



LMA PROSEAL: AN ALTERNATIVE TO ENDOTRACHEAL INTUBATION IN OPEN APPENDECTOMY OPERATION.' IN THE DEPARTMENT OF ANESTHESIOLOGY, MEDICAL COLLEGE, KOLKATA

Anaesthesiology

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ABSTRACT

INTRODUCTION One of the important responsibilities of an Anaesthesiologist is to maintain a patent airway during any surgical procedure. Since the early days of Anaesthesia, various efforts have been made to dispel the problem of airway maintenance.

AIMS AND OBJECTIVES The study entitled "LMA ProSeal: An alternative to endotracheal intubation in open appendectomy operation" was conducted with the aims to compare the efficacy of LMA ProSeal and Endotracheal Tube in patients undergoing Open Appendectomy under General Anaesthesia.

MATERIAL AND METHODS

Study Area: This study was conducted in Medical College, Kolkata (West Bengal), under the department of Anaesthesiology in General Surgery Operation Theatre (C. B. Top OT/ Green OT Complex), after clearance from the Hospital ethical committee, during the period from 1st May 2013 to 31st January 2014. A written informed consent was taken from all patients included in the study.

Study Population: Patients posted for open Appendectomy operation with BMI between 18.50 – 24.99 kg/m² and body weight between 30 – 60 kg.

Sample Size: 100

RESULTS AND OBSERVATIONS The effects were observed by monitoring heart rate, blood pressure and SPO₂ preoperatively (as baseline), after intubation or placement of LMA ProSeal at 1 min, 3 mins, 5 mins and every 5 mins thereafter till the reading at removal of the device. For both the groups baseline ETCO₂ was taken from connection of ETCO₂ cable following placement of airway devices.

SUMMARY AND CONCLUSION The study revealed that both the airway devices (ET tube and LMA ProSeal) were successful in operative procedure (open appendectomy) in all the patients without any significant complication. In experienced hands and following a strict protocol of insertion, the LMA ProSeal can prove to be an efficient and safe alternative to endotracheal tube for airway management of elective patients undergoing laparotomy procedure like open appendectomy.

KEYWORDS

Lma Proseal, Endotracheal, Tubation, Open Appendectomy And Anesthesiology

INTRODUCTION

One of the important responsibilities of an Anaesthesiologist is to maintain a patent airway during any surgical procedure. Since the early days of Anaesthesia, various efforts have been made to dispel the problem of airway maintenance.

Management of airway has come a long way and it is now more than 100 years old. German surgeon Friedrich Trendelenburg (1844 - 1924) was the first person who performed endotracheal anaesthesia for a patient with a tracheostomy in 1871¹. On April 23rd 1895, in Berlin, Alfred Kirstein performed the first direct examination of the interior of the larynx. Kirstein named his instrument, "The autoscope" and direct examination of the larynx he termed "autoscopy". Since then training in direct laryngoscopy and endotracheal intubation has become the most vital skill to be learned by an Anaesthesiologist.

Endotracheal intubation is one of the most significant developments of Anaesthesia for maintenance of airway and is considered one of the best ways of securing the airway.

Although invention of Endotracheal Tube is a great achievement, it is not free from complexities. The most common and important being the deleterious haemodynamic consequences in response to laryngoscopy and intubation due to reflex sympathoadrenal stimulation². The major cause of sympathoadrenal response to tracheal intubation is due to the stimulation of supraglottic region by tissue irritation induced by direct laryngoscopy.

The mechanisms of the responses to laryngoscopy and orotracheal intubation are proposed to be by somato-visceral reflexes. Stimulation of proprioceptors at the base of the tongue during laryngoscopy induces impulse-dependent increases of systemic blood pressure, heart rate and plasma catecholamine concentrations. Subsequent orotracheal intubation recruits additional receptors that elicit augmented hemodynamic and epinephrine responses as well as some vagal inhibition of the heart³. Subsequent tracheal intubation should stimulate additional receptors in the larynx and the trachea, thus enhancing the haemodynamic responses.

Difficult tracheal intubation and inability to maintain a patent airway remains an important cause of anaesthetic morbidity and mortality. The unanticipated difficult airway occurs with a low but consistent incidence in anaesthesia practice. Difficult direct laryngoscopy occurs in 1.5–8.5% of general anaesthetics and difficult intubation occurs with a similar incidence. Failed intubation occurs in 0.13–0.3% general anaesthetics.

Therefore, although Endotracheal Intubation is regarded as the Gold Standard for maintenance of airway, the immediate and life threatening complication of 'Cannot Intubate, Cannot Ventilate' can arise anytime with anyone and anywhere. There are numerous devices and techniques available, which can bail us out of such situations where conventional laryngoscopy and intubation fail. Devices such as the laryngeal mask airway in the setting of unanticipated difficult airway, are effective in establishing a patent airway, may reduce morbidity and are occasionally lifesaving⁴.

Dr. Brain's interest in the human airway led him to make plaster of Paris casts of a cadaver pharynx, in order to explore the actual and potential space in the glottic area⁵. Dr. Brain noticed the similarity between the general size and shape of the detached Goldman mask cuff and the available size and space in the pharynx as defined by his plaster of Paris moulds. The next step, which resulted in Dr. Brain's first prototype of the laryngeal mask airway, was to incorporate a 10 mm plastic tube into the floor of the mask in such a way that the tube emerged behind the wider posterior end of the mask⁶. The mask appeared to work better in females than male patients. Through his study with cadavers, Dr. Brain surmised that either obstructions or leaks were occurring with certain patients. Dr. Brain concluded that the smaller size would be more suitable for female patients than for male⁶.

AIMS AND OBJECTIVES

The study entitled "LMA ProSeal: An alternative to endotracheal intubation in open appendectomy operation" was conducted with the aims to compare the efficacy of LMA ProSeal and Endotracheal Tube in patients undergoing Open Appendectomy under General Anaesthesia.

The objectives of the study were:

1. To compare LMA ProSeal with an endotracheal tube (ET tube) for hemodynamic parameters before, during and after the procedure.
2. To compare LMA ProSeal with an endotracheal tube (ET tube) usage for the incidence rates of complications such as coughing, laryngospasm or bronchospasm, vomiting, hypoxia and sore throat.
3. To compare LMA ProSeal with an Endotracheal tube (ET tube) usage for episodes of gas-tric insufflations or regurgitation.

MATERIAL AND METHODS**Study Area:**

This study was conducted in Medical College, Kolkata (West Bengal), under the department of Anaesthesiology in General Surgery Operation Theatre (C. B. Top OT/ Green OT Complex), after clearance from the Hospital ethical committee, during the period from 1st May 2013 to 31st January 2014. A written informed consent was taken from all patients included in the study.

Study Population:

Patients posted for open Appendicectomy operation with BMI between 18.50–24.99 kg/m² and body weight between 30–60 kg.

Sample Size: 100

Sample size was calculated using “PS: Power and Sample Size Calculation software” (91).

The study was planned with 1 control per experimental subject. The response within each subject group was normally distributed with standard deviation 3.5 as per previous studies. Difference in the experimental and control means was approximated at 2.0 based on calculations from previous studies. The Type I error probability was kept at 0.05. Power of the study was kept at 0.8 as per previous similar studies. Therefore, based on software calculation, we needed 49 experimental subjects and 49 control subjects to be able to reject the null hypothesis that the population means of the experimental and control groups are equal with probability (power) 0.8 (92,93,94,95,96). So, a total of 100 patients were enrolled for the study.

Sample Design:

A total of 100 patients were selected for the study. The patients were randomized into two groups of 50 each.

One of the group was administered the LMA ProSeal (Group P) and the other group was given Endotracheal Intubation (Group E).

Randomization was done using systematic random sampling (97). So, the 1st case was allocated to Group P and thereafter every alternate patient was placed in Group P and the remaining unallocated patients went to Group E.

INCLUSION CRITERIA:

- Patients of ASA grade I/II posted for open Appendicectomy.
- Within normal range of BMI between 18.50–24.99 kg/m² (98).
- Body weight between 30–60 kg will be selected for the study.
- Fasting as per ASA guidelines.

EXCLUSION CRITERIA:

- Patients with an anticipated difficult airway
- ASA grade III/IV
- Underweight/overweight/obese patients
- Full stomach

RESULTS AND OBSERVATIONS

Our study showed that a total of 100 normotensive adult patients were taken for this study, where the cardiovascular changes, efficacy of positive pressure ventilation, emergence and complications if any were observed and compared between patients receiving the ET tube and LMA ProSeal taken up for open Appendicectomy of duration between 30 to 45 minutes. The effects were observed by monitoring heart rate, blood pressure and SPO₂ preoperatively (as baseline), after intubation or placement of LMA ProSeal at 1 min, 3 mins, 5mins and every 5 mins thereafter till the reading at removal of the device. For both the groups baseline ETCO₂ was taken from connection of ETCO₂ cable following placement of airway devices.

We found that the 100 patients selected for the study were randomized into two groups of 50 each. One of the group was administered the LMA ProSeal (Group P) and the other group was given Endotracheal

Intubation (Group E). Randomization was done using systematic random sampling (97). So, the 1st case was allocated to Group P and thereafter every alternate patient was placed in Group P and the remaining unallocated patients went to Group E. The youngest patient in group E was 14 years and the oldest patient was of 36 years and in group P, the youngest patient was 14 whereas the oldest patient was of 29 years age. In group E, minimum weight was 34 kg and maximum weight was 60kg. In group P, minimum weight was 45 kg and maximum weight was 60kg.

We showed in Group E, 15 cases, 21 cases and 14 cases were completed by 35mins, 40mins and 45 mins respectively. Similarly, in Group P, 19 cases, 17 cases and 14 cases were completed by 35 mins, 40 mins and 45 mins respectively. The patients on whom surgery was completed at 40 and 45 mins have obviously been monitored at 35 mins. So, in both the groups we have 50 patients who were monitored at already mentioned time intervals till 35 mins. Therefore, results at 35 mins are stronger than at 40 and 45 mins. Again all the patients were monitored both at removal and 5 mins after removal of the devices for which the results at these two time intervals are strong. The mean change of SPO₂ in both the groups were compared to the baseline values. In Group E, SPO₂ change was statistically insignificant to the baseline values throughout the study. In Group P statistically significant difference in mean SPO₂ at 3min and 30min was clinically acceptable. All throughout the study period the SPO₂ varied between 99 to 100% in both the groups.

Our study showed it can be observed that HR increased after instrumentation. In Group E, change was highly significant (P<0.01) after intubation, at 1min, 3 min and 5 min. Thereafter HR touched baseline and HR change remained insignificant throughout the procedure till removal of ET tube when HR increase was again highly significant which became insignificant at 5 mins after removal. In Group P, the change was highly significant (P<0.01) after device placement and at 1min. Thereafter HR touched baseline and HR change remained insignificant throughout the procedure, at removal of LMA-ProSeal as well as at 5 mins after removal. Between Group E and Group P, HR variation was highly significant after device placement, at 1min, 3min and 5 min. Thereafter, HR variation was insignificant until device removal when again HR variation was highly significant between the two groups which became insignificant 5mins after device removal. The rise in mean HR was more with ET tube as compared to LMA ProSeal. 4 patients complained of sore throat after removal of the ET tube while in Group P, 3 patients complained of the same. This was compared statistically by Fisher's exact test which showed to be insignificant (P>0.05).

DISCUSSION

Airway management continues to be of paramount importance to the anaesthesiologist. Till date, the cuffed tracheal tube was considered as gold standard for providing a safe glottic seal for procedures under general anaesthesia.

The advent of endotracheal intubation was seen as a great boon by anaesthesiologists. Intubation of the trachea is the most secure and life saving intervention performed to establish and maintain a patent airway. Despite tremendous advancement in anaesthesiology, the problems and complications related to the practice of laryngoscopy and intubation account for one of the major causes of morbidity and mortality in the practice of anaesthesia⁷.

The disadvantages of tracheal intubation, which involves rigid laryngoscopy are in terms of concomitant haemodynamic responses and damage to the oropharyngeal structures at insertion. Postoperative sore throat is also a serious concern. This precludes the global utility of the tracheal tube and requires a better alternative⁸.

The LMA ProSeal is a second generation supraglottic device. It has some added features of the LMA classic⁹.

This study was conducted with the aim of comparing LMA ProSeal as an alternative airway device to the ET tube in 100 patients undergoing open Appendicectomy. The LMA ProSeal was compared with the ET tube in terms of cardiovascular changes (haemodynamic response), efficacy of controlled ventilation, emergence and complications if any. The effects were observed by monitoring heart rate, blood pressure, and SPO₂ preoperatively as baseline, after intubation or placement of the LMA ProSeal, at 1min, 3mins, 5mins and every 5mins thereafter till removal of the devices. For both the groups, baseline value for ETCO₂ was taken from connection of ETCO₂ cable following the placement of airway devices.

Fujii et al (1995) in another study of similar nature found that the pulse rate was consistently elevated for 3 mins in LMA group and for 5 mins in ET tube group¹⁰. However, in their study they have taken both normotensive and hypertensive patients while we have included only normotensive patients. In our study we have found that pulse remains elevated for 1min in Group P after instrumentation while in Group E it remained elevated for upto 5mins after instrumentation.

Wilson IG et al (1992) in a similar study found that the mean maximum increase in systolic arterial pressure after laryngoscopy and tracheal intubation was 51.3% compared with 22.9% for laryngeal mask insertion ($P < 0.01$)¹¹. In our study the magnitude of increase in SBP was 18.36% in Group E and 10.56% in Group P after the device placement.

Braude et al (1989) compared the haemodynamic response of insertion of the LMA with tracheal intubation in patients and showed a significant increase in systolic pressure, one minute after the insertion of the LMA. This increase in arterial pressure was a similar, but attenuated, response to that after tracheal intubation¹². Similarly in our study also there was an increase in SBP after instrumentation in both the groups but the mean difference of the change in SBP was much less marked in Group P as compared to Group E. (18.36%, Group E vs 10.56%, Group P).

When intergroup comparison was done, it was observed that the difference between the two groups was statistically significant after instrumentation, at 1min and 3min after which variation was insignificant till device removal when DBP variation was again highly significant and became insignificant 5min afterwards. The rise in DBP from baseline on instrumentation was significantly more with ET tube as compared to LMA ProSeal (19.14%, Group E vs 12.82%, Group P). Also extubation was associated with a significant rise in DBP (92.5mmHg) in Group E whereas removal of LMA ProSeal was not associated with any significant rise in DBP (83.06mmHg) in group P.

Table 1: Association of Complications

Group	Complications					
	Sore throat*		Gastric distension		Aspiration	
	-	+	-	+	-	+
Group E	46	4	50	0	50	0
Group P	47	3	50	0	50	0
Total	93	7	100	0	100	0

Table 2: Association of duration of surgery

Group	Duration of Surgery		
	35min	40min	45min
Group E	15	21	14
Group P	19	17	14

Table 3: Association of Mallampati scoring

Group	MPS	
	I	II
Group E	25	25
Group P	26	24
Total	51	49

Table 4: Association of ASA Physical classification

Group	ASA grade	
	I	II
Group E	28	22
Group P	27	23
Total	55	45

SUMMARY AND CONCLUSION

So, from this study it was observed that LMA ProSeal proved to be an effective airway device in open appendicectomy under general anaesthesia with lesser degree of sympathetic stimulation during device insertion as compared to tracheal intubation. LMA ProSeal also proved to have 100% success rate at insertion, Ryle's tube placement along with no significant complications during the operative procedure.

The study revealed that both the airway devices (ET tube and LMA ProSeal) were successful in operative procedure (open appendicectomy) in all the patients without any significant complication.

In experienced hands and following a strict protocol of insertion, the LMA ProSeal can prove to be an efficient and safe alternative to endotracheal tube for airway management of elective patients undergoing laparotomy procedure like open appendicectomy.

Disclosure of conflict of interest: No conflict of interest in this study

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