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A comparative analysis of the LMA-Classic™ and the disposable Soft Seal™ Laryngeal Mask in spontaneously breathing patients: A randomized prospective study

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Abstract

Background: We performed a comparative trial in 60 spontaneously breathing adult patients under, general anesthesia to compare the performance of the reusable LMA-Classic™ [LMA-C] and the disposable Soft Seal™ LMA [LMA-S].

Material-Method: Sixty patients aged 18-65 years [ASA I-I] were randomly assigned into two equal groups to receive either the LMA-C or the LMA-S for airway management during general anesthesia. Anesthesia was induced with 1µg/kg fentanyl and 2-3 mg/kg propofol intravenously until the loss of verbal response and eyelash reflex. The anesthesia maintenance was provided by a mixture of 50% nitrous oxide-oxygen and sevoflurane 1-2% in a fresh gas flow of 3 L/min. The targeted endpoint for the depth of anesthesia was to achieve a BIS value of 40±10. The cuff pressure was adjusted to 60 cmH_2O with a hand-held aneroid manometer and recorded every half hourly throughout the surgical procedure. The outcomes of the study were to assess the clinical performance and the cuff pressure changes of both airway devices.

Results: Demographic characteristics and the duration of anesthesia were comparable. Both LMA-C and LMA-S showed similar clinical characteristics in terms of successful insertion at the first attempt, the insertion time and the ease of insertion. The cuff pressure was significantly higher in the LMA-C group compared to the LMA-S [97.96±13.23 and 73.72±7.92 cmH_2O respectively]. The sore throat at the 2nd hour was reported in a total of 9 patients; 6 of them were the LMA-C and 3 of them were the LMA-S received patients [0% vs. 10%; $p<0.05$]. However, there was no such difference at the 24th hour postoperatively. The incidence of blood staining was similar in both masks with a insignificant difference [11% in the LMA-C and 13.33% in the LMA-S].

Conclusion: The Soft Seal™ LMA is a safe, effective and useful disposable airway device alternative in non-paralyzed patients under general anesthesia. The lower cuff pressure changes and the postoperative sore throat incidence may be considered as a clinical superiority to the LMA®-Classic™.

Key words: laryngeal mask, cuff pressure, comparative effectiveness research

Introduction

Supraglottic airway devices [SADs] are widely used tools for airway management in spontaneously breathing

patients during general anesthesia classified as 1st-generation devices having a breathing lumen and 2nd-generation SADs with the additional lumen for gastric drainage. Since the laryngeal mask airway [LMA®] have been invented by Brain and patented in the UK in 1982, various devices have been introduced into the clinical practice [1]. LMA®-Classic™ [Intavent Orthofix Ltd, Maidenhead, Berkshire, UK] is constructed from medical grade silicone and is reusable after steam autoclaving with a maximum recommended re-use of 40 times [2]. After the 2000s, the debates about the complete removal of all biologic debris and proteinaceous material from the reusable LMA™s have led to the development of disposable SADs [3]. A single-use laryngeal mask airway [Soft Seal™, Portex Ltd, Hythe, UK] having a rounder cuff and wider airway tube than LMA®-Classic™ have been introduced to the clinical practice with a latex-free, thermosensitive plasticized polyvinyl chloride construction [Figure-1]. After that, many comparative studies have been published concerning the advantages or disadvantageous of the Soft Seal™ LMA [4-7]. Today, there is a considerable interest to the disposable equipment in healthcare so the disposable airway devices are taken a big attention.

The objective of this single-blind randomized study is to compare the LMA®-Classic™ and the Soft Seal™ LMA in non-paralyzed patients and evaluate the clinical characteristics of the two airway devices with the review of the literature.

Material-Method

After institutional review board approval and informed consent, a prospective randomized single-blind study was conducted on 60 patients of American Society of Anesthesiologists [ASA] physical status I-II between 18–65 years of age in both gender, undergoing elective surgery in a supine position in whom no 4 sized laryngeal mask insertion was appropriate. The exclusion criteria were as follows: the patients <18 yr old; the requirement of position during surgery, the predicted difficult airway, the patients having a body mass index of 35kg/m^2 or more, the known gastroesophageal reflux, mouth opening<2.5 cm, cervical deformities, oral or nasal surgery, requiring position changing during operation, predicting duration of surgery more than 2 hrs .

No premedication was administered to the study groups. Intraoperative monitoring included gas analyzer, end-tidal CO_2 [$EtCO_2$], pulse oximeter [SpO_2], intermittent non-invasive blood pressure monitor, continuous electrocardiogram and peak airway pressure. Prior to induction of anesthesia, the cuff was tested for leakage and water-soluble lubricant was applied to the posterior surface as a routine procedure. As our standard clinical practice, the cuff was inflated with room air at 15 cmH_2O above the atmospheric pressure before insertion. The patient's head was supported on a silicone ring pillow with neck flexed and head extended.

Following pre-oxygenation for 3 min, general anesthesia consisted of 1μg/kg fentanyl and 2-3 mg/kg propofol intravenously until the loss of verbal response and eyelash reflex. The patients were randomly allocated into two groups of 30 each to receive either LMA®-Classic™ [LMA-C] or Soft Seal™ LMA [LMA-S]. Mask size was selected according to the body weight of the patient as the manufacturers' recommendations. During insertion, if the relaxation of the jaw and mouth opening of the patient was inadequate further bolus doses of propofol were administered. For insertion, the mask was held like a pen at the mask tube facing the aperture anteriorly. The chin was grasped with non-dominant hand and the tongue was pressed by the thumb while advancing the mask. The mask pushed into the hypopharynx until feeling a resistance. Successful placement was confirmed by rising

up of the device during inflation, auscultation, observation of chest movements, capnography waveform interpretation and absence of an audible leak. The failed attempt was accepted on more than three occasions. The oropharyngeal leak was assessed by the auscultation of laryngeal inlet under the manual ventilation with the reservoir bag and the lowest pressure was indicated at which the leakage of gas could be hearth by the stethoscope. Both devices were fixed by taping the device with a bite-block of rolled gauze swabs. The cuff was inflated with a hand-held aneroid manometer [Endotest; Rüsch, Kernen, Germany] to achieve a cuff pressure of 60 cmH_2O and recorded every half hourly throughout the surgical procedure. The maintenance of anesthesia was provided by a mixture of 50% nitrous oxide-oxygen and sevoflurane 1-2% in a fresh gas flow of 3 L/min via a circle breathing system. The targeted endpoint for the depth of anesthesia was to achieve a BIS value of 40±10. No neuromuscular blocking agents were used throughout the surgery and spontaneous breathing was allowed. The patients underwent manually assisted ventilation with the spontaneous breathing adjusted the end-tidal CO_2 35-45 mmHg. At the end of the procedure, masks were removed following the protective reflexes had to return normality. During removal of masks, the cuff was not deflated completely to avoid the secretion entering the trachea and provoking the spasm.

All investigators have a great practice for laryngeal mask insertion since it first became available. The study was conducted according to the ethical principles outlined in the Helsinki Declaration and guideline of the Good Clinical Practice.

Data collection

The demographic data concerning the age, sex, body weight, and ASA physical status, the surgical characteristics and the anesthetic management of the patients were recorded. The clinical implications related to both masks were evaluated. The number of insertion attempt was recorded and three occasions were allowed before the attempt was considered as a failure. The insertion time was assessed the time between taking up the mask by the investigator and providing the satisfactory ventilation. All laryngeal masks in both groups were inserted by the same investigators and graded as the very easy, easy or difficult insertion. At the time of removal of the mask, the presence or absence of the blood was noted. Patients were asked about the presence of a sore throat at 2nd and 24th hours postoperatively by another observer blinded to the study.

Statistical analysis

The analysis was performed using SPSS Inc Software [ver.18.00 PASW Statistics for Windows, Chicago]. Continuous variables were expressed as the mean ± standard deviation [SD]; whereas categorical values were expressed as numbers [n] and percentages [%]. Patient characteristics [age, weight], duration of anesthesia, total drug doses and cuff pressure changes were assessed with Student's t-test; quantitative variables were assessed with Fisher Exact and chi-square test. The success of mask insertion and the incidence of a sore throat were tested with Fisher Exact test. A $p<0.05$ value was considered significant.

Results

All patients enrolled in the study were included in the statistical analysis. Patient characteristics, the doses of induction drugs and duration of anesthesia were expressed in Table-1 [$p>0.05$].

The success rate in the first insertion attempt of both masks was comparable [$p>0.05$]. In the LMA-C group, the first insertion attempt success was clinically higher than the LMA-S group in an insignificant difference. The insertion time was 19±5.5 and 18.23±5.26 seconds in the

LMA-C and the LMA-S groups respectively [p>0.05]. The ease of insertion was similar for both masks with 3 [10%] patients in the LMA-C and 2 [6.6%] patient in the LMA-S group being graded as difficult. The cuff pressure increased in both device but in the LMA-C group, the cuff pressure was significantly higher at the end of the surgery [p<0.001] [Table-2]. Both masks were tolerated well throughout the surgery and no unexpected outcome was noted.

The blood staining was similar in both masks [11% in the LMA-C and 13.33% in the LMA-S]. The sore throat at the 2nd hour was reported in a total of 9 patients; 6 of them were the LMA-C and 3 of them were the LMA-S received patients [20% vs. 10%; p<0.05]. After 24 hr, no statistical significance between the two groups was indicated [p>0.05].

Discussion

This study indicated that the disposable Soft Seal™ LMA and re-usable LMA®-Classic™ demonstrated a similar clinical performance in spontaneously breathing patients regarding the first attempt success rate and the ease of insertion. The lower cuff pressure changes at the end of the surgery and the less postoperative sore throat with the Soft Seal™ LMA provided a clinical superiority in this tool.

The first attempt success rate results in our study were lower than that reported by Brimacombe el al. [8] but they compared the two devices in paralyzed patients. The difference was probably due to the facilitating effect of the neuromuscular blockers on the insertion of the masks. Our results were better than the report of by Cao et al. [9] [84% for reusable and 79% for disposable laryngeal mask]. This could be explained by the choice of drugs used for induction and maintenance of anesthesia was left to the choice of the anesthesiologist in this study. The first attempt insertion success rates found in our study were comparable to the report of Peach et al [5] in which the first time insertion rate was reported as 88% for disposable and 91% for reusable masks. They also reported that the median insertion time was significantly longer in the Soft Seal™ LMA in expert hands. This idea was supported by Tan et al. [10] and this time difference based on the wider tube and stiffer polyvinyl chloride constitution of the disposable Soft Seal™ LMA. However, our findings did not support this suggestion; the first attempt success rate and insertion time were comparable between groups.

It's been previously reported that the construction of the cuff was the main factor for increasing the cuff pressure. [11]. The silicon based cuff of the reusable LMA®-Classic™ is highly permeable to N_2O diffusion and yield to the increase in the cuff pressures during the maintenance of anesthesia [12,13]. A comparative study about the cuff pressure changes with or without N_2O in anesthesia gas mixture revealed that N_2O was highly diffused to the cuff of the LMA®-Classic™ and increased the intracuff pressure [14]. However, because of the polyvinyl chloride based cuff structure of disposable laryngeal mask, the intracuff pressure remained unchanged during N_2O anesthesia [15]. In our study, the cuff pressure increased from 60 cmH_2O to 97.96±13.23 cmH_2O in LMA-C group and 73.72±7.92 cmH_2O in LMA-S group. In parallel to previous studies, our results clearly demonstrated that the cuff pressure increased significantly in the re-usable LMA®-Classic™ having silicon cuff during N_2O anesthesia.

It's likely that a sore throat after laryngeal mask placement is multifactorial, arising from mucosal trauma, ischemia and stretching of pharyngeal muscles [5]. The use of neuromuscular blockers does not change the overall incidence of pharyngolarnygeal discomfort [16]. The incidence of sore throat for LMA-Classic™ ranges from

6% even up to 40% in many reports [4, 5, 15, 17, 18, 19] . It's been shown that if cuff pressure limited to 60 cmH_2O, this resulted in a very low incidence [5%] of a sore throat [20]. In our study, the incidence of the sore throat was 20% and 10% for the LMA-Classic™ and SoftSeal™ LMA respectively which was similar the findings of van Zundert et al [4]. Both devices were tolerated well throughout anesthesia and the removal of the masks. The presence of mild bloodstaining in both masks was clinically negligable.

Although the fiberoptic evaluation of the correct position of the LMA was recommended as the gold standard by Brimacombe et al. [21], it's not always necessary during clinical practice. In special cases in which the ideal LMA placement is desirable (cervical deformities congenital anomalies etc) or the position changes during surgical procedure, it proved to be a valuable tool [22, 23]. Fiberoptic evaluation was not carried out in this study.

In a limitation, this study did not seek the cost-effectiveness of both masks because of the price variability between institutions and countries.

Table1. The patients' characteristics and the data related to the anesthetic management

Variables	LMA-C (n=30)	LMA-S (n=30)	P
Age (yr)*	47.64±16.49	46.20±17.79	NS
Gender (M/F) ** (n/%)	19 (63.33)/11(36.67)	17(56.67)/13(43.33)	NS
Weight (kg)*	72.54±15.79	69.36±16.50	NS
ASA (I/II)**(n/%)	18 (60.00)/12 (40.00)	14 (46.67)/16 (53.33)	NS
Duration of anesthesia (min)*	49.78±7.50	45.92±4.99	NS
Total drug consumption* Fentanyl (µg) Propofol (mg)	 87.15±15.0 175.60±30.00	 85.90±22.6 180.25±25.9	NS

*Data were expressed as mean ± SD or** the number of patients (n) and the percentage (%)

ASA: American Society of Anesthesiologists, NS: non-significant; p>0.05

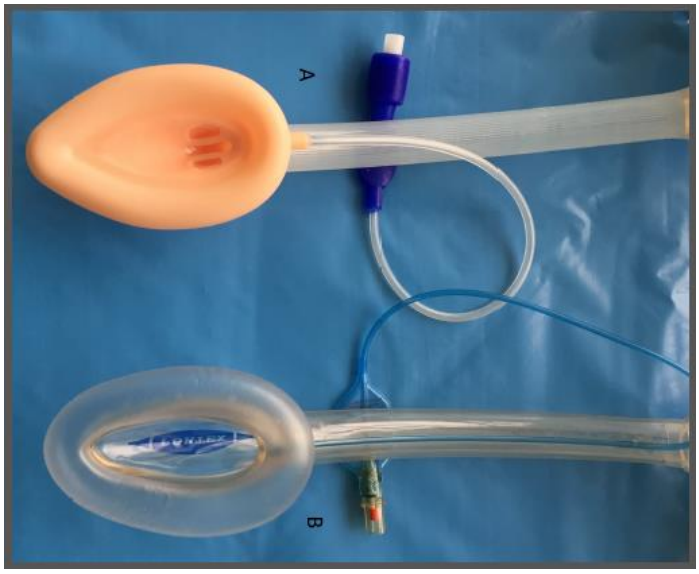
Table 2. The data regarding the performance of the two masks.

Variables	LMA-C (n=30)	LMA-S (n=30)	p
Insertion time (sec)*	17.10±11.76	13.49±5.44	NS
Success at the first attempt (%) **	93.33	86.66	NS
The mean cuff pressure at the end of the surgery (cmH_2O)*	97.96±13.23	73.72 ±7.92	**p<0.001**[#]

*Data were expressed as mean ± SD or** the percentage (%),

[#] p<0.001 statistically highly significant

Figure 1. The re-usable LMA-Classic™ (A) and the disposable Soft Seal™ LMA (B). Note the larger diameter of tube, the deeper bowl of the mask and the absence of laryngeal bars in the Soft Seal™ LMA.



Conclusion

We concluded that the Soft Seal™ LMA and the LMA-Classic™ showed similarity in terms of clinical performance. The lower cuff pressure changes and the less postoperative sore throat incidence in the disposable Soft Seal™ LMA made this tool more beneficial during nitrous oxide anesthesia. Our findings imply that continuous cuff pressure monitoring may be considered if the LMA-Classic™ was used during N_2O anesthesia. This may be more important in the patients having prolonged anesthesia duration.

The authors declared no conflict of interest.

Author contribution

1. Concept and design of study or acquisition of data or analysis and interpretation of data: OS, BC, EB

2. Drafting the article or revising it critically for important intellectual content: BC

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