

# The Pro-Seal LMA<sup>tm</sup> And The Tracheal Tube: A Comparison Of Events At Insertion Of The Airway Device

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## Citation

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## Abstract

The Pro-Seal LMA is a recently introduced supra-glottic airway device. We aimed to study the events at insertion of this device and compare them with tracheal intubation. One hundred patients scheduled for laparoscopic abdominal surgeries under general anesthesia were subjected to either Pro-Seal LMA or tracheal tube insertion. The number of attempts and the hemodynamic changes at insertion were observed. Insertion of the Pro-Seal LMA had a lower first attempt success than tracheal tube (88% Vs 100%  $P < 0.01$ ). It was eventually successful in all patients at the end of three attempts (100%). There were no cases of insertion failure with either of the devices. The extent of rise in heart rate and MAP were significantly higher with tracheal tube than Pro-Seal LMA ( $P < 0.01$ ). Pro-Seal LMA, though difficult to introduce, showed no incidence of failure. The markedly attenuated hemo-dynamic response at insertion of PS-LMA is a definite advantage over tracheal intubation.

## INTRODUCTION

Tracheal tube is always considered to be the gold standard device<sup>1</sup> to maintain an airway during laparoscopic procedures. This is because of its inherent ability to provide positive pressure ventilation under high airway pressures and to prevent occurrences of gastric inflation and aspiration into the lungs. On the other hand, disadvantages of tracheal intubation in terms of concomitant hemo-dynamic responses,<sup>2</sup> situations of failed intubation and damage to the oropharyngeal structures at insertion are also a serious concern and need to be mentioned. This precludes the global utility of the tracheal tube and asks for a better alternative. With the advent of newer supra-glottic airway devices these drawbacks of tracheal tube are avoided.

Laryngeal mask, as a new concept in airway management was first introduced by Archie Brain in 1983.<sup>3</sup> Though it was a highly satisfactory device in securing an airway, its lacunae with positive pressure ventilation (PPV), 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 Pro-Seal LMA in the late 1990's, with improved ventilatory characteristics. It also offered protection against regurgitation and gastric insufflation. Archie Brain gave a detailed description of his newly designed device in 2000.<sup>4</sup>

The Pro-Seal LMA has a dorsal cuff, in addition to the

peripheral cuff, that extends over the posterior surface of the mask. This arrangement pushes the mask anterior to provide a better seal around the glottic aperture and permits high airway pressures without leak. A drain tube parallel to the ventilation tube passes through the bowl of the mask and tip of the cuff to lie at the upper esophageal sphincter. This permits drainage of passively regurgitated gastric fluid away from the airway and serves as a passage for gastric tube. The PS-LMA may therefore, be more suitable than the classical LMA(c-LMA) in patients with decreased total lung compliance who require PPV and for surgical procedures in which intra-operative gastric drainage or decompression is desirable.

The PS-LMA is a relatively new airway device to the developing nations. We hence made an earnest attempt to compare this device with the standard tracheal tube for the ease at insertion and the hemo-dynamic changes occurring while doing it.

## METHODS

A clearance was obtained from the ethical committee of the hospital and University of Allahabad, India. This prospective randomized single blinded study was conducted on 100 healthy patients of either sex aged 18 – 55 years, ASA physical status I & II and body weight between 40 – 70 kg, who underwent laparoscopic procedures under general anesthesia in the Department of Anesthesiology and Critical

Care, Swaroop Rani Nehru hospital, Allahabad during the time period July 2006 to November 2007. All the patients gave written informed consent. Patients with predicted difficult airway (mouth opening < 2 fingers, modified Mallampati class 3 & 4), obesity (body mass index > 30 kg.m<sup>-2</sup>), systemic hypertension, oro-pharyngeal pathology, lung diseases associated with low compliance/high airway resistance and patients susceptible to the risk of aspiration (gastro-esophageal reflux disease, hiatus hernia and pregnant patients) were excluded from the study. Demographic characteristics like age, height, weight and detailed medical histories were obtained from the patients.

The 100 selected patients were randomly allotted into two groups of 50 each; PS-LMA and TT, by a computer generated table. Pre-anesthetic evaluation was done. Patients were pre-medicated with tab.Alprazolam 0.5 mg and tab.Ranitidine 150 mg the night before surgery, in both the groups. In the pre-operative room, half an hour before the scheduled surgery, inj. Midazolam 2mg i.m., along with inj. Glycopyrolate 0.2mg i.m., was administered.

Once inside the operation theatre, the patients were made to lie on the table comfortably and all the routine monitors i.e., non-invasive blood pressure, pulse oximeter and ECG were attached and the baseline values of blood pressure, heart rate and SpO<sub>2</sub> documented.

Inj.Butorphanol 2mg i.v., was given to all the patients five minutes before the scheduled induction. All the patients were pre-oxygenated with 100% O<sub>2</sub> for three minutes. Anesthesia was induced with inj.Lignocaine 2% 20 mg preservative free i.v., followed by inj.Propofol 2mg.kg<sup>-1</sup> i.v., injected slowly until adequate depth of anesthesia was attained and inj. Rocuronium bromide 0.75 mg.kg<sup>-1</sup> was given to facilitate insertion of the corresponding airway device.

In PS-LMA group, an appropriate sized PS-LMA {LMA-PROSEAL<sup>TM</sup> Laryngeal Mask Company, (U.K.) Limited, HP10 0HH, UK} was inserted as per recommendations based on weight criteria; i.e., size 3 for patients weighing 30-50 kg and size 4 for 50-70 kg. Introducer tool technique was used in all the patients of this group. A clear water based lubricant gel (LUBIC<sup>®</sup> – NEON INDIA) was applied on the dorsal surface of the device. With the patient in sniffing position, the device mounted on the introducer was inserted. A slight lateral approach was used if resistance was encountered in the oro-pharynx and a jaw thrust maneuver applied. The cuff was then inflated with up to 20 ml of air

for size 3 and 30 ml of air for size 4 PS-LMA. After connecting to the Bain circuit, lungs were manually ventilated to check for an effective airway. A normal thoraco-abdominal movement and a normal capnographic tracing were taken as an effective attainment.

A failed attempt was the removal of the device from the mouth following inability to secure an effective airway. A maximum of three attempts were allowed before the insertion is marked a failure. In the PS-LMA group, if insertion failed, tracheal intubation is to be performed then and in the TT group on insertion failure, fiberoptic bronchoscope assisted tracheal intubation is the rescue method to be implemented. Four additional tests were performed to ascertain correct placement of the PS-LMA; pressure leak test for airway sealing pressures, depth of PS-LMA insertion assessment using integral bite block, lubricant jelly test and passage of a gastric tube.

In TT group, the trachea was intubated with a standard fresh tracheal tube of appropriate size after laryngoscopy. The cuff was inflated until no leak was audible.

The changes in heart rate and blood pressure were noted at the time of insertion of the airway devices. Anesthesia was maintained with Isoflurane, 33% Oxygen in Nitrous Oxide and neuro-muscular blockade with intermittent doses of inj.Rocuronium i.v. At the end of the procedure, reversal of neuro-muscular blockade was achieved with inj. Neostigmine 0.05mg.kg<sup>-1</sup> and inj. Glycopyrolate 0.01 mg.kg<sup>-1</sup>.

### **STATISTICAL ANALYSIS**

All the data were tabulated and analyzed with Microsoft Excel 2003. Statistical analysis was performed using 'Z' test of significance for categorical data and 't' tests of significance for continuous data. P values less than 0.05 were considered statistically significant.

### **RESULTS**

Complete data were obtained from all the 100 patients in the study. The PS-LMA and TT groups were comparable for their demographic features. There were no significant differences between the groups in the duration of peritoneal insufflation and of total anesthesia.(Table 1).

Any incidence of failure at insertion of the device and the need for an alternative one was compared between the groups. Both the groups showed 100% success at insertion of the corresponding devices and no incidence of switching over to the alternate choice. The TT group had a

significantly high first attempt success rate (100% Vs 88% in PS-LMA,  $P<0.01$ ). Eventually at the end of three attempts, the PS-LMA group showed a 100% success at insertion (Table 2). Despite the inability to secure an airway at first attempt using the introducer tool technique in the PS-LMA group, we did not change the technique of insertion in the successive attempts. There were no instances of mal-positioning of the Pro-Seal LMA as confirmed by the set of tests.

There was a significant rise in HR and MAP in both the PS-LMA ( $P<0.05$ ) and the TT groups ( $P<0.01$ ) from their baseline values during insertion of the respective devices (Table 3). On comparing the degree of rise in HR and MAP between the groups, TT group showed a higher rise in these parameters than PS-LMA group ( $P<0.05$ ).

**Figure 1**

Table 1: Comparison of Demographic factors and duration.

Variable	PS-LMA	ET	P-value
N	50	50	
Age (Yrs) (Mean $\pm$ SD)	36.72 $\pm$ 8.410	37.18 $\pm$ 8.302	0.876*
Gender (M:F)	6:44	5:45	0.1021 ( $\chi^2$ )*
Height (m) (Mean $\pm$ SD)	1.56 $\pm$ 0.066	1.55 $\pm$ 0.064	0.9272*
Weight (Kg.) (Mean $\pm$ SD)	57.26 $\pm$ 6.040	57.5 $\pm$ 5.448	0.8351*
BMI (kg.m <sup>-2</sup> ) (Mean $\pm$ SD)	23.46 $\pm$ 1.333	23.63 $\pm$ 1.4511	0.552*
Duration of Anesthesia (min) (Mean $\pm$ SD)	75.52 $\pm$ 5.9158	75.62 $\pm$ 5.642	0.9312*
Duration of Carboxipertoneum (min) (Mean $\pm$ SD)	53.82 $\pm$ 4.951	53.84 $\pm$ 5.592	0.984*

\* Not significant

**Figure 2**

Table 2: Number of attempts at insertion

No. of Attempts	Group	
	PSLMA	ET
1	44*	50
2	5	0
3	1	0

\* Z = 2.611

P < 0.01

**Figure 3**

Table 3: Haemodynamic changes at insertion

	PSLMA		ET		P Value
	HR (beats/min) (Mean $\pm$ SD)	MAP (mmHg) (Mean $\pm$ SD)	HR (beats/min) (Mean $\pm$ SD)	MAP (mmHg) (Mean $\pm$ SD)	
Baseline	79.79 $\pm$ 4.64	93.90 $\pm$ 4.36	80.66 $\pm$ 6.18	93.56 $\pm$ 5.29	
Insertion	88.08 $\pm$ 5.34	100.98 $\pm$ 4.26	103.46 $\pm$ 8.80	111.4 $\pm$ 5.67	
Value					
P Value	<0.05	<0.05	<0.01	<0.01	
% Change in HR	10.44 $\pm$ 3.51		28.29 $\pm$ 5.209		<0.01
% Change in MAP		7.583 $\pm$ 2.27		19.12 $\pm$ 2.093	<0.01

## DISCUSSION

This study was carried out at a tertiary referral centre in North India and since tracheal intubation is the standard method adopted for laparoscopic procedures in this part, we used it as the control group. Anesthesia technique was standardized between the groups. In our study, we found that the Pro-Seal LMA did not fail to secure an airway despite the difficulty faced at insertion. The hemo-dynamic changes observed were minimal with this device while with tracheal tube, significant changes were observed.

All the patients in the tracheal tube group were subjected to intubation successfully at first attempt (100%). There was no need for further attempts in this group. On the other hand, PS-LMA group had 88% (44/50) first attempt success at insertion ( $P<0.01$ ). This steadily rose to 98% at second attempt and eventually 100% at the end of three attempts. However there was no failure at insertion as per the protocol set by us.

Our findings in the PS-LMA insertion correlate well with previous similar studies. Lim Y et al<sup>5</sup> have compared PS-LMA with tracheal tube for gynecological laparoscopies. They have concluded that the number of attempts for successful insertion was similar between the groups but effective airway time was shorter for the PS-LMA and that all the devices were successfully inserted within three attempts. In contrast to them, we were able to intubate in all the patients of the TT group at the first attempt. Further we have not monitored the effective airway attainment time. Brimacombe J et al,<sup>6</sup> the pioneers in the usage of laryngeal mask airways have compared different techniques of PS-LMA insertion. Though the purpose of their study is different from ours, the observation in terms of first time

success rate at insertion of PS-LMA by introducer tool (IT) technique and the number of attempts for successful airway attainment coincide with our study. An 88% first time success rate for PS-LMA insertion in pediatric cases was reported by Sinha A et al<sup>7</sup> in their study.

A result different from ours has been shown by Piper SN et al<sup>8</sup> who on comparing PS-LMA with tracheal tube in gynecological laparoscopy found that the insertion of the former was easier than the latter and that no significant difference occurred in terms of insertion times. Though there are many studies showing the supremacy of guided insertion of PS-LMA over other techniques, no studies have reported significant differences in insertion success between digital and IT methods.

Laryngoscopy and tracheal intubation are the main forte of a successful anesthesiologist. Hence the 100% first attempt success in the TT group in our study where difficult airways were excluded, is an occurrence on expected lines. On the other hand, bulky morphology of PS-LMA in contrast to c-LMA may be the prime factor for the difficulty faced at insertion of this device.

Appreciable rise in HR and MAP observed at laryngoscopy and tracheal intubation is an established fact. This is reinforced by many studies in the past. Our experience with respect to these hemo-dynamic changes at tracheal intubation is similar to the previous reports. PS-LMA, in contrast to tracheal tube produced a hemo-dynamically acceptable rise in HR and MAP in our study.

A few studies on PS-LMA have observed that the hemo-dynamic stress responses to insertion and removal were greater for the tracheal tube than the PS-LMA.<sup>5,9</sup> Likewise, two non-randomized studies of 335 patients with varying anesthetic techniques found that hemo-dynamic variables change less than 10% at PS-LMA insertion.<sup>10,11</sup> Our findings are in close agreement with these studies. A study in the past that compared the hemo-dynamic changes at c-LMA and tracheal tube insertion has reported minimal hemo-dynamic responses to c-LMA insertion with a 0 - 20% increase in HR and MAP.<sup>12</sup> Fujii Y and co-workers<sup>13</sup> have observed a rise in HR and MAP during both LMA and TT insertion and that it was more pronounced in the latter group. This was correlated with a significant increase in plasma adrenaline and nor-adrenaline concentrations. With one study reporting that the hemo-dynamic changes are comparable between PS-LMA and c-LMA insertion,<sup>14</sup> these above mentioned works on c-LMA form an indirect support

to our observations.

As our study is based on the analysis of ease of insertion and the concomitant hemo-dynamic changes, the exclusion of patients with difficult airways and systemic hypertension is a definite shortcoming on our part. We earnestly aim to rectify these lacunae in future studies. In summary, the Pro-Seal LMA, though challenging for beginners is easy to insert by introducer tool technique in experienced hands. It also evokes a hemo-dynamic response of lesser magnitude than the tracheal tube.

### CORRESPONDENCE TO

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