Egyptian Journal of Anaesthesia (2015) **31**, 277–281

HOSTED BY

Egyptian Society of Anesthesiologists

Egyptian Journal of Anaesthesia

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Research Article

A controlled, double blind, study of adding Nalbuphine to Propofol for laryngeal mask insertion conditions and hemodynamics in adults

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Received 9 January 2015; accepted 25 March 2015
Available online 28 May 2015

KEYWORDS

Laryngeal mask airway (LMA);
American Society of Anesthetists (ASA);
Mean arterial pressure (MAP)

Abstract *Purpose:* The purpose of this study was to evaluate laryngeal mask airway placement conditions achieved with Nalbuphine/Propofol combination when given intravenously as well as hemodynamic changes if any.
Methods: 60 ASA grade 1 and 11 patients of age group 20–60 years, scheduled for general anesthesia with spontaneous breathing were randomly allocated to receive intravenously either Fentanyl 2 μg/kg, controlled group (Group F, $n = 30$) or Nalbuphine 0.2 mg/kg (Group N, $n = 30$), before induction of anesthesia with Propofol 2–2.5 mg/kg. Heart rate and arterial blood pressure were measured before induction of anesthesia and at 1, 3, and 5 min after LMA insertion. Assessment of LMA insertion was done using 6 variables: mouth opening, gagging, swallowing, head and limb movements, laryngospasm and resistance to insertion. Incidence and duration of apnea were recorded.
Results: The incidence of coughing/gagging was higher in the F group (50%) compared to the N group (30%), ($P = 0.019$). Swallowing was also statistically significant ($P = 0.017$), being higher in F group (50%), compared to N group (16.6%). Limb moving followed the same pattern being higher in the F group (40%) compared to (13.3%) in the N group, ($P = 0.008$). Laryngospasm was seen in neither group. There was also statistically significant difference ($P = 0.007$) in the incidence of apnea between the control group (F) 86.6% and (N) group. Heart rate variation and MAP changes were not statistically significant in either F or N groups.
Conclusion: The addition of Nalbuphine to Propofol for LMA insertion provides excellent insertion conditions with stable hemodynamics in adults.

1. Introduction

One of the most basic yet crucial skills in modern anesthetic practice is airway management and failure to secure a patent airway might end up in catastrophe [1].

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Peer review under responsibility of Egyptian Society of Anesthesiologists.

http://dx.doi.org/10.1016/j.egja.2015.03.009

Laryngeal mask airway is one of our airway armamentaria which is non-invasive supra-glottic device with less adverse cardiovascular response than tracheal tubes simply because entry through the vocal cords into the larynx is not required [2,3]. However, deep level of anesthesia is required for safe and uneventful LMA insertion as coughing, laryngospasm, and gagging may lead to desaturation, adverse cardiovascular response and risk of regurgitation and aspiration [4–6]. Propofol has been postulated the induction agent of choice for LMA placement and this is owing to its depressant action on upper airway reflexes. Nevertheless, Propofol has its downside as it has cardiorespiratory depressant action plus purposeless patient movement [7]. So, it is not recommended as standalone drug for LMA insertion and wide range of adjuvants have been used clinically to obtain best LMA insertion criteria with negligible side effects [8,9]. The ideal adjuvant has not been reached yet [10,11]. Nevertheless, opioids have teamed up with Propofol to reach success rate up to 95% but apnea, chest tightness, and hypotension are still main unwanted side effects [12].

Nalbuphine is a potent analgesic. Receptor studies show that it binds to mu, kappa, and delta receptors, but not to sigma receptors. Nalbuphine is primarily a kappa agonist/partial mu antagonist analgesic. Its cardiovascular stability, long duration of analgesia, no respiratory depression, less nausea and vomiting and potential safety in over dosage make it an ideal analgesic to use in children [13,14]. In this research, Nalbuphine/Propofol combination was investigated for best hemodynamic and laryngeal mask airway placement conditions.

2. Patients and methods

After approval of the hospital research panel, a total of 60 American Society of Anesthetists (ASA) grade 1 and 11 patients, aged 20–60, enlisted to undergo elective day case surgery under general anesthesia with spontaneous breathing using a classic laryngeal mask airway (cLMA, the Laryngeal Mask Company, Glamorgan CF 45, UK) were assigned to the study. Hernia repair, hydroceles, varicoceles, and orthopedic elective surgeries were the most common surgeries, followed by biopsies, and postburn plastic flap. Written informed consent was obtained from each patient. Those with suspected difficult intubation, known allergy to Fentanyl, Nalbuphine or Propofol, seizures, neuromuscular disease, cardiovascular pathology, hepatic or renal disease and long surgery (more than 3 h) were excluded from the study. Patients received nothing per os 6 h before the surgery and were premedicated with oral midazolam (0.5 mg/kg) in the morning of the surgery. In the operating table, intravenous access was established and standard anesthesia monitors were connected to the patients. The monitored parameters were heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial blood pressure (MAP), respiratory rate (RR), end tidal CO2 (ET CO2) and oxygen saturation (SpO2). ECG, ETCO2 and SpO2 were monitored continuously. Recording of these parameters was done at the following time intervals: baseline value, immediately before LMA insertion, one minute after LMA insertion and thereafter 3 min and 5 min. Sealed pre-coded envelopes, were used to randomly assign patients into 2 groups: group F = Fentanyl group (n = 30), and group N = Nalbuphine group (n = 30).

Fentanyl was given in a dose 2 μg/kg intravenously over 10 s to group F. Nalbuphine in a dose of 0.2 mg/kg was given as a bolus intravenous dose to group N. Pre-oxygenation was carried out with 100% oxygen for 5 min. General anesthesia was induced with Propofol in the dose of 2 mg/kg with 1/2 mL Lidocaine 2% given over 15 s [14], then, we ventilated the lungs for 60 s with 100% oxygen, immediately followed by testing loss of corneal reflexes and jaw relaxation before attempting insertion of cLMA.

LMA insertion (size selected on basis body weight) was done by anesthetist who was unaware of the research methodology [15]. In case of cLMA malposition or malfunction, it was removed, and a further dose of Propofol (1 mg/kg) was given. 60 s later reinsertion was attempted. Endotracheal intubation was carried out after 3 unsuccessful trials of cLMA insertion and lung ventilation.

Once the cLMA was successful, spontaneous breathing was allowed as the mode of ventilation. If apnea occurred (defined as absence of respiration for 30 s), ventilation was manually assisted through cLMA with 100% oxygen to maintain the arterial oxygen saturation above 95% until regular spontaneous respiration resumed. Anesthesia was maintained with 66% air in oxygen and 1–2% Sevoflurane.

Our primary outcome was successful insertion of cLMA. Secondary outcomes were, occurrence of apnea or/and drop in blood pressure (20% decrease of systolic blood pressure under baseline value).

Based on six variables on a 3 point scales cLMA insertion criteria were assessed by two blinded investigators as follows [16–19]:

1. Resistance to mouth opening: Nil/Slight/Gross
2. Resistance to insertion: Nil/Slight/Gross
3. Swallowing: Nil/Slight/Gross
4. Coughing/gagging: Nil/Slight/Gross
5. Limb/head movements: Nil/Slight/Gross
6. Laryngospasm: Nil/Slight/Gross

For our study purpose occurrence of any of the above variables that did not require cLMA reposition or reinsertion was labeled as slight, where gross was the term given to any episode that leads to cLMA reposition or reinsertion.

2.1. Statistical analysis

Fisher exact test was used to compare dichotomous parameters. Shapiro-Wilk test analyzed the normal distribution of demographic and procedural data.

A two factor ANOVA using ROC MIXED procedures was used to analyze repeated measurements of continuous variables. Data were reported as mean ± SD or median (interquartile range). A power analysis was initially done, assuming that LMA placement conditions were continuous data with normal distribution. In a previous study [16], the summed score SD of LMA placement conditions intergroup was 2.5. In order to achieve an intergroup difference of more than 2, a sample size of 30 patients in each group would be required. This would create a power of 80% and P value ($P < 0.05\%$) was accepted as statistically significant. LMA insertion conditions were compared using the Kruskal–Wallis test, and the Mann–Whitney test was used for multiple intergroup comparisons.