VideolaryngoscOpy with McGrath™ vs direct LaryngosCopy for the positioning of A double lumeN endOtracheal tube (VOLCANO study)

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Summary

BACKGROUND

The placement of the double-lumen tube (DLT) can be challenging, as the endobronchial tube is larger (thus worsening the glottic view) and stiffer (increasing the risk of trauma and reducing maneuverability during placement) (1,2). An anatomically easy airway may prove more demanding when double-lumen tube placement is required. The success rate and intubation time can vary significantly (3,4).

The superiority of videolaryngoscopy (VLS) over direct laryngoscopy (DL) is evident regarding the placement of the single-lumen orotracheal tube (SLT) (5,6). Its use is now "recommended" as the first attempt in anticipated difficult airways and "advised" for all routine intubations (7,8).

19 prospective randomized controlled trials have compared the effectiveness of six VLS devices for intubating with DLT compared to DL in patients with anticipated easy airways (9). The main endpoints included glottic view, intubation time, success rate, intubation difficulty rating, incidence of malpositioning, postoperative sore throat, hoarseness, intubation-related complications, and intubation-related stress response. Except for superior glottic view with VLS compared to DL (10,11), consistent results have not emerged across different studies (9,10,11). This heterogeneity may be attributed to differences in operators' experience, type of VLS used, and definition of the primary endpoint. Conducting a randomized controlled study with adequate and larger sample size compared to previous ones and a homogeneous population can ascertain whether VLS can, as in the case of SLT, add value in DLT placement, guiding clinicians towards its routine use.

It is necessary to clarify that current guidelines on DLT intubation do NOT recommend the "1st choice" use of VLS (12), a recommendation that already exists for SLT placement (7,8). For this reason, in clinical practice, both devices are effectively used interchangeably, based primarily on the preferences of the clinician, who also possesses comparable competency in both direct laryngoscopy and videolaryngoscopy.

AIMS

To compare the effectiveness of a single videolaryngoscope, the Mc Grath™, versus direct laryngoscopy in the placement of the double-lumen tube in surgery.

ENDPOINTS

Primary Endpoint

First-attempt intubation success, defined as orotracheal intubation confirmed by sustained capnographic waveform.

Secondary Endpoints

Correct endobronchial positioning of the DLT, assessed by fiberoptic bronchoscopy; need for external laryngeal manipulation (BURP); postoperative pharyngeal pain, hoarseness, evidence of trauma; hemodynamic impact (defined as the need for volume resuscitation/pharmacological support of circulation or tachycardia and/or hypertension during and immediately after the procedure).

EXPERIMENTAL DESIGN AND RANDOMIZATION

Experimental Design

Multicenter, non-profit, randomized controlled trial. The study duration is 24 months from the date of approval by the Ethics Committee.

Randomization

On the day of the intervention, eligible patients will undergo randomization. Randomization will be generated by a computer using a random sequence, stratified by center and based on the anticipation of a difficult airway, with blocks of different sizes in the random sequence. The randomization result will be made available to the operating room anesthesiologist.

Setting

- First Center

  Department of Anesthesia and Intensive Care 1U - Città della Salute e della Scienza (Molinette) – Torino - Director Prof. Luca Brazzi – P.I. Dr. Gerardo Cortese

- Second Center

  Department of Anesthesia and Intensive Care, Policlinico Universitario – Campus Biomedico – Roma – Director Prof. Felice Eugenio Agrò – P.I. Prof. Rita Cataldo

Protocol Amendment

Any variation to this protocol will be reported to the local Institutional Review Board by the principal investigator through submission of a modification request according to local/internal regulations.

Safety Assessment

The study is interventional. Intubation via DL and intubation via VLS are two practices routinely used in the operating room, therefore no additional risks are expected for enrolled patients.

STUDY POPULATION

Inclusion Criteria

All patients aged >18 years who are candidates for one-lung ventilation via double-lumen tube and do not fall into the explicitly stated categories of "Exclusion Criteria."

Exclusion Criteria

- Patients who refuse to consent to participation in the study.
- Patients scheduled for awake intubation due to pre-operative evaluation findings of predictors of difficult oxygenation that contraindicate intubation under general anesthesia.
- Patients with anatomical anomalies leading to tracheal and/or laryngeal displacement/compression.
- Patients with contraindications to double-lumen tube placement.

METHODS

The patient is admitted to the operating room and positioned on the operating table. Standard monitoring used in thoracic surgery operating rooms is applied, including Oxygen Saturation (SaO2 %), Electrocardiogram (ECG), non-invasive Blood Pressure (NIBP), and neuromuscular monitoring (NMT).

All patients are placed in a modest anti-Trendelenburg position (20°), and if obese (BMI > 30 kg/m2), they are positioned in the Ramped position with a wedge cushion.

After preoxygenation with a facial mask (Target = etO2 > 90%), general anesthesia induction is performed with an opioid drug (Fentanyl 0.3 micrograms/kg IBW), hypnotic (Propofol 2 mg/kg IBW or Etomidate 0.2

mg/kg IBW), and, following calibration and baseline assessment of NMT, a neuromuscular blocking agent (Rocuronium 1 mg/kg IBW) is administered.

Upon reaching a Train-of-Four (TOF) value of 0 on the NMT, the procedure proceeds based on the previous randomization: either direct laryngoscopy with a size 3 blade or indirect videolaryngoscopy with the McGrath model and MAC Blade (standard, semi-McIntosh curvature).

Subsequently, intubation with a double-lumen tube (DLT) of size determined by the operator according to the patient's clinical parameters is performed. The laryngoscopy or videolaryngoscopy procedure is carried out according to the usual practice of the operator involved in the intubation.

The operator dedicated to the intubation procedure (consultant doctor/resident doctor) must have a minimum experience of >15 correct placements of double-lumen tubes performed independently with both devices involved in the study.

At the end of the intubation procedure, the endobronchial tube is connected to the anesthesia machine, and mechanical ventilation is initiated (in Volume-Controlled Ventilation (VCV), Pressure-Controlled Ventilation (PCV), or Pressure-Regulated Volume Control (PRVC) mode depending on the operator's preference) with a tidal volume of 6-8 ml/kg IBW.

Correct endotracheal intubation is confirmed by the detection of at least 7 valid and sustained capnographic waveforms.

In case of failure of the first-choice technique, the operator proceeds with subsequent attempts using different devices according to a stepwise strategy: from DL to VLS MAC Blade, from VLS MAC Blade to VLS X3 (Hyper Angulated, H-A).

If multiple intubation attempts fail, the patient is managed according to the department's existing algorithm for unexpected difficult airway management.

The data will be collected according to the attached CRF.

DATA COLLECTION

The following data will be recorded during the procedure (Yes/No, number, drop down menu):

- Success on the first attempt (Y/N)
- If the single attempt ends with tube removal from the oral cavity due to a change in strategy (Reason recorded: satisfactory glottic view but inability to intubate/need for reoxygenation/device change/...)
- If > 1: number of attempts required (number)
- Device change for intubation (transition from DL to VLS, transition from VLS MAC Blade to VLS X3 H-A)
- Change in tube size (increase in size/decrease in size)
- Operator change (Y/N)
- Measurement and side of the double-lumen tube placed (measurements and side 28-41/Right-Left)
- Use of bougies/introducer for intubation (Y/N)
- Use of rescue techniques for reoxygenation (facial mask/laryngeal mask)
- Total intubation time (Number: seconds): from insertion of the laryngoscope blade into the oral cavity (T0) to appearance of the capnographic waveform (T1)
- Glottic view score (Number: Cormack scale)
- Dosage of drugs used (Drop-down menu: drug/mg)
- Hemodynamic parameters at the beginning (T0) and end of the procedure (T1): (NIBP, HR, SaO2%)
- Periprocedural adverse events (desaturation < 90%, bleeding compromising glottic view, gastric material reflux, hypotension/hypertension/brady-tachyarrhythmias requiring fluid/pharmacological correction...)

DATA MANAGEMENT AND STATISTICAL ANALYSIS

Data Management

The data collected for the study, obtained from the anesthesia record, will be recorded using the web application REDCap and stored directly in a centralized database. Data will be collected using specific time definitions:

entry into the study (enrollment), randomization, and measurement of pre-, intra-, and post-procedural parameters to obtain primary and secondary endpoints. Access to the database depends on operator authentication and occurs through an encrypted channel. Only authorized individuals have access to data from their own center.

Sample Size Calculation

The literature reports a highly variable success rate in DLT placement on the first attempt with DL, estimated at around 64% when considering various studies. Based on this observed value, a sample size of 335 patients per arm allows us to achieve 80% power with a 5% alpha error rate in testing a hypothesis of a 10% absolute improvement over the observed value (expected value of 74%).

The total sample size, considering potential consent withdrawals, is estimated to be 738 patients, of which 100 will be enrolled at the Department of Anesthesia and Intensive Care 1U, Città della Salute e della Scienza di Torino – Molinette. As required by the updated CONSORT guidelines, a flow diagram will be developed, including the number of patients assessed, randomized, analyzed, and excluded.

Statistical Analysis

The main statistical analyses will be performed on the intent-to-treat population, which includes all randomized patients.

All data collected during the protocol before randomization will be described using appropriate statistical summaries, such as mean and standard deviation, median and interquartile range, or frequency and proportion depending on the distribution of the variable. Statistics will be presented stratified by treatment arm.

The primary endpoint of intubation success on the first attempt will be compared between the two arms using the chi-square test (or Fisher's test if necessary). Both relative effects measured with risk ratio and their 95% confidence intervals will be evaluated.

Secondary quantitative endpoints (time and scoring) will be compared between the two arms using independent samples t-tests or the Wilcoxon test depending on the distribution type.

A Data Safety Monitoring Board will be established for interim evaluation of the adequacy of the calculated sample size.

OTHER CONSIDERATION

Ethical consideration

The study will be conducted following the principles of the Declaration of Helsinki and national regulations regarding the conduct of clinical trials. Clinical experimentation will be carried out in accordance with Good Clinical Practice standards (D.M. 27 April 1992) and subsequent amendments (D.M. 15 July 1997 and D.L. 211/2003). The study must be approved by each center, following approval from the coordinating center (Città della Salute e della Scienza di Torino - Molinette).

Protocol Amendments

Any modifications to the protocol will be made in the form of amendments. No changes to the protocol are permitted during the study period.

Informed Consent

All patients will be informed about the study procedure on the day of the preoperative anesthesiological assessment. Each patient must sign the written informed consent, as approved by the Local Ethics Committee.

BIBLIOGRAPHY

1. Benumof JL. Difficult tubes and difficult airways. J Cardiothorac Vasc Anesth. 1998 Apr;12(2):131 2.
2. Brodsky JB. Lung separation and the difficult airway. Br J Anaesth. 2009 Dec;103 Suppl 1:i66-75.
3. Brodsky JB, Lemmens HJ. Left double-lumen tubes: clinical experience with 1,170 patients. J Cardiothorac Vasc Anesth. 2003 Jun;17(3):289-98.
4. Langiano N. et al. Airway management in anesthesia for thoracic surgery: a "real life" observational study. J Thorac Dis. 2019 Aug;11(8):3257-3269. doi: 10.21037/jtd.2019.08.57. Erratum in: J Thorac Dis. 2022 Sep;14(9):3651-3652.
5. Prekker ME. et al. DEVICE Investigators and the Pragmatic Critical Care Research Group. Video versus Direct Laryngoscopy for Tracheal Intubation of Critically Ill Adults. N Engl J Med. 2023 Aug 3;389(5):418-429. doi: 10.1056/NEJMoa2301601. Epub 2023 Jun 16. PMID: 37326325. Cochrane
6. Hansel J. et al. Videolaryngoscopy versus direct laryngoscopy for adults undergoing tracheal intubation. Database Syst Rev. 2022 Apr 4;4(4):CD011136. 10.1002/14651858.CD011136.pub3. PMID: 35373840; PMCID: PMC8978307. doi:
7. Law JA. et al. Canadian Airway Focus Group. Canadian Airway Focus Group updated consensus based recommendations for management of the difficult airway: part 1. Difficult airway management encountered in an unconscious patient. Can J Anaesth. 2021 Sep;68(9):1373-1404.
8. Apfelbaum JL. et al. 2022 American Society of Anesthesiologists Practice Guidelines for Management of the Difficult Airway. Anesthesiology. 2022;136(1):31-81.
9. Yao W, Li M, Zhang C, Luo A. Recent Advances in Videolaryngoscopy for One-Lung Ventilation in Thoracic Anesthesia: A Narrative Review. Front Med (Lausanne). 2022 Jun 13;9:822646. doi: 10.3389/fmed.2022.822646. PMID: 35770016; PMCID: PMC9235869.
10. Yoo JY. et al. Comparison of the McGrath videolaryngoscope and the Macintosh laryngoscope for double lumen endobronchial tube intubation in patients with manual in-line stabilization: A randomized controlled trial. Medicine (Baltimore). 2018 Mar;97(10):e0081. doi: 10.1097/MD.0000000000010081. PMID: 29517671; PMCID: PMC5882448.
11. Bakshi SG, Gawri A, Divatia JV. McGrath MAC video laryngoscope versus direct laryngoscopy for the placement of double-lumen tubes: A randomised control trial. Indian J Anaesth. 2019 Jun;63(6):456-461. doi: 10.4103/ija.IJA_48_19. PMID: 31263297; PMCID: PMC6573042.
12. Merli G. et al; SIAARTI Studying Group on Difficult Airway. Recommendations for airway control and difficult airway management in thoracic anesthesia and lung separation procedures. Minerva Anestesiol. 2009 Jan-Feb;75(1-2):59-78; 79-96. English, Italian. Epub 2008 Nov 6. PMID: 18987567.
13. Chrimes N. et al. Preventing unrecognised oesophageal intubation: a consensus guideline from the Project for Universal Management of Airways and international airway societies. Anaesthesia. 2022 Dec;77(12):1395-1415. doi: 10.1111/anae.15817. Epub 2022 Aug 17. PMID: 35977431; PMCID: PMC9804892.