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Use of Proseal Laryngeal Mask Airway in Contrast to Endotracheal Tube for Routine Laparoscopic Cholecystectomy under General Anaesthesia- A Randomized Comparative Study

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Abstract

Evidence based data in the very recent years suggest that in spite of tremendous advances in contemporary anaesthetic practice, advances, airway management continue to be of paramount importance to anesthesiologists. In this RCT (Randomized Control Clinical Trial), the ultimate aim was to depict the anaesthetic safely of the patients of routine laparoscopic cholecystectomy (ASA II & III) in terms of haemodynamic and laryngeal adverse outcomes in BIRDEM General Hospital, Bangladesh. A total number of 200 patients (100 patients with endotracheal tube & 100 patients with LMA) were selected on the basis of simple random sampling. In each patient, after preoxygenation, anaesthesia was introduced with propofol, fentanyl and vecuronium. Anaesthesia was maintained with N2O, O2, Halothane and vecuronium. Ventrilation was set at 8 ml/kg and respiratory rate was 12/min. The ultimate result of this study suggest that in Group A (ETT group), mean±SD of age was 41±1.1 and in Group B (LMA group), it was 37±1.7. Demographic status suggests that the average BMI in both groups were 28.9 and 30.6 respectively. In ETT group, majority of patients (69%) had ASA grade II, in contrast, in LMA group, it was 52%. Average anaesthetic duration in both group were 45 & 50 minutes respectively. There found no significant difference in haemodynamic parameter between both groups at different phases of peroperative period. Laryngeal complications, like tube leakage and gastric insufflation were found in 2 & 3 patients respectively with the use of LMA. Regarding laryngeal morbidity following tube removal, coughing and trauma to lip, teeth, and tongue were slightly higher in with ETT than LMA tube. The incidence of sore throat was slightly higher with the use of LMA (07%) in contrast to ETT (05%), but complications like dysphagia, dysphonia, and dysarthia were found to be same in both groups. P-values suggest less significant result here.

Keywords: Laryngeal mask airway; Endotracheal tube; Laparoscopic cholecystectomy

Introduction

Laryngeal mask airway (LMA) was introduced by Dr. Brain in 1980s and caused a revolution in airway management [1]. Today, this device has a special position in anesthesiology procedures and among many of anesthesiologists [2,3]. LMA provides a proper way for ventilating the patient while protecting his or her airway [4].

Nowadays, LMA is used as a proper device for protecting the patient's airway during many of the operations [5,6]. However, American society of anesthesiologists [3,7,8] Australian and European council of resuscitation, and American heart Association [9-11] approve the usage of LMA only in emergency situations and in cardio-pulmonary resuscitation. The reason for this issue seems to be the inadequate evidence on the efficacy and safety of LMA. Many studies were conducted on usage of LMA for protecting the patients' airway during surgery and showed that this device has many benefits including easier insertion, no need for laryngoscope [12], fewer homodynamic complications [13], and less harmful complication for the larynx and vocal cords[14]. Furthermore, LMA is better tolerated by patients [15] and learning of its usage is easy for physicians and other health care providers [16-20]. Also, LMA is a cost beneficent device [21]. It needs to be mentioned that some complications have also been reported for LMA. The most important of these complications are related to digestive system including vomiting and aspiration [12,22] and to larynx including sore throat, coughing, vocal cord paralysis [23,24], and acute epiglottis [25].

Complications such as nausea and vomiting and laryngeal complications such as coughing and sore throat are most common complications after general anesthesia. Nausea and vomiting usually happen in one third of patients after the general anesthesia [26] and can be followed by serious complications such as aspiration, pneumonia and even rupture of esophagus [27]. The sore throat and other laryngeal complications also happen in 60% of patients in the post general anesthesia period [28]. It should be mentioned that such complications can result in delay of patients' discharge, increased health care costs, and decreased patients' satisfaction [29-38]. Therefore, any effort taken to decrease such complications would be important. Several studies have been conducted related to comparison the cardio-respiratory, digestive and laryngeal perioperative complications by using ETT and LMA. In a group of studies no difference has been observed in perioperative complications. For example, in a study conducted by Splinter and Small man, no difference was indicated between ETT and LMA regarding the sore throat and coughing in the perioperative period [39]. Other studies have indicated that the risk of complication after use of LMA were further than ETT [40,41]. Finally, some other studies have reported that a risk of nausea, vomiting [42], sore throat [43-48], and coughing [49,50] after use of LMA were less than ETT. As it turned out, in spite of the increase in the application of LMA, there is still controversy about the efficacy of LMA in comparison to ETT. This problem restricts the wide application of LMA. Therefore, the aim of present study was to compare the perioperative cardi-respiratory, digestive (nausea and vomiting) and laryngeal (sore throat and coughing) complications by using ETT and LMA in perioperative period of selective laparoscopic cholecystectomy under general anaesthesia.

Materials and Methods

This randomized controlled clinical trial was designed to be conducted among the 200 patients (100 patients with endotracheal tube & 100 patients with LMA) of routine laparoscopic cholecystectomy in BIRDEM General Hospital, Bangladesh from a period of 15.11.2014 to 15.07.2016 with a view to depict the of safety of Laryngeal Mask Airway in contrast to Endotracheal Tube in terms of peroperative and immediate postoperative complications. Respective patients of 20 to 60 years age group with ASA II or III included as study population. Different pathology (for which operation was done), BMI, co-morbidity were confounding variable here. Patients with congenital anomaly and morbid obesity were excluded from study population. Simple random sampling was used as the sampling technique. In each patient, after preoxygenation, anaesthesia was introduced with propofol, fentanyl and vecuronium. Anaesthesia was maintained with N2O, O2, Halothane and vecuronium. Ventrilation was set at 8 ml/kg and respiratory rate was 12/min. Patients with endotracheal tube (ETT) were included in Group a (Control group) & patients with LMA were in Group B (Experimental group). Data were processed, presented in tabulated form and discussed with compare & comparison on the basis of statistical analysis.

Results

Age and sex distribution of both group of patients is depicted in Table 1 which suggests that majority (47%) of the patients of Group A were in 40 to 50 years age group whereas, in a case of Group B, most of the patients (35%) were in group B.

	Group A (n=100)			Group B (n=100)		
Age in years	**No. of patients**	**%**	**Mean±SD**	**No. of patients**	**%**	**Mean±SD**
20-30	13	13	41±1.1	17	17	37±1.7
30-40	24	24		19	19	
40-50	47	47		35	35	
50-60	16	16		29	29	
Total	**100**	**100**		**100**	**100**	

Table 1: Age & sex distribution in both control and experimental groups.

Figure 2 reveals the demographic distribution and duration of anaesthetic period (minutes) of patients in both control and experimental groups.

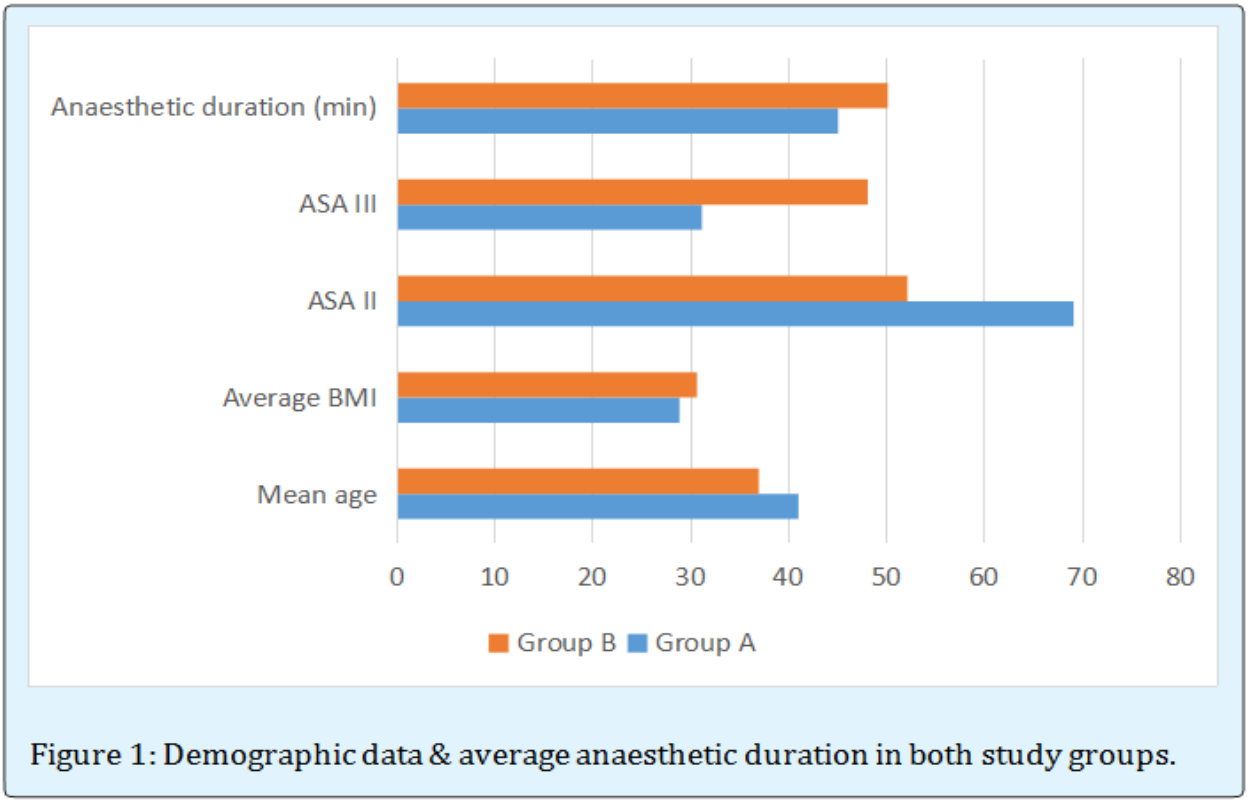

Figure 1: Demographic data & average anaesthetic duration in both study groups.

Haemodynamic status in different time of peroperative period is represented in Figure 2 in terms of heart rate (HR) and mean arterial pressure (MAP).

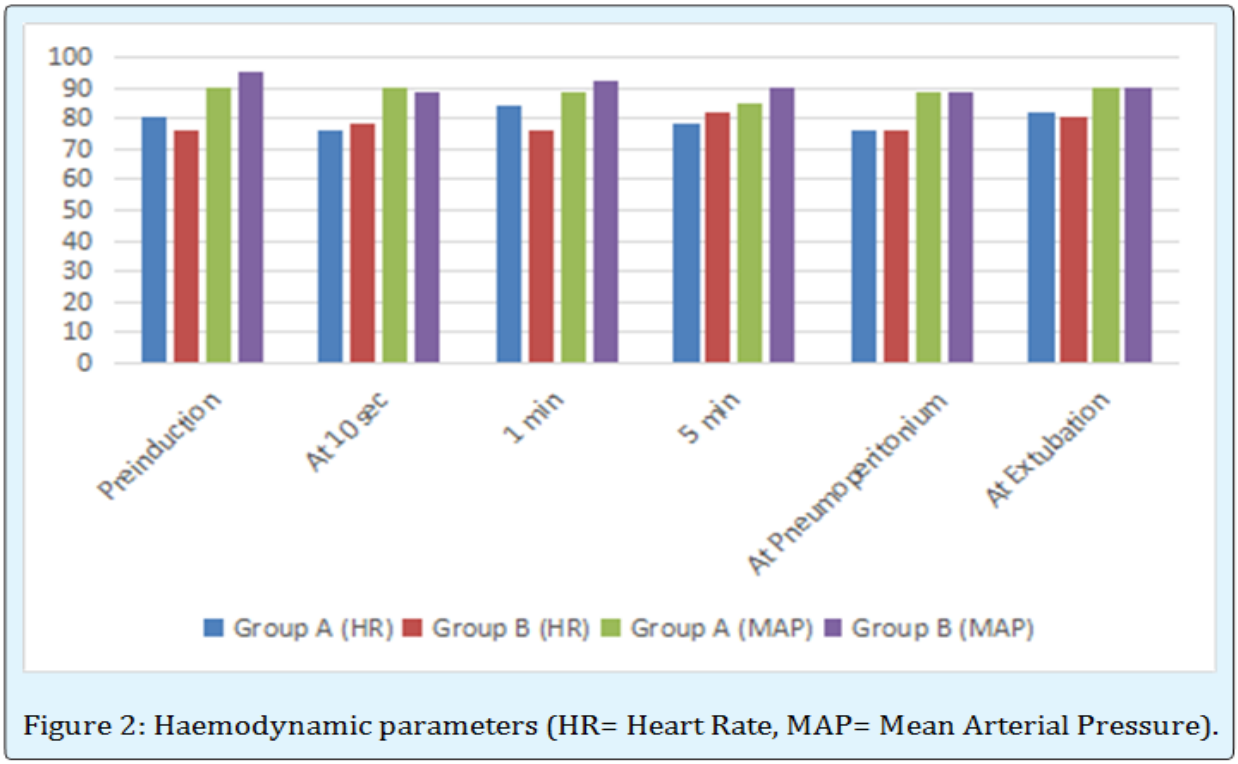

Figure 2: Haemodynamic parameters (HR= Heart Rate, MAP= Mean Arterial Pressure).

Laryngeal morbidity at different phases is represented in Table 2 which suggests no significant difference between the findings in ETT and LMA groups. P-values are statistically less significant here.

	Group A	Group B	P-value
Intraoperative			
Leak	---	02	0.5
Gastric insufflation	---	03	
Aspiration, regurgitation	---	00	
At removal			
Coughing	07	04	0.4
Blood stain device	05	05	
Trauma to lip, teeth, tongue	04	01	
Postoperative			
Vomiting	01	01	0.5
Sore throat	05	07	
Dysphagia, dysphonia, dysarthia	00	00	

Table 2: Laryngeal morbidity in Group A & B.

Discussion

In Group A (control group), majority of the patients (47 out of total 100 patients) were in 40 to 50 years of age group followed by 24 patients (out of total 100 patients) were in 30 to 40 years age group. Mean±SD of age in this group was 41±1.1, in contrast, in experimental group, most of the patients were in (35 out of total 100 patients) were in 40 to 50 years of age group followed by 29 patients (out of total 100 patients) were in 50 to 60 years age group. Mean±SD of age in this group was 37±1.7. Demographic data (Figure 2) suggests that the average BMI in both group were 28.9 and 30.6 respectively. In ETT group, most of the patients (69%) had ASA grade II, whereas in LMA group 52% patients had ASA grade II. Average anaesthetic duration in both group were 45 & 50 minutes respectively. Haemodynamic status in both groups in terms of heart rate and mean arterial pressure was depicted in figure 2 which suggest no significant difference in between both groups at different phases of peroperative period. In question of laryngeal complications, table 2 suggests that tube leakage and gastric insufflation were found in 2 & 3 patients respectively with the use of LMA. No case of regurgitation and aspiration was recorded. Regarding the issue of

laryngeal morbidity immediately following removal of tube, it was reflected that coughing and trauma to lip, teeth, tongue were slightly higher in Group A an contrast to Group B. But the prevalence of blood stain on device found same (05%) in both groups. The incidence of sore throat was slightly higher with the use of LMA (07%) in comparison to ETT (05%), but postoperative complications like dysphagia, dysphonia, and dysarthia were recorded to be same in both groups. P-values suggest less significant result here. In a study of Namita S et al. [51]. It was found that in case of haemodynamic status, there was no significant comparative result between ETT and LMA groups also. In issue of Intraoperative laryngeal morbidity, the prevalence of tube leakage and gastric insufflation were 1 case and 3 cases respectively in LMA group, whereas, regarding postoperative sore throat, it was recorded to be slight higher in LMA group (07%). But following removal of tube, the difference of laryngeal complications in between both groups suggests less significant result.

Conclusion

In summary, the result of this study is highly suggestive of the effectiveness and safety of LMA tube in terms of per and postoperative haemodynamic and laryngeal complications in comparison to endotracheal tube.

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