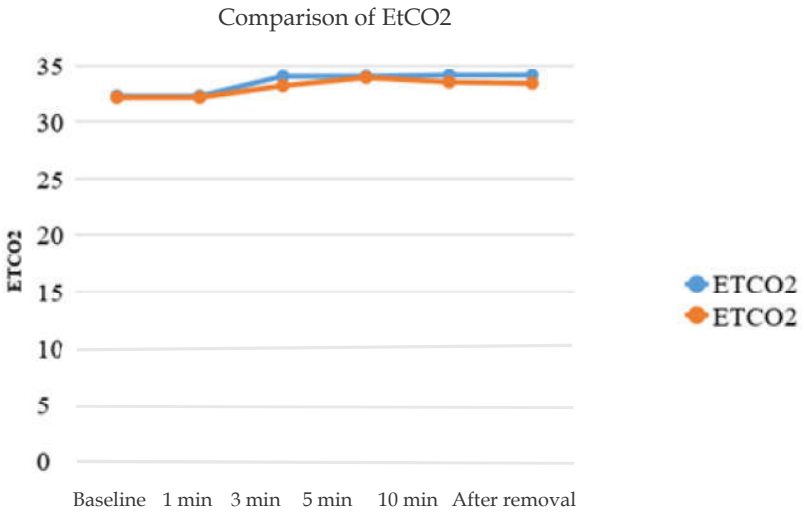
End Tidal Carbondioxide	Group P Mean ± Sd	Group E Mean ± Sd	p Value	Significance
Baseline	33.3 ± 1.03	32.2 ± 1.33	>0.05	Not Significant
1 Min After Insertion	32.3 ± 1.03	32.2 ± 1.60	>0.05	Not Significant
3 Min After Insertion	34 ± 1.23	33.2 ± 2.26	>0.05	Not Significant
5 Min After Insertion	34 ± 1.23	33.9 ± 1.47	>0.05	Not Significant
10 Min After Insertion	34.1 ± 1.25	33.5 ± 1.30	>0.05	Not Significant
After Removal	34.1 ± 1.25	33.4 ± 1.50	>0.05	Not Significant

in both the groups at 1 min, 3 mins, 5 mins and 10 mins after insertion of device and after removal of device.

Comparison of SpO_2

As shown in table 14 and graph 8, Baseline SpO_2 was 99.7 ± 0.7 in group P and group E. There was no statistically significant difference in SpO2 at 1min, 3mins, 5 mins and 10 mins after insertion of device and removal of device.

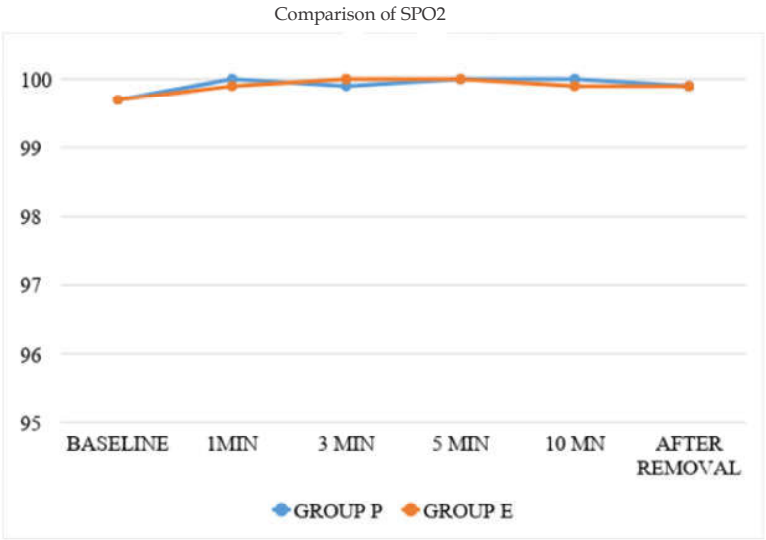
Lalwani J, Dubey KP *et al.* reported there was no significant difference in mean SpO_2 and $EtCO_2$ level recorded at different time intervals between PLMA and ETT groups (p-value >0.05) [19].



Graph 7: Comparison of $EtCO_2$ between two groups

Table 14: Comparison of SpO_2 between two groups

SpO_2	Group P Mean ± Sd	Group E Mean ± Sd	p Value	Significance
Baseline	99.7 ± 0.7	99.7 ± 0.7	>0.05	Not Significant
1 Min After Insertion	100 ± 0	99.9 ± 0.53	>0.05	Not Significant
3 Min After Insertion	99.9 ± 0.53	100 ± 0	>0.05	Not Significant
5 Min After Insertion	100 ± 0	100 ± 0	>0.05	Not Significant
10 Min After Insertion	100 ± 0	99.9 ± 0.53	>0.05	Not Significant
After Removal	99.9 ± 0.53	99.9 ± 0.53	>0.05	Not Significant



Graph 8: Comparison of SpO_2 between two groups

Perioperative complications

As shown in table 15, after extubation there was significant incidence of cough as compared to after removal of PLMA. In group P, only 6% of patients reported cough and in group E 30% of patients reported cough. Difference between two groups was statistically significant (p-value < 0.05).

As shown in table 15, Group E had more patients with sore throat than group P, this difference was statistically significant (p-value < 0.05).

Maltby JR, Beriault MT *et al.* reported that the incidence of cough was higher after endotracheal extubation [20].

Sinha *et al.* also reported that the incidence of cough was higher after endotracheal extubation [21].

Higgins PP, Mezei G *et al.* concluded that patients with tracheal tube had the greatest incidence of sore throat (45.4%) followed by patients with LMA (17.5%) [22].

As shown in table 15, blood on the posterior surface of PLMA was observed in three (10%) patients in group P but in group E only in two (6.66%) cases blood on ET tube was observed after extubation. This difference was statistically significant (p-value < 0.05).

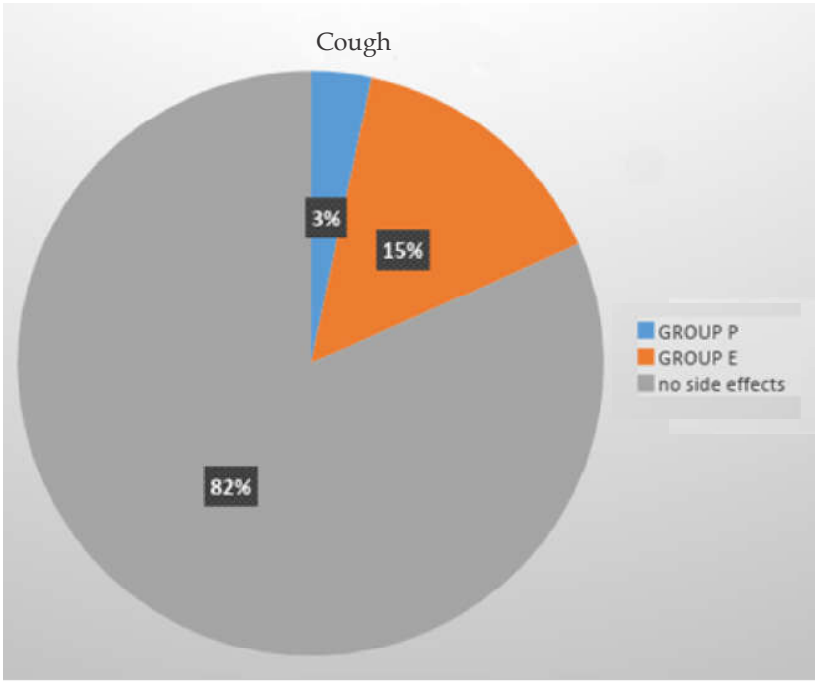
Lim Y, Goel S *et al.* reported 7% incidence of blood staining on PLMA and 6% in ET tube [17].

There was no incidence of aspiration in either group of patients during induction of anaesthesia, intraoperative period or after removal of the respective airway device. Kelly F, Sale S, Lardner D, Cox R *et al.* also reported the similar findings [23,24].

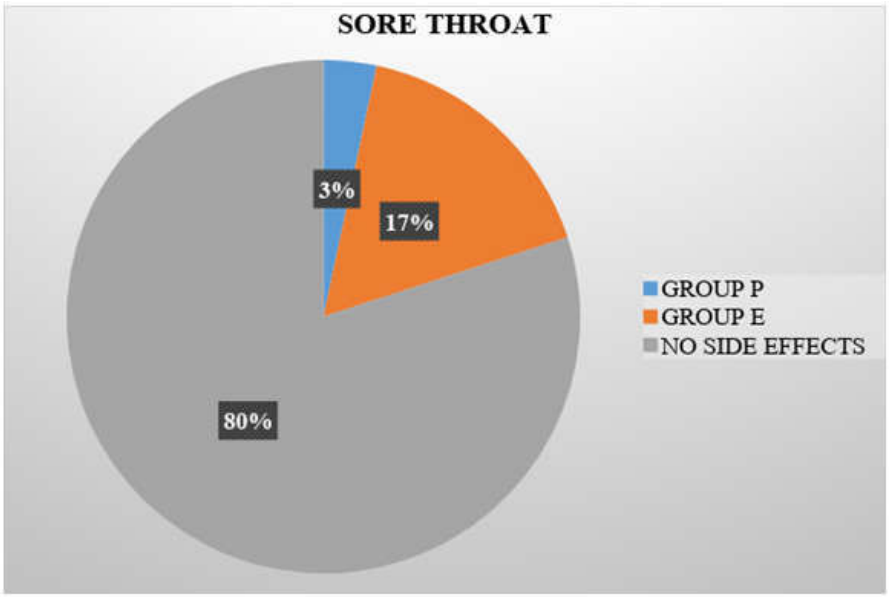
There was no incidence of laryngospasm or bronchospasm in either group of patients perioperatively.

Table 15: Incidence of perioperative complications in both groups

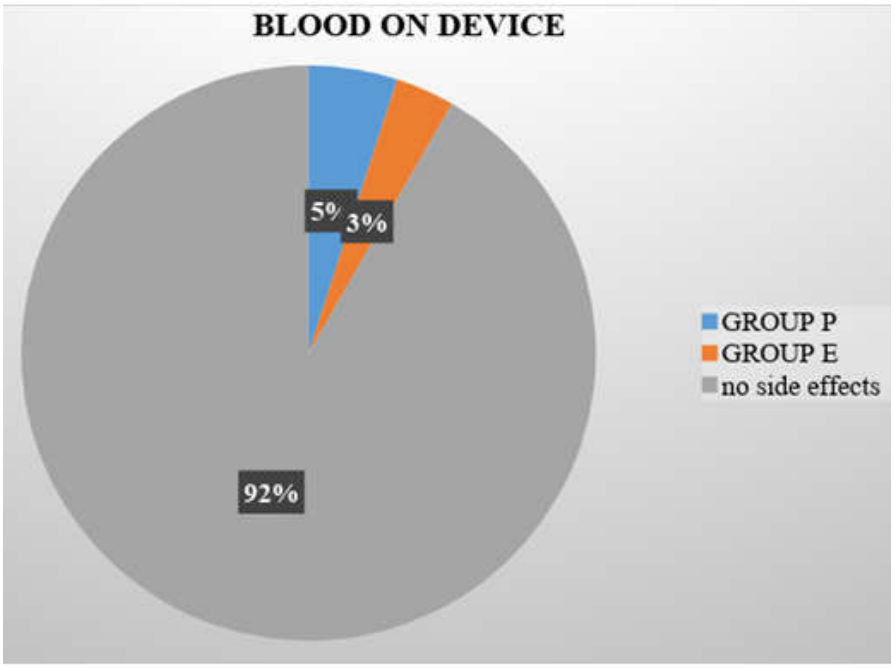
Complications	Group P		Group E		p Value
	Number	%	Number	%	
Cough	2	6.66	9	30	<0.05
Laryngospasm	0	0	0	0	
Bronchospasm	0	0	0	0	
Blood on device	3	10	2	6.66	<0.05
Aspiration	0	0	0	0	
Sore Throat	2	6.66	10	33.33	<0.05



Graph 9: Comparison of Cough Between two Groups



Graph 10: Comparison of Sore Throat Between two Groups:



Graph 11: Comparison of Blood on Device Between two Groups:

Conclusion

Based on our observations, results and discussion, we conclude that in the patients undergoing elective surgeries, Proseal LMA is suitable and safe alternative to endotracheal tube for airway management with respect to ease of insertion, haemodynamic parameters and reduced perioperative complications.

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