Statistical Analysis Plan

Comparison of 3 direct laryngoscopes: Inscope DL blade size 3.5 and DL blade 3.5 Sun-Med GreenLine®/D™ to DL blade 3 SunMed GreenLine®/D™ for tracheal intubation in patients undergoing lumbar spine surgery, a prospective randomized study

11/06/2016

NCT02955511

Data Analysis:

The total study size is estimated to be 120 patients. A sample size of 40 patients in each group is determined by power analysis based on:
The primary and secondary hypotheses, namely the mean time required to complete the intubation process, for each of 2 DL groups compared with the control (standard DL) group and with each other (i.e., Group 1 vs. Group 2, Group 1 vs. Group 3, Group 2 vs. Group 3). In a single factor ANOVA study, sample sizes of 40, 40, and 40 are obtained from the 3 groups whose means are to be compared. The total sample of 120 subjects achieves 88% power to detect a difference of at least 10 seconds using the Tukey-Kramer (Pairwise) multiple comparison test at a 0.05 significance level. The common standard deviation within a group is assumed to be 8.60.

The following items will be analyzed:

1. Demographic information (weight, height, BMI, age, gender)
2. Airway evaluation: Mallampati class, mouth opening, presence or absence of teeth, gaps, thyro-mental distance, neck range of motion (Patients will be asked to move their neck in extension, flexion, rotation, and lateral binding)
3. Vital signs (MAP, heart rate, end-tidal CO2 and SpO2) obtained at standardized intervals before, during and after tracheal intubation
4. Type and amount of drugs administered during induction
5. Assessment of the glottic view using the Cormack Lehane and POGO scoring systems at the time of tracheal intubation
6. Times from the passage of the blade between the teeth to obtain glottic view, to placement of the tracheal tube and the appearance of an end-tidal CO2 waveform
7. The number of intubation attempt(s) An intubation attempt was defined as the insertion of the laryngoscope blade in to the mouth of the patient, regardless of whether an attempt was made to insert a tracheal tube
8. The need to change to a different intubating device, and use of adjuvant airway device (eg, LMA, Bougie, fiberoptic bronchoscope, videolaryngoscope)
9. The use of suction and frequency
10. The presence and severity of trauma to the lip, tongue, gum, or teeth during intubation
11. The presence and severity of sore throat, any changes in voice, trauma to the lip, tongue, gum, or teeth in the recovery area

12. Blade Stained with Blood
13. Any complications

Definitions:

Intubation attempt: laryngoscope blade is inserted into the study participant. A failure will be recorded if the assigned laryngoscope is removed from the mouth to re-position twice.

Intubation Time: The time starts when the tip of laryngoscope blade passes the upper incisors and the time stops when the endotracheal tube is placed in the trachea, the cuff in inflate, and positive end-tidal CO2 detected.

Time to visualized vocal cords: The time starts when the tip of the video laryngoscope passes the upper incisors, and the time stops when the provider has clearly visualized the vocal cords.

Ease of intubation: Immediately after the surgery, the performing anesthesiologist will be asked to judge the ease of intubation with each device on a scale from 1 to 4, where 1 = easy insertion without need of adjustment; 2 = need of one adjustment; 3 = two or more adjustments to obtain optimal visualization of the vocal cords, and 4 = impossible visualization and blind intubation or necessary use of an alternative airway device.

The provider will clear secretions as necessary to visualize and report the secretions encountered on a scale from 1 to 10, where 1 = no secretions and no visual obstruction 10=severe visual obstruction, unable to clear without removing device.

Postoperative evaluation: sore throat (0 = none and 10 = maximum discomfort), and whether they have postoperative dysphonia. Furthermore, the incidence of postoperative airway complications will be reported.