STUDY PROTOCOL

Nasal Intubation Using King Vision Video Laryngoscopy

suny2

(NCT03126344)

April 27, 2017

STUDY PROTOCOL

Title: A randomized controlled comparison of non-channeled king vision, McGrath MAC video laryngoscope and Macintosh direct laryngoscope for nasotracheal intubation in patients with predicted difficult intubations.

Background: King Vision and McGrath MAC video laryngoscopes (VLs) are increasingly used. However, it remains unclear whether non-channeled King Vision or McGrath MAC VL, compared with conventional laryngoscope, provide shorter intubation time and a higher first success rate for NTI when used by experienced provider in management of predicted difficult intubation. It is also unclear whether non-channeled King Vision VL is superior to McGrath MAC VL when used for NTI.

Objective: To evaluate the performance of nasotracheal intubation in patients with predicted difficult intubations using non-channeled King Vision VL, McGrath MAC VL or Macintosh laryngoscope by experienced intubators.

Study Design: A single blind, three parallel arms, randomized controlled trial comparing NTIs using non-channeled King Vision VL, McGrath MAC VL and Macintosh DL in adults with predictors of difficult airways.

Subjects: Consecutive patients, between 18 and 60 years old with American Society of Anesthesiologists (ASA) classification of I or II, and requiring NTI for elective oral and maxillofacial surgery, were screened in the Preoperative Evaluation Unit of our institute.

Sample size: Based on the analysis of power analysis software, we take the type I error α as 0.05, the expected effect is 0.8, and the ideal test efficacy level is 0.8, then the minimum sample size of each group is 26. In order to reduce the loss of follow-up error, add 20% on this basis, then each group needs about 30 cases.

Recruitment method: Inpatients

Inclusion criteria: EGRI score 1–7.

Exclusion criteria: EGRI score > 7, history of reflux or diagnosed oesophageal disease, severe obstructive sleep apnea (OSA) and morbid obesity (body mass index > 40 kg/m^2)]

Study Methods:

1. Determine the subjects: select the patients who need nasotracheal intubation for elective operation, and determine 90 subjects strictly according to the inclusion and exclusion criteria, 30 in each group.
2.Group: Patients were randomly assigned to King Vision group, McGrath group or Macintosh group via a computer-generated randomization table: King Vision video laryngoscope group (group K, n = 30), McGrath MAC video laryngoscope group (group M1, n = 30) and Macintosh laryngoscope group (group M2, n = 30).

3.Anesthetic methods: the anesthetic methods of three groups were the same. Patients were asked which nostril was clearer. If both sides were equal and the surgeon had no objection, the right nostril was chosen.

No premedication was administered. Lactated Ringer's solution infusion was started intravenously to deal with the fluid loss from the overnight fast after entering the operating theatre. A standard preparation was then performed, including heart rate (HR), lead II ECG, SpO2 (pulse oximetry), and end expiratory carbon dioxide. A Bispectral (BIS) index sensor was attached to the patient's forehead in conjunction with the BIS Monitor. Cannulation of right radial artery was performed under local anesthesia for invasive blood pressure monitoring.

All patients were preoxygenated by a facemask in the position of neutral. Prior to anesthesia induction, the nasal mucosa was well prepared with 1% tetracaine hydrochloride jelly for 2 min and five drops of ephedrine hydrochloride nitrofurazone (containing approximately 2 mg ephedrine) in all patients. Baseline hemodynamic data were recorded by an investigator after a stabilization period of 10 min.

The nasotracheal tube used was reinforced endotracheal tube (ETT, Safety-Flex with Murphy Eye, oral/nasal, Athlone, Ireland; ID 6.5mm in female and ID 7.0mm in male patients) and was well lubricated with 1 % tetracaine hydrochloride jelly. Dosing of induction medications was given at the discretion of the attending anesthesiologists. Induction agents included midazolam (0.02 mg/kg), propofol (1.5~2 mg/kg) and fentanyl (2 μg/kg). Upon loss of consciousness and jaw relaxation, manual ventilation was tested. If manual ventilation was available, cissatracurium besilate (0.15 mg/kg) was administrated and post induction values were recorded 3 min after induction. Unsuccessful manual ventilation led to study exclusion.

The anesthesiologist tried to intubate when the Train of Four (TOF) count reached zero and BIS value decreased to 50. NTI was performed in a standard manner. First, a preformed ETT was inserted into the nostril and advanced to the posterior nasopharyngeal wall. Second, a laryngoscope blade was introduced into the mouth to expose the glottis. If it's necessary, the BURP maneuver (backward, upward, right-sided pressure) on the thyroid cartilage was attempted to obtain good glottis visibility. And ultimately, the ETT was inserted into the trachea with the aid of Magill's forceps, head flexion, or cuff inflation if necessary.

4. Observation outcome:

(1) Primary outcome: the intubation time

(2) Secondary outcome measures included time to expose the glottis (laryngoscopy time) and the view of glottis opening valued by Cormack-Lehane grade. A Cormack-Lehane grade IV was defined as laryngoscopy failure. A blinded investigator also recorded the hemodynamic changes (MAP, HR) during the procedure of NTI. The maximum values of invasive MAP were recorded. After successful intubation, the subjective sensation of the intubator (ease of device insertion, quality of view on display and ease of tube advancement) was graded as excellent, good, fair and poor. Other intubation parameters included incidences of bleeding or dental injury, number of assist maneuvers (use of BURP maneuver, Magill's forceps, or cuff inflation). Twenty-four hours after the procedure, a nurse anesthetist blinded to group assignment recorded the severity of sore throat and hoarseness.

Statistical analysis

Our sample size estimation was based on previous studies (11,23), in which the standard

deviations (SD) of intubation time were estimated as 8 and 13.7 seconds. To detect a intergroup difference of 10 seconds in intubation time with α of 0.05 and β of 0.8, we estimated that 30 patients would be enough for each group. To compensate for patients dropping out during the study, additional patients (10%) were added. The final sample size of 33 patients was in each group.

Mean (SD) or Median (IQR [range]) was used to describe the parametric data. The number (percentage) was used to describe nonparametric data. Statistical analyses were performed with Prism 5.0 for Windows (GraphPad Software, Inc., La Jolla, California, USA). Binary data for three groups were analyzed using chi-square test and each two groups were compared with chi-square segmentation method or Fisher's exact test as appropriate. One-way analysis of variance (ANOV A) with post-hoc Bonferroni's Multiple Comparison test was used to analyze parameter data for changes within groups. The Kruskal-Wallis ANOV A with post-hoc Dunn's test was used to analyze ordinal data. A p value less than 0.05 was considered as significant.