Study Protocol

2021-1-18

Project name	Application of Visual Laryngeal Mask Airway Combined with Endotracheal Intubation in Non-head and Neck Surgery Under General Anesthesia		
Name of project leader	Xia Ruan, Yahong Gong	Title	Associate Professor
Department	Department of Anesthesiology		
Telephone contact	86-10-69152001	Fax	
E-mail	sheyaruan@sina.com		
Research Cooperation Unit	N/A	Head of Research Cooperation Unit	N/A
Study Start Date	February 1, 2021	Estimated duration of the study	1.5 Year
Research site	Peking Union Medical College Hospital		
Does this study include genetic analysis?	□ yes ;■ no;		
Does this study include radiation?	□ yes ;■ no;		
Does the researcher have a conflict of interest □ Yes (please specify): ■ not;			

a. Background information on subjects: (Gender, age, health status, and other characteristics.)
Patients undergoing non-head and neck surgery with endotracheal intubation under general anesthesia, ASA Ⅰ-Ⅱ.

b. Number of subjects (sample size), inclusion criteria, exclusion criteria:
50 subjects to be included
Selection criteria:
1. The operation of non-head and neck surgery with endotracheal intubation under general anesthesia.
2. ASA Ⅰ-Ⅱ.
3. Age 18~70 years old.
4. Voluntary signature of informed consent.
Exclusion criteria:
1. ASA Ⅲ-Ⅳ;
2. Weight <30kg or BMI>40kg/m2;
3. Patients with high risk of regurgitation;
4. Complicated with severe respiratory diseases;
5. Complicated with oropharyngeal lesions affected laryngeal mask placement;

6. Complicated with oropharyngeal pain in the last two weeks.

c. Methods of intervention

1. Preoperative

The coordinators screen patient who meets the exclusion criteria before operation, visit the patient the day before operation, explain the research plan, and randomly divide the patient into visual group or non-visual group after the patient consents and signs the informed consent.

2. Intraoperative

After entering the operating room, the patient received routine general anaesthesia monitoring, and anesthesia induction was conducted after three-party verification. Propofol (plasma target-controlled concentration: 3.5ug/ mL), midazolam (0.05mg/kg), fentanyl (2ug/kg) and rocuronium (0.6mg/kg) were used to induce the drugs.

After anesthesia induction, visual laryngeal mask airway was placed in the visual group and endotracheal intubation was guided under visual conditions. In the non-visual group, after judging the position of laryngeal mask by clinical experience, endotracheal intubation was inserted blindly. Selection of laryngeal mask airway (LMA) model based on: the ideal body weight of the patient, 3 was selected for the body weight of 30-50kg, 4 for the body weight of 50-70kg and 5 for the body weight > 70kg. The endotracheal tube intubation time, intubation times and intubation success rate of the two groups were recorded.

During the operation, propofol and fentanyl are used for anesthesia maintenance, and the anesthesiologist adjusts the anesthesia depth according to his/her own experience. Ten minutes before the end of the operation, endotracheal intubation was removed and the laryngeal mask airway was retained. The displacement rate of the laryngeal mask airway, the volume of secretion in airway and the incidence of laryngeal spasm were compared between the two groups.

3. Postoperation

After the surgery, the residual muscle relaxation was antagonized, and the laryngeal mask was removed after the patient regained consciousness and reached the extubation criteria. The hemodynamic parameters and the severity of cough during laryngeal mask airway removal were recorded. The incidence and severity of oropharyngeal pain, oropharyngeal numbness, hoarseness, nausea, and vomiting were assessed immediately after the patient woke up and was followed up before leaving the recovery room and on the first day after surgery.

d. Outcomes

1) Compare the intubation time, intubation times and intubation success rate of endotracheal intubation through laryngeal mask airway under visual and non-visual conditions.

2) Compare the displacement rate of laryngeal mask airway after endotracheal intubation removal under visual and non-visual conditions.

3) Compare the incidence of oropharyngeal pain and hoarseness after endotracheal intubation through laryngeal mask airway under visual and non-visual conditions.