Tracheal Intubation with the Rigid Tube for Laryngoscopy

Study Protocol and Statistical Analysis Plan – 05/11/2017

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Inclusion criteria

The study will include adult patients with ASA physical status 1–3, requiring surgery for an ENT pathology and having a presumed difficult airway which will be divided in two groups: anatomically difficult airway group according to The Simplified Airway Risk Index Scale(SARI), with a SARI score ≥ 5, and patients with obstructing airway pathology: oropharyngeal tumors, cervical masses, previous neck surgery or radiotherapy, also with predicted difficult intubation forming group 2.

The two groups are needed because ENT pathology is generating a particular challenge in airway approach which is different from the rest of the pathology and the main goal is to show the efficiency of Rigid Tube for Laryngoscopy (RTL) versus gold standard in intubating patients with various types of airway issues. We decided to include at least ten patients in each group, a reasonable number for testing a new method of airway control. Signed informed consent was obtained from all patients explaining the procedure in simple words and detailing the risks and the safety measures.

Exclusion criteria

Stridor or marked laryngeal or tracheal stenosis, vocal cords polyps, emergency surgery, high aspiration risk, decompensated cardiac and pulmonary disease, very poor dentition and patient refusal were criteria of exclusion from the study. We've also decided to reject from the study patients who exhibit a Cormack-Lehane grade 1 glottis view when conventional laryngoscopy is performed. In case of difficult mask ventilation causing marked desaturation, requiring prompt action to secure the airway, we will take the first chance to secure the airway considering potentially unsafe the use of the experimental RTL. The

investigator underwent a training period before starting the study, consisting in ten direct laryngoscopies with the RTL under an ENT specialist guidance to get used to manoeuvring the RTL and acquire a reasonable level of skill in using it.

A pre-anaesthetic exam was performed with careful assessment of the airway. Patients with features predictive for difficult intubation gathering at least 4 points on the SARI score and with no known airway pathology were included in group 1. Patients from the group 2, with obstructing airway pathology had a perioperative endoscopic examination of the airway with a flexible rhino-laryngoscope which is meant to evaluate the distorted anatomy and exclude glottic or subglottic stenosis which could contraindicate blind intubation over an intubating tube introducer (gum elastic bougie).

Premedication consisted of 1 or 2 mg of Midazolam given intravenously 15 minutes before the intervention, in the preoperative room. Standard hemodynamic and respiratory monitoring were applied: ECG, non-invasive arterial blood pressure, oxygen saturation, respiratory frequency, end-tidal CO2. Difficult airway kit was prepared. The RTL was in position with the light source attached. Patients were pre oxygenated for 5 minutes and induction of anesthesia with propofol- succinylcholine and fentanyl was performed. After 1 minute of mask ventilation, we noted the oxygen saturation on the pulse oximeter, classical laryngoscopy was performed with a McIntosh curved blade laryngoscope, and CormackLehane glottis visualization was registered- possible values: 1,2,3,3.5,4.

The RTL intubation starts with the head in extension and in sniffing position, using a retromolar approach, with teeth protection. The approaching side was chosen based on patient pathology and it could be changed during the procedure if the investigator considered so. We used a 1.2-2.2 cm wide and 15-30 cm long tube depending on patient preoperative assessment and pathology. During advancement of the RTL, the investigator is careful to apply the minimum of pressure so the oro-pharyngeal tissue and dentition should not be injured. The RTL was advanced slowly until it reached the epiglottis, then the

epiglottis was lifted, and the vocal cords visualised. The thyroid cartilage was a land point when advancing the RTL, keeping the RTL on its direction and holding pressure on it and thus adjusting the larynx position so the epiglottis and glottis should be easier to visualise with the RTL. After a proper alignment between the RTL and the glottis was achieved, the bougie was introduced through the RTL into the glottis, the RTL extracted, and the standard cuffed intubating tube with lubricated tip was placed in the trachea gently, over the bougie. Secretions were aspirated through the RTL as needed. If the glottis is visualised during the RTL advancement, it will be withdrawing slowly, and the larynx will be manipulated with the left hand from the thyroid cartilage until the glottis comes into sight. A second attempt will be started advancing slower, heading to the thyroid cartilage while looking for epiglottis. Once epiglottis is lifted the RTL must be directed as anteriorly as possible, returning to the epiglottis and starting new lifting if not successful. We decided to stop the attempt at 120 s or if the patient desaturated to 80%.

We note the Cormack-Lehane glottis visualization at classical laryngoscopy- with values ranging from 1 to 4, the time from classical laryngoscopy until the airway was secured in seconds, the lowest oxygen saturation during the procedure and any other complications occurring during procedure. we document every patient data regarding airway, ENT pathology and difficult airway history. We recorded images to document the challenging cases and prove the efficiency of the RTL. We also took notice of any complications that may have arisen during or after the procedure.

Statistical analysis plan

The statistical part will consist of creating a table with the pre-anaesthetic and demographic variables – mean and standard deviation. The results will be included in a table and graphic image and the data which will be analysed are:

- time for conventional laryngoscopy and for intubation with the RTL- mean and SD
- grade of glottis view as from Cormack-Lehane scale- median and full range

- haemoglobin oxygen saturation during the procedure with the lowest noted as mean and SD

- complications during and after the procedure