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Is Endotracheal Tube Use Mandatory in Patients Undergoing Nasal Septum Surgery? Randomized, Controlled, Prospective Clinical Trial

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Protocol

This study is approved in Malatya Clinical Research Ethics Committee with the protocol code of 2018-165 and carried out at Department of Anesthesiology, Inonu University Medical Faculty in accordance with the criteria of Helsinki Agreement.

The study is planned as a prospective, randomized clinical trial. For randomization, the patients will be assigned to the study groups entirely by chance, and selection bias was prevented. MedCalc for Windows, version-16 statistical software (medcalc.com.tr.) will be used. A total of 80 patients with elective nasal septum surgery will be randomly assigned to the groups of Supreme LMA (Group L, n = 40) and ETT (Group E, n = 40).

Patients who agreed to participate voluntarily were informed about the potential risks and predictable outcomes of the study. The study will be performed on 80 patients between 18-65 years old, American Society of Anesthesiologists (ASA) I-II group planned for effective nasal septum surgery. Preoperative anesthesia evaluation (I) higher than ASA II (II) Patients with severe respiratory, hepatic or renal dysfunction (IV) Patients with history of allergy to anesthesia medications (V) of neurology and psychiatry patients (VI) Body mass index (BMI) of 30 Patients with obstructive airway history (cervical spine pathology, modified Mallampati grade 4 or thyromental distance <65 mm, VIII) will be excluded from the study who had a high risk of regurgitation or aspiration.

General anesthesia will be standardized for all patients. Patients who were taken to the operation room will be routinely given 3 minutes preoperative oxygenation. Vital finding parameters in supine position; Noninvasive blood pressure (NIBP), pulse oximetry (SpO2), heart rate (HR), monitoring will be performed.

Anesthesia induction of both groups; remifentanil 3 µg.kg-1 IV will be performed with propofol 2.5 mg.kg-1 IV and muscle relaxant will not be used. Intubation will be performed by the same anesthesiologist who experienced at least 5 years success rate of over 90% in orotracheal intubation and laryngeal mask placement after the patients had lost consciousness and chin looseness was formed sufficiently.

After the third attempt, the cases in which endotracheal tube and Supreme LMA could not be placed correctly will be excluded from the study and airway safety will be ensured.

In the maintenance of anesthesia, 1 MAC value will be used in desflurane 50% O2 / air mixture and remifentanil infusion (0.1 mcg / kg / min IV). In both groups, mechanical ventilation will be achieved with volume controlled ventilator mode (Dräger Primus ventilator, Dräger AG, Lübeck, Germany). Intraoperatively, 4 L / min of fresh gas flow will be adjusted to be 8 mL / kg tidal volume, and respiratory rate of 35-45 mm Hg EtCO2.

In Group L, LMA will be guided by the guideline: <50 kg, size 3; 50-70 kg, size 4; 70-100 kg, size5. In Group E; 8 male and 8 female patients will have endotracheal tube. In Group L, the intracuff pressure will be adjusted to 60 cm H2O and in Group E the cuff pressure will be adjusted to 20 H2O using a manometer (Portex Cufator Endotracheal Tube Manometer, Portex® Limited, Hythe, Kent, UK). The airway device will be then connected to the anesthetic circuit. The correct position of the tubes in both groups; the absence of leakage sound from the mouth, chest expansion during ventilation, capnography and auscultation will be confirmed. A nasogastric tube will be inserted into the LMA drainage tube.
Air leakage to the stomach will be controlled by checking for bubbles (foam) at the proximal end of the nasogastric tube. Depth of anesthesia will be monitored with the bispectral index (BIS; VISTA Monitoring System, Massachusetts, USA) monitoring. Two cerebral NIRS and BIS sensors will be placed in the right and left frontal areas under the hairline and covered with tape to prevent exposure to light.

Patients who opened their eyes with eye, breathing regularly, respiratory rate was 12-20 / min, oxygen saturation greater than 95% will be extubated and taken to the recovery room (PACU).

Outcome Measures
In Group L and E, oropharyngeal leak pressures will be measured while the head will be in neutral position. The flowmeter O2 current will be set at 3 L / min and the expiratory valve will be closed. When an investigator who did not know which type of airway device was placed, another researcher looked at the current pressure value from the aneroid manometer and confirmed that the pressure remained constant (pressure gauge stability test). This value was recorded as the value of oropharyngeal leakage pressure. To prevent lung exposure to barotrauma, the expiratory valve was opened when the peak inspiratory pressure reached 40 cmH2O, and the test will be terminated.

At the end of the surgery, in Group L and E, the presence of blood will be observed through a tubular fiberoptic bronchoscope. Posterior oropharynx will be carefully aspirated at the end of surgery in patients with endotracheal tube. After extubation, presence of blood around ETT cuff and distal blood will be examined. In the presence of blood, a four-scale scale will be used at the level of glottis-trachea and distal trachea. (1 = no, 2 = mild, 3 = moderate, 4 = severe). Mean arterial pressure (MAP), heart rate (HR), and peripheral oxygen saturation (SpO2) immediately prior to anesthesia induction, 5, 15, 30, 45, 60 after confirmation of airway placement 75. EtCO2 will be recorded per minute and every 15 minutes during the operation. Demographic data, duration of surgery and total anesthesia duration will be recorded.

Orogastric tube placement; very easy, easy, difficult, very difficult in the form of a 4-point scale will be used.

Pharyngolaryngeal adverse events (laryngospasm, bronchospasm, nausea, vomiting, coughing, desaturation (SpO2 <94) and re-intubation need will be observed in the operation room and PACU at 5, 15, 25 and 45 min. Sore throat, nausea, vomiting, dysphonia and dysphagia will be evaluated and recorded at 2, 4, 6, 12 and 24 hours postoperatively. Postoperative adverse effects will be evaluated as follows: laryngospasm; airway obstruction due to muscle rigidity in the chest and abdomen, Bronchospasm; especially during expiration, increased respiratory effort and wheezing. Dysphonia; difficulty in speech because of difficult speech or pain. Difficulty in swallowing; difficulty in swallowing or painful swallowing.

Sore-throat; it was defined as constant pain felt independently of swallowing. The evaluation was made with 0 ile10 numerical pain rating scale (NRS: Numeric Rating Scala). According to NRS, sore throat score will be evaluated as; 0-1: none, 2-4: mild, 5-7: intermediate and 8-10: severe.

5 point scale was used to determine the severity of nausea / vomiting. (0 = no nausea, 1 = mild nausea, 2 = moderate nausea, 3 = vomiting less than 2 times per hour, 4 = vomiting more than 2 times per hour).

Cough; cough in the postoperative period (less than 5 coughs will be ignored within the first minute after removal of the mask or tube, more than 5 coughs will be counted),

Statistical Analyzes

Type I error (alpha) 0.05, the power of the test (1-beta) 0.9, the primary output variable in the air (glottis / trachea) for the amount of blood effect of 0.71 and the alternative hypothesis (H1) is two-way to be found a significant difference using this test A total of 80 patients were required, with a minimum sample size of 40 in each group (*Kaplan A, Crosby GJ, Bhattacharyya N. Airway Protection and the Laryngeal Mask Airway in Sinus and Nasal Surgery. Laryngoscope 114: April 2004.*)