International Journal of Research in Medical Sciences
Patodi V et al. Int J Res Med Sci. 2016 Dec;4(12):5334-5340
www.msjonline.org
pISSN 2320-6071 | eISSN 2320-6012
DOI: http://dx.doi.org/10.18203/2320-6012.ijrms20164205

Original Research Article

A comparative study between ProSeal laryngeal mask airway and endotracheal tube for ease of insertion and haemodynamic changes in patients undergoing laparoscopic cholecystectomy under general anaesthesia

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Received: 04 October 2016
Accepted: 04 November 2016

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ABSTRACT

Background: The endotracheal tube is considered a gold standard for providing a safe and effective glottic seal, especially for laparoscopic procedures under general anaesthesia. However, haemodynamic pressor responses associated with its use might be detrimental. The ProSeal LMA minimizes this response without compromising the airway with lesser incidence of complications. The aim of this study was to compare ProSeal LMA and Endotracheal tube with respect to intra-operative haemodynamic responses and ease of insertion of device and nasogastric tube in patients undergoing laparoscopic surgeries under general anaesthesia.
Methods: This prospective randomized study was conducted on sixty patients, aged 20-60 years; of ASA grade 1 or 2, 30 in each group, posted for laparoscopic cholecystectomy under general anaesthesia. After induction with propofol and neuromuscular blockade with rocuronium, PLMA or ETT was inserted. The haemodynamic responses and insertion time of device and nasogastric tube were noted. Postoperative complications, if any were also noted.
Results: The mean time of insertion of PLMA was 37.40±16.09 seconds and for intubation (ETT) was 31.17±20.89 seconds which was statistically not significant (P >0.05). The mean time of insertion of nasogastric tube was 18.84±6.84 seconds in PLMA group and 73.00±71.06 seconds in the ETT group which was highly significant, (P <0.001). There was a statistically significant increase in the heart rate(HR),systolic blood pressure (SBP),diastolic blood pressure (DBP) and mean arterial pressure (MAP) at intubation that persisted till 5 minutes of intubation and also at the time of extubation in ETT group, (P <0.05). However, the haemodynamic parameters remained comparable to baseline values, after insertion of ProSeal and at its removal in PLMA group (P>0.05).
Conclusions: ProSeal LMA proved to be a suitable alternative to endotracheal tube for airway management with stable haemodynamics in patients undergoing laparoscopic cholecystectomy under general anaesthesia.

Keywords: Ease of insertion, Endotracheal tube, Haemodynamics, Laparoscopic surgeries, ProSeal LMA

INTRODUCTION

Airway management is very crucial for an anaesthesiologist despite significant advances in the anaesthetic practice from time to time. The cuffed endotracheal tube was considered as the gold standard for providing an adequate and effective glottic seal for positive pressure ventilation, prevents gastric insufflation and aspiration particularly for laparoscopic procedures under general anaesthesia where pneumoperitoneum decreases the pulmonary compliance, reduces functional residual capacity and increases airway pressures. However, the use of endotracheal tube may be associated with various problems like haemodynamic pressor response, dental trauma, cough and sore throat. So this warrants searching for a newer alternative device which

reduces haemodynamic variations along with other complications.[1-4]

In 2000, Dr. Brain invented the ProSeal laryngeal mask airway with a double cuff and a double lumen which seperates the respiratory and gastrointestinal tract along with providing an effective seal, improved and adequate controlled ventilation which was a useful advancement in the field of anaesthesia.[5] So we hypothesized that ProSeal LMA can be used as an effective alternative to ETT in laparoscopic surgeries as it provides stable haemodynamics with adequate ventilation and minimal postoperative complications.

This study was conducted to compare the ProSeal LMA and the endotracheal tube in laparoscopic cholecystectomy under general anaesthesia with regards to intra-operative haemodynamic responses, the ease of insertion of device and nasogastric tube, adequacy of ventilation and also occurrence of any post-operative complications like cough, sore throat, laryngospasm and tracheal aspiration.

METHODS

This prospective randomized comparative study was conducted in the Department of Anesthesiology at our medical college's attached hospital after obtaining approval from the institutional ethical committee and patient's written and informed consent. Sixty adult patients were included of either sex belonging to (American Society of Anesthesiologists) ASA grade 1 or 2, aged 20-60 years, posted for elective laparoscopic cholecystectomies under general anaesthesia. Patients with anticipated difficult airway, obesity (body mass index>35kg/m^2), oropharyngeal pathology, cardio-pulmonary disease, cervical spine fracture or instability or patients at increased risk of aspiration (gastro-oesophageal reflux disease, hiatus hernia, and pregnant patients) were excluded from the study.

All the patients were allocated randomly into two groups of 30 each; using computer generated random number table and sequentially numbered opaque sealed envelopes; PLMA Group who underwent insertion of a ProSeal LMA (n=30) and ETT Group who underwent insertion of an Endotracheal tube (n=30).

All the patients were undergone routine preanaesthetic evaluation before the surgery and explained about the anaesthetic technique and perioperative course. They were kept nil per oral overnight. After arrival in the operation theatre, 18G intravenous (IV) cannula was secured and Ringer lactate solution started through it.

All standard monitors noninvasive blood pressure (NIBP), pulse oximeter (SpO_2), electrocardiogram (ECG), Capnography ($EtCO_2$) were attached and baseline parameters were recorded. Intravenous midazolam 0.02 mg/kg, glycopyrrolate 0.005 mg/kg, and fentanyl 1-2 μg/kg were administered 1-2 min before induction. After pre-oxygenation with 100% O_2 for 3-5 minutes, anaesthesia was induced with propofol 2-2.5 mg/kg till the loss of verbal commands.

Neuromuscular blockade to facilitate placement of device was achieved by rocuronium 0.8 mg/kg intravenously. The patient was manually ventilated by facemask using intermittent positive pressure ventilation (IPPV) with 100% oxygen for 90 seconds. Following adequate paralysis, the corresponding airway was inserted in each group.

In PLMA group, size 3 or 4 ProSeal LMA (according to weight) was inserted and cuff inflated with 20-30 ml of air with standard technique. In ETT group, endotracheal intubation (with appropriate size endotracheal tube) was performed using direct laryngoscopy. The time interval between holding the airway device to confirmation of correct placement by bilateral air entry on chest auscultation was noted. Correct placement of the devices was confirmed by adequate bilateral chest movement on manual ventilation, bilateral equal air entry on chest auscultation, normal capnography waveforms and oxygen saturation more than 95%. Also nasogastric tube of appropriate size was inserted in all patients using lubricated jelly.

Anaesthesia was maintained with oxygen, nitrous oxide, halothane and rocuronium. A tidal volume of 8 ml/kg, respiratory rate of 12/min and I/E ratio of 1:2, $EtCO_2$ between 35 to 45 mmHg was maintained for adequate ventilation.

At the end of the procedure, anaesthetic agents were discontinued and patients were kept on 100% oxygen with PLMA or ETT in situ. Patients were reversed with intravenous neostigmine 0.05 mg/kg and glycopyrrolate 0.01 mg/kg. The patient was extubated or the device removed once the patient became fully awake and met all the criteria of recovery from neuromuscular blockade. The patients were monitored in the post-anaesthesia care unit. Any incidences of sore throat, cough or any other complications were noted.

The patients were observed for various parameters; Insertion characteristics (attempts or ease of insertion and time taken for insertion) of the PLMA or ETT and the nasogastric tube (NGT). The ease of insertion and attempt were graded as: Easy insertion -insertion at first attempt with no resistance; difficult insertion -insertion with resistance or at second attempt; failed insertion - insertion not possible.

Haemodynamic parameters (HR,SBP,DBP,MAP) were recorded: Preoperatively (baseline), at the time of insertion, at 1,2 and 5 mins after insertion of device, after achieving pneumoperitoneum, at 30 mins and during removal of devices. Oxygen saturation (SpO_2) and end-tidal carbon dioxide ($EtCO_2$) were also recorded.

Statistical analysis

The sample size was calculated to be 30 patients in each group showing a significant difference between the two groups with regard to different study parameters and based on previous studies, with type 1 error of 0.05 and a power of 0.9. Statistical analysis was done using Chi-Square test, Fisher's Exact test and Student's paired and unpaired t-test. Null hypothesis was assumed. Data were analyzed using the statistical software (SPSS version 17.0, Chicago, IL, USA). Data were expressed as Mean±SD and percentage. P value of >0.05 was considered to be statistically not significant, a P value of <0.05 was statistically significant and a P value of <0.001 was highly significant.

RESULTS

In present study, both the groups were comparable with respect to demographic profile i.e. age, weight and sex, (P>0.05). ASA grade and Mallampati grade were also comparable, (P>0.05) (Figure 1).

The ProSeal LMA was inserted easily in the first attempt in 66.67% patients whereas 33.33% patients required a second attempt and the mean time of insertion of PLMA was 37.40±16.09 seconds however, in ETT group, intubation was successful in first attempt in 96.7% patients and 18.3% patients required a second attempt with mean time of intubation was 31.17±20.89 seconds.

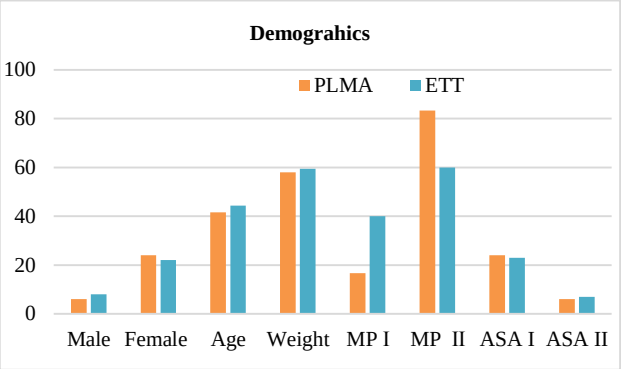

Figure 1: Demographic data.

The mean time of device insertion was statistically not significant (P>0.05). However the mean time of insertion in ETT group was shorter as compared to PLMA group (Table 1).

Table 1: Comparison of characteristics of two airway devices in both groups.

Airway parameters	PLMA (n=30)	ETT (n=30)	P value
Attempts of device insertion (1/2/3/failed)	20/10/0/0	29/1/0/0	-
Time taken for insertion of device(seconds)	37.40±16.09	31.17±20.89	>0.05
Attempts of NGT insertion (1/2/3/failed)	30/0/0/0	15/13/2/0	
Time taken for insertion of NGT(seconds)	18.80±6.84	73.00±71.06	<0.05

Data expressed as number and Mean±SD, P<0.05 considered as significant.

Table 2: Comparison of mean HR (bpm) at various time intervals.

Time Interval	PLMA group (bpm)		Intra group P value	ETT group (bpm)		Intra group P value	inter group P value
	Mean	SD		Mean	SD		
Preop	86.20	13.57		86.20	8.14		1.000
Insertion	84.13	15.40	0.140	98.40	13.90	0.000	0.000
1 min	85.13	13.66	0.502	103.83	11.70	0.000	0.000
3 min	85.67	14.20	0.766	101.90	13.77	0.000	0.000
5 min	85.47	11.55	0.703	94.47	20.00	0.020	0.037
Pneumo	86.60	10.77	0.831	91.00	13.59	0.081	0.170
30 min	85.33	9.79	0.674	86.13	16.61	0.983	0.821
Removal	88.93	10.80	0.169	99.33	13.13	0.000	0.001

PLMA- Proseal Laryngeal Mask Airway; ETT- Endotracheal Tube; P>0.05, not significant; P<0.05, significant.

Nasogastric tube was inserted in all patients in the first attempt in the PLMA group with mean time of insertion was 18.84±6.84 seconds, whereas nasogastric tube was inserted in first attempt in 50% patients and 6.7% patients required 3 attempts in the ETT group with a mean insertion time of 73.00±71.06 seconds which was significantly higher than the PLMA group, (P<0.05) (Table 1). The mean heart rate (HR) increased significantly from 86.20±13.57 bpm to 98.40±13.90 at insertion, 103.83±11.70 bpm at 1 min and 101.90±13.77

bpm at 3 min and 94.47±20.00 bpm at 5 min in the ETT group , (P<0.05), (Table 2). The mean SBP increased from its baseline value, 133.07±10.75 to 148.27±16.47 mm Hg at 1 min,142.80±20.04 mmHg at 3 min and 141.67±9.53 at 5 min, after intubation in ETT group which was statistically significant, (P<0.05), (Table 3).

Table 3: Comparison of systolic blood pressure (mmHg) at various time intervals.

Time interval	PLMA group (mmHg)		Intra group P value	ETT group (mmHg)		Intra group P value	Inter group P value
	Mean	SD		Mean	SD		
Preop	152.20	113.44		133.07	10.75		0.362
Insertion	125.67	9.87	0.194	139.73	20.33	0.126	0.001
1 min	123.07	9.67	0.156	148.27	16.47	0.000	0.000
3 min	117.43	21.85	0.100	142.80	20.04	0.011	0.000
5 min	122.03	8.90	0.147	141.67	19.53	0.022	0.000
Pneumo	123.13	8.10	0.165	124.53	15.30	0.014	0.659
30 min	128.07	7.64	0.247	128.80	10.42	0.164	0.757
Removal	131.87	6.66	0.334	141.40	7.19	0.000	0.000

PLMA- ProSeal Laryngeal Mask Airway; ETT- Endotracheal Tube; P>0.05, not significant; P<0.05, significant.

Table 4: Comparison of diastolic blood pressure (mmHg) at various time intervals.

Time interval	PLMA group (mmHg)		Intra group P Value	ETT group (mmHg)		Intra group P value	Inter group P value
	Mean	SD		Mean	SD		
Preop	83.53	6.60		85.93	10.04		0.278
Insertion	79.60	7.60	0.002	88.77	20.31	0.397	0.024
1 min	77.80	8.16	0.000	94.87	7.66	0.000	0.000
3 min	78.47	7.42	0.000	93.87	10.40	0.000	0.000
5 min	81.53	7.44	0.075	89.07	12.88	0.159	0.007
Pneumo	81.13	6.12	0.071	82.27	8.82	0.132	0.565
30 min	82.00	5.25	0.201	87.93	7.31	0.288	0.001
Removal	83.33	4.88	0.851	90.40	6.59	0.011	0.000

PLMA- ProSeal Laryngeal Mask Airway; ETT- Endotracheal Tube; P>0.05, not significant; P<0.05, significant.

Table 5: Comparison of mean arterial pressure (mmHg) at various time intervals.

Time interval	PLMA group (mmHg)		Intra group P value	ETT group (mmHg)		Intra group P value	Inter group P value
	Mean	SD		Mean	SD		
Preop	106.42	39.13		101.64	8.76		0.517
Insertion	94.96	7.23	0.094	105.76	17.49	0.179	0.003
1 min	92.89	8.27	0.047	112.67	8.89	0.000	0.000
3 min	91.46	9.88	0.033	110.18	10.99	0.000	0.000
5 min	95.03	6.84	0.099	106.60	12.65	0.039	0.000
Pneumo	95.13	6.21	0.115	96.36	9.98	0.042	0.571
30 min	97.36	5.46	0.205	101.56	7.19	0.965	0.013
Removal	99.51	4.69	0.344	107.40	4.51	0.000	0.000

PLMA- Proseal Laryngeal Mask Airway; ETT- Endotracheal Tube; P>0.05, not significant; P<0.05, significant

The mean DBP was also increased significantly at 1 and 3 min after intubation, (P<0.05), (Table 4).

Similarly, the mean arterial pressure increased from baseline 101.64±8.76 mmHg to 112.6±8.89 mmHg at 1 min, 110.18 ±10.99 mmHg at 3 min and 106.60±12.65 mmHg at 5 min in the ETT group,(P<0.05) whereas no statistically significant haemodynamic changes were observed from their baseline values in the PLMA group, (P>0.05).

Similarly, at removal and extubation, the heart rate and mean arterial pressure also increased significantly, P<0.05 whereas in the ETT group as compared to the PLMA group, whereas in PLMA group, these parameters remained comparable to baseline values, (P>0.05) (Table 5).

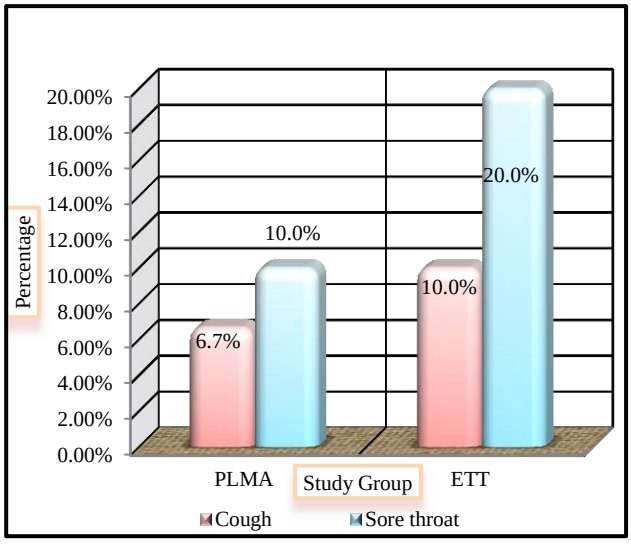

Figure 6: Comparison of complications.

The incidence of cough was 6.7% and 10% while that of sore throat was 10% and 20% in group PLMA and ETT respectively. (Figure 2) The mean oxygen saturation (SpO_2) was also comparable in both the groups, (P>0.05).

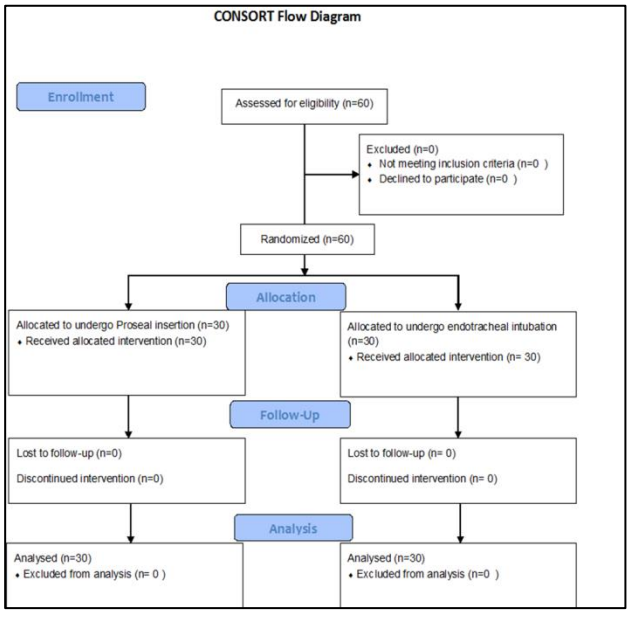

Figure 3: Consort flow diagram showing the flow of participants through each stage of a randomized trial.

DISCUSSION

The achievement of smooth induction and recovery with stable intraoperative haemodynamics and minimal postoperative complications remains an important anaesthetic goal during general anaesthesia in laparoscopic surgeries. The laryngoscopy and tracheal intubation leads to haemodynamic pressor response due to oropharyngeal stimulation and may prove to be detrimental for the patients with low cardiac reserve.[1] The ProSeal LMA, a supraglottic airway device with its additional features has proven to be favourable particularly in these situations.

PLMA has an added advantage of reduced risk of gastric insufflation, regurgitation and aspiration of gastric contents and proved to be efficient in laparoscopic surgeries where increased intra-abdominal pressure created by pnemoperitoneum required higher peak airway pressures for adequate pulmonary ventilation.[1,2,6] So with above hypothesis, we conducted a prospective randomized study in 60 adult patients undergone laparoscopic cholecystectomies and compared the haemodynamic responses, the ease of insertion of device and nasogastric tube and any complications in both groups.

The 66.67% of patients had easy insertion of ProSeal LMA while 33.3% patients required a second attempt with mean time of insertion being 37.40±16.09 seconds while, in the ETT group, intubation was successful in first attempt in 96.7% patients and 18.3% patients required a second attempt and the mean time of intubation was 31.17±20.89 seconds. The duration of insertion of ProSeal and endotracheal tube was statistically not significant, (P>0.05) however the mean time of insertion in ETT group was shorter. Saraswat et al and Kannan et al also reported no significant difference between the insertion time of ProSeal and endotracheal tube which concurs with present study.[9,10] Usually anesthesiologist's have more experience and confidence in traditional direct laryngoscopy and endotracheal intubation as compared to other alternative devices and PLMA is not used so frequently even in routine practice in all institutions. So it needs expertise for successful placement of PLMA in first attempt and with lesser time. It is always hesitating to use an alternative device unless it is indicated in some particular situation. This may be the cause of longer mean insertion time of device in PLMA group as compared to ETT group in our study however this was statistically not significant.

In the PLMA group, nasogastric tube was inserted in all patients in the first attempt with mean time of insertion of 18.84±6.84 seconds. This was comparable with study done by Shroff et al who reported a mean insertion time of 14 seconds in the PLMA group.[7] Sharma et al also had a 100% first attempt success rate of nasogastric insertion with Proseal LMA however 50% patients had first attempt success rate, while 43.3% and 6.7% required second and third attempt respectively in the ETT group with a mean insertion time of 73.00±71.06 seconds which was significantly higher than the PLMA group (P value < 0.001).[8] This may be due to presence of additional gastric

channel along with the length of ProSeal which may be helpful for insertion of nasogastric tube as endotracheal tube obliterates the passage of nasogastric tube while insertion.

The HR, SBP, DBP and MAP significantly increased from the baseline value at intubation that persisted till 5 minutes in the ETT group ($P < 0.05$). Similarly the rise in HR, SBP, DBP and MAP was observed at extubation, ($P<0.05$). However, the haemodynamic parameters remained comparable to the baseline values ($P>0.05$) after insertion of ProSeal and at its removal. Saraswat et al reported significant increase in heart rate and the mean arterial pressure 10 seconds after intubation that lasted till 3 minutes after intubation and also during the time of extubation in the ETT group.[9]

Sharma B et al reported that there were no significant haemodynamic changes at 1 and 5 min after insertion of PLMA, ($P<0.05$).[3] Similarly Kannan S et al concluded in their study that SBP, DBP and MAP were lower in group PLMA at 1 and 2 min after insertion and its removal, ($P<0.05$).[10] Piper et al also reported higher mean arterial blood pressures after intubation than after insertion of PLMA, which was significant, ($P<0.01$).[11] Similarly, Patel et al reported that there was rise in heart rate both during insertion and extubation in ETT group as compare to ProSeal LMA group and this change was highly significant,($P<0.01$) The findings of Shroff et al, Carron et al and Kannan et al also concurred with present findings.[7,10,12,13]

However, Lalwani et al and Dave et al found that heart rate was increased significantly in both ETT and PLMA group whereas in our study, HR is increased significantly in ETT group only.[14,15] This haemodynamic pressor response may be attributed to the sympathetic stimulation during laryngoscopy and intubation and this is due to sympathoadrenal response to tracheal intubation arises from stimulation of the pharyngeal wall and supraglottic region by tissue tension induced by laryngoscopy. This is mediated via vagal and glossopharyngeal afferents. The reflex circulatory response is seen with an increase in the plasma catecholamine levels after laryngoscopy.[13] Among the catecholamine's, noradrenaline levels show a greater surge after laryngoscopy and intubation.

This transient pressor response to laryngoscopy and tracheal intubation like hypertension and tachycardia is of not much significance in healthy patients but it may prove to be detrimental in patients with low cardiac reserve like myocardial insufficiency, hypertension or cerebrovascular disease.[2] The catecholamine's secreted due to stress response may increase heart rate and myocardial oxygen demand or consumption significantly which may lead to cardiac arrhythmias and myocardial ischemia.

The ProSeal LMA is a supraglottic airway device which does not require laryngoscopy and visualization of vocal cords for insertion so this makes the placement of ProSeal LMA less stimulating and easier than endotracheal intubation and therefore it provokes a lesser sympathetic response while its insertion as compared to ETT. The attenuation of the pressor response is due to diminished catecholamine release and lower cortisol levels after insertion of the ProSeal LMA.[2,13,16] The PLMA forms effective seal around the glottis opening which provides adequate ventilation and oxygenation along with CO_2 insufflation and pnemoperitoneum in reverse trendelenburg position without any significant gastric distension and pulmonary aspiration. Maltby et al also reported that both of the devices have equal effectiveness in terms of adequate ventilation and oxygenation in their study groups.[6] The PLMA has an additional feature of gastric drainage channel and higher sealing pressures which may protect against regurgitation and gastric aspiration.[16]

The incidence of cough and sore throat was comparatively more in the ETT group than in the PLMA group. Saraswat et al and Maltby et al also reported a higher incidence of cough and sore throat after intubation in ETT group.[6,9] Lim et al and Carron et al also reported that there was a significant incidence of cough after extubation as compared after removal of PLMA.[13] The lower incidence of cough and sore throat with ProSeal LMA could be due to the fact that it exerts less mucosal pressure and does not hamper the pharyngeal perfusion pressures.[5] The cuff of PLMA is less stimulating to pharyngeal mucosa as compared to ETT cuff in trachea which may be the cause of reduced incidence of postoperative nausea and vomiting also in these patients.[16]

Limitations

We were not able to make significant differences between two devices to secure an airway particularly in laparoscopic surgeries as we could not reveal that one device is far superior to the other device in terms of different parameters we have studied, this may be due to smaller sample size of our study. So it might be possible that further studies with larger sample size would make significant differences between the two techniques and the results could be better appreciated.

CONCLUSION

Present study concluded that the ProSeal LMA provides a reliable and secured airway with stable intraoperative haemodynamics and lesser postoperative complications so can be effectively used as an alternative to endotracheal tube in elective laparoscopic surgeries under general anaesthesia. However, PLMA requires expertise for its easier insertion and placement.

Funding: No funding sources
Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Patodi V, Singh M, Sethi SK, Depal VN, Jain N, Kumar V. A comparative study between ProSeal laryngeal mask airway and endotracheal tube for ease of insertion and haemodynamic changes in patients undergoing laparoscopic cholecystectomy under general anaesthesia. Int J Res Med Sci 2016;4:5334-40.