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Anaesthesia protocol evaluation of the videolaryngoscopy with the McGrath MAC and direct laryngoscopy for tracheal intubation in 1000 patients undergoing rapid sequence induction: the randomised multicentre LARA trial study protocol

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ABSTRACT

Introduction Rapid sequence induction of anaesthesia is indicated in patients with an increased risk of pulmonary aspiration. The main objective of the technique is to reduce the critical time period between loss of airway protective reflexes and rapid inflation of the cuff of the endotracheal tube to minimise the chance of aspiration of gastric contents. The COVID-19 pandemic has reinforced the importance of first-pass intubation success to ensure patient and healthcare worker safety. The aim of this study is to compare the first-pass intubation success rate (FPS) using the videolaryngoscopy compared with conventional direct laryngoscopy in surgical patients with a high risk of pulmonary aspiration.

Methods and analysis The LARA trial is a multicentre, patient-blinded, randomised controlled trial. Consecutive patients requiring tracheal intubation are randomly allocated to either the McGrath MAC videolaryngoscope or direct laryngoscopy using the Macintosh laryngoscope. The expected rate of FPS is 92% in the McGrath group and 82% in the Macintosh group. Each group must include a total of 500 patients to achieve 90% power for detecting a difference at the 5% significance level. Successful intubation with the FPS is the primary endpoint. The secondary endpoints are the time to intubation, the number of intubation attempts, the necessity of airway management alternatives, the visualisation of the glottis using the Cormack and Lehane Score and the Percentage Of Glottic Opening Score and definite adverse events.

Ethics and dissemination The project is approved by the local ethics committee of the Medical Association of the Rhineland Palatine state (registration number: 2020–15502) and medical ethics committee of the University of Freiburg (registration number: 21–1303). The results of this study will be made available in form of manuscripts for publication and presentations at national and international meetings.

Trial registration NCT04794764.

Strengths and limitations of this study

- This trial aims to determine whether videolaryngoscopy is superior to direct laryngoscopy in anaesthetised patients with a high risk of pulmonary aspiration and undergoing rapid sequence induction. The criterion for superiority is the first-pass intubation success rate.
- The study plan is to include 1000 adult patients in a multicentre, patient-blinded and randomised controlled superiority study.
- All training levels of anaesthesiologists (trainee, specialist and expert) in the operating room are included.
- Patients with definite predictors of a difficult airway are excluded.
- One type of videolaryngoscope (VL) using a Macintosh-type blade is evaluated. The results cannot be transferred to other kinds of VLs (eg, hyperangulated blade and channelled blade).

INTRODUCTION

Background and rationale

Pulmonary aspiration of gastric contents is a feared complication of anaesthetic procedures. Rapid sequence induction and intubation (RSII) is an anaesthesia technique designed to reduce the time period between loss of airway reflexes and inflation of the tracheal tube cuff in patients with a high risk

of pulmonary aspiration. Because the airway is unprotected during this critical time period, regurgitation and aspiration of gastric contents may occur. The first publication of the RSII components into a structured technique appeared in 1970.[1] The traditional components of this specific anaesthesia technique included oxygen administration, rapid injection of a predetermined dose of thiopental immediately followed by succinylcholine, application of cricoid pressure (CP) and avoidance of positive pressure ventilation.[1] These components are controversially discussed in the anaesthesia literature and several authors surveyed variations on what in UK and Scotland often is practiced as a standard technique.[2–4] In case of a difficult or failed airway, longer or repeated intubation attempts are associated with adverse clinical outcomes like hypoxaemia, regurgitation of gastric contents or cardiac arrest.[5] The National Audit Project 4 illustrated that 47% of anaesthesia-related events are associated with primary airway problems and a failed intubation was the most frequently recorded event.[6] Morris and Cook in a national postal survey reported that a failure to intubate at rapid sequence intubation had been seen by 45% of respondents but harm was uncommon.[3]

For tracheal intubation a direct laryngoscopy (DL) technique using a Macintosh blade is globally the first choice for most anaesthetists. First-pass intubation success rate (FPS) using DL in the operating room varies and ranges from 44% to 96%.[7–15] Multiple international guidelines for airway management emphasise the need to limit the number of intubation attempts to avoid mortality.[16–19] Furthermore, in the context of the current coronavirus pandemic, tracheal intubation is reported to be an aerosol generating procedure and is associated with an increased risk of respiratory transmission to healthcare workers.[20] Based on this potential risk, laryngoscopy should be undertaken with the device most likely to achieve the highest FPS in all circumstances: for most fully trained airway managers, this is likely a videolaryngoscope (VL). Distancing the laryngoscopist's face from aerosolised and expelled droplets may reduce the concentration of aerosols in direct contact with the anaesthesia providers' mucous membranes. Therefore, guidelines and recommendations suggested advantages with the videolaryngoscopy, which may add some distance from the provider to the patient and increase the FPS to offer protection.[21]

Videolaryngoscopy, defined as a laryngoscopic device with a high-resolution digital camera placed at the tip of the blade, allows a wide viewing angle and makes alignment of the oral, pharyngeal and tracheal axes unnecessary. Currently, several different types of VLs are available, each with a diverse blade shape, geometry and user interface, and tracheal tube insertion strategy. VLs are currently categorised and available in different categories: Macintosh-type blades (similar to that of standard direct laryngoscopes), angulated blade with a sharper/hyperangulated curve compared with a Macintosh blade and VL with anatomically shaped blades, including a guide channel allowing to direct the tracheal tube towards the glottis. The advantages of the VL are the possibility to share visualisation of the airway to facilitate teaching, rapid learning curve compared with the conventional DL and minimal head or neck manipulation. Consequently, VL may reduce the number of failed tracheal intubation attempts and should be considered for patients with an unanticipated difficult airway, as a rescue device.[22] In addition, several data exists to imply that the use of VL is associated with a lower complication rate, including soft tissue bleeding, sore throat or dental trauma.[23–25] Systematic reviews and meta-analysis showed that despite an optimised visualisation of the glottis, the use of a VL affects time required for tracheal intubation.[23 26] Compared with DL, the use of VL showed a steeper learning curve.[27] Over the last two decades, several studies have compared different VLs to DL or to each other, focusing on tracheal intubation with the primary endpoint FPS,[7 9 11 13] and time to ventilation[13 23 25 26] in patients undergoing elective surgery in the operating room.[7–15 23 26] Most of these studies had methodological weaknesses, including studies with a small sample size,[7–15 28] retrospective study design,[29 30] performing laryngoscopy by experienced providers[7–9 12–15 28] or performing RSII in emergency departments[28–35] and excluded patients with a risk of pulmonary aspiration.[8 9 12–15] or documented easy tracheal intubation at a prior surgery per previous anaesthetic records.[29] One prospective study in an emergency department shows an improved glottic visualisation, but no differences in FPS between the VL and the DL.[28] Two other studies performed as retrospective analysis suggested advantages of a higher FPS and a less frequent oesophageal intubation rate using a VL compared with the DL.[30 31]

VL with a Macintosh-type blade similar to that of a standard direct laryngoscope allows glottic visualisation either under direct vision or enabling the operator to visualise the glottis indirectly on a video screen. Most of anaesthesiologists are familiar with these techniques and apply VL with a Macintosh-type blade in patients with an initially failed intubation. However, several authors and guidelines recommended the use of VL with a hyperangulated blade to facilitate tracheal intubation in difficult airway management.[12–15 23]

The currently available literature indicates no evidence that the use of VL reduces the number of intubation attempts or that the use of a VL influenced the time required for successful intubation.[23 25 26 28] Despite the optimised visualisation of the glottis, the duration of tracheal intubation can be prolonged, and intubation attempts can fail.[36] Especially in RSII, the time and number of intubation attempts were associated with a worse outcome.[5] The main limitations of VL in RSII are the time to intubation and the potential poor sight in patients with regurgitation of gastric contents. Despite of the advantages of the videolaryngoscopy, DL is the most commonly used device for RSII.[2–4]

We chose to study the McGrath MAC (McG; Medtronic, Dublin, Ireland) VL because it is a portable, relatively

inexpensive device with a Macintosh-type blade similar to that of the Macintosh laryngoscope (DL; Stoss Medica, Wiesbaden, Germany). It, therefore, provides both a direct view of the glottis and an indirect view on the monitor display, which can be beneficial in the case of impossible alignment of the oro–pharyngo–laryngotracheal axes. Our specific choice of the McG was based on the following considerations:

- The Macintosh-based curved blade of the McG is comparable to the conventional Macintosh blade;
- The video display of the McG allows visualisation of the glottis by the operator along with study measurement or teaching by a consultant when tracheal intubation is performed by an inexperienced provider.
- The McG is available with a disposable blade in different sizes and allows a swift change to treat more patients consecutively.

The aim of this study is to evaluate whether the use of the McG improves the FPS for tracheal intubation compared with the DL in elective and urgent surgical patients with an expected normal airway undergoing general anaesthesia induction by RSII.

We hypothesise that tracheal intubation using the McG decreases the frequency of failed intubation and airway complications during RSII.

Study aims and objectives

Primary objective

The primary objective is to compare the initial or first-pass success rate of endotracheal intubation with the McG VL to DL using a Macintosh blade in patients undergoing elective or urgent surgery and requiring RSII.

Secondary objective

The secondary objective is to compare the clinical performance of both devices, glottic visualisation, correlation between clinical experiences in airway management and success rates and airway complications.

METHODS AND ANALYSIS

This manuscript was written in accordance with the Standard Protocol Items: Recommendations for Interventional Trials guidelines (online supplemental figure 1).[37]

Study design and setting

The LARA trial is a multicentre, randomised controlled superiority trial and performed in five hospitals (two tertiary and three general hospitals) in the operating room. All laryngoscopists are anaesthesiologists with different levels of clinical experience using DL and videolaryngoscopy. After a specific introduction to the study protocol, all anaesthesiologists from the study centres participated in this trial.

Eligibility criteria

Inclusion criteria

Patients having elective or urgent surgery under general anaesthesia with a high risk of pulmonary aspiration (indication of the RSII technique) and requiring mechanical ventilation via an endotracheal tube (ETT) are recruited.

Exclusion criteria

Patients are not included in this study if they have one or more of the following:

- Anticipated difficult airway (eg, unanticipated difficult airway in the medical history (eg, Cormack and Lehane (C&L) ≥III) or Airway Difficult Score (ADS)[38] >8 (which is associated with a high probability of difficult tracheal intubation and indication for awake tracheal intubation)).
- Age <18 years.
- Severe life-threatening injury requiring immediate surgical intervention.
- Pregnancy or breast feeding.
- Participation in other studies.
- Unable to provide informed written consent or under guardianship.

Patient population and allocation

Patient inclusion is planned between June 2021 and December 2021. The history and physical examinations of all patients scheduled for surgery are screened preoperatively for predictors of difficult airway. Patient recruitment is conducted by one of the study physicians. After eligibility is confirmed and written informed consent is obtained, enrolled participants are randomised 24 hours before the intervention (elective surgery) or 6–12 hours before in patients requiring urgent surgery. A web-based service (QuickCalcs, GraphPad Software, La Jolla, California, USA) is used for allocating patients to either McG or DL. The schedule of enrolment and intervention is shown in online supplemental figure 1, and the participant timeline is described in table 1.

Sequence generation

Based on the randomisation list, a study nurse in the Clinical Research Unit who is not involved in patient recruitment allocates the patients in the McG or DL group. The software used to collect the data in the paper-based case report form (CRF) automatically allocated the patients, thereby ensuring concealment and anonymity.

Blinding

Blinding to the type of laryngoscopy is only possible for the patient. The performing anaesthesiologist is informed of treatment group prior to induction of anaesthesia.

Intervention

Concomitant treatments in both groups

First, patients admitted requiring elective tracheal intubation are evaluated for predictors of anticipated difficult intubation. The expertise of the participating anaesthesiologists ranges from 'beginner' (residents) to 'expert' (consultants). All anaesthesiologists received hands-on training and theoretical introduction to the use of the McG and DL. Tracheal intubation is performed in both

Table 1 Participant timeline

	Study period				
	Enrolment	Intervention	Intubation		Extubation
Timepoint	$D_{0\ (elective\ surgery)}$	$D_{1\ (elective/\ urgent\ surgery)}$	$D_{1\ (time\ to\ view)}$	$D_{1\ (time\ to\ intubation)}$	$D_{1–2}$
Eligibility assessment	X	X			
Informed consent	X	X			
Randomisation	X	X			
Demographic data and physical examination	X	X			
Preoxygenation		X			
Induction of anaesthesia		X			
TOF measurement		X			
Time measurement		X	X	X	
Glottic view		X	X		
Intubation success		X			
Complications		X	X	X	X

D_0, day of enrolment/allocation; D_1, day of surgery; D_2, hospital room, postoperative care unit or intensive care unit stay; D, day; TOF, train-of-four.

groups following the protocol outlined below (online supplemental figure 1).

A. All patients are monitored for ECG, oxygen saturation (SpO_2) and arterial blood pressure (non-invasive or invasive as appropriate). In the McG group, a malleable stylet in a 'hockey-stick' shape is always used for tube placement. This is in accordance with the clinical standard of the participating centres.[16] Preoxygenation is achieved using the device chosen by the provider based on patient characteristics and clinical standard operating procedure (EtO_2>80%). In the study locations, a Pallas/Primus/Perseus (Dräger Lübeck, Germany) anaesthesia respiratory system is used:
   - Tidal volume breathing with normal breaths for at least 3 min or with 8 deep breaths over 60 s.[39 40]
   - Anaesthesia ventilator in pressure support mode (8 mbar, Positive Endexpiratory Pressure (PEEP): 5 mbar and fractional inspired oxygen: 1.0).[40 41]

B. After sufficient preoxygenation, anaesthesia is induced with sufentanil (0.2–0.5 µg/kg) or fentanil (1–2 mg/kg) and propofol (1–3 mg/kg), and anaesthesia is maintained with either propofol infusion (Total Intravenous Anaesthesia (TIVA)) or volatile anaesthetics. After the patient is deeply anaesthetised, muscle relaxant will be given and the neuromuscular transmission is monitored using acceleromyography of the adductor pollicis. The individual choice of neuromuscular blocking agent depends on the duration of the surgery, need of perioperative neurological monitoring, the absence of allergies and organ dysfunction. The following agents and specific dosages are used:
   - Rocuronium (0.9–1.2 mg/kg).
   - Succinylcholine (1.5–2 mg/kg).

If rocuronium is used, the train of four (TOF) is used for continuous quantitative monitoring of neuromuscular transmission. Complete muscle relaxation is confirmed in the absence of tactile and measured twitches in response to maximal TOF stimulation of the ulnar nerve at the adductor pollicis. The importance of obtaining adequate neuromuscular blockade was emphasised with study personnel.

C. The laryngoscopy attempt begins with a TOF count of 0/4 (for rocuronium) or muscle fasciculation (for succinylcholine) decreases and is performed using the device indicated by default randomisation:
   - Macintosh laryngoscope (DL).
   - McG VL: DL or indirect laryngoscopy can be performed at the discretion of the anaesthesiologist.

The provider selects the method for visualisation of the glottis, either direct or indirect, using the McG monitor. The anaesthesiologist should achieve the best possible view of the laryngeal structures. External laryngeal manipulations (ELM) could be used to improve the view of the glottis to achieve a C&L I or II. The direct entry of the camera under the epiglottis may provide a better view of the glottis than the indirect lifting of the epiglottis by placing the Macintosh blade tip on the vallecula when using the VL. To analyse the incidence of lifting manoeuvres and the associated laryngeal view, we record this technique as a secondary endpoint. The size of the ETT and the size of the blade are dependent on the standard operating procedure of the hospital (blade size in both groups: #3 for average patients and #4 for very tall patients (>190 cm height); standard ETT size: 7.5 ID used for female and male patients). The method of visualisation of the glottis and size of the ETT/blade is recorded in the CRF.

D. The laryngoscopy attempt is defined as successful if the tracheal tube is placed (until the black mark on the ETT was threaded between the vocal cords) with a single blade insertion within 120 s and without manipulation of the laryngoscope by another provider.[26] The 'time to intubation' is defined as the time measured from the opening of the patient's mouth until confirmation of the first wave of CO_2 of the anaesthesia respirator. An anaesthesia nurse measures the intubation time using the built-in timer on the anaesthesia respirator. An interim time is recorded as soon as the vocal cords were seen ('time to view').

An intubation attempt is defined as an introduction of the laryngoscope blade into the oral cavity and its removal regardless of whether an ETT was successfully inserted or not. If this first attempt fails, the provider makes a second laryngoscopy attempt with the same device. Mask ventilation is only recommended between the attempts if SpO_2 decreases (≤90%). A total of two laryngoscopy attempts are allowed. If DL fails after second attempt, the clinician calls for a consultant and changes to a preferred technique (eg, McG, Supraglottic Airway (SGA) and flexible or rigid endoscope) and records the direct and/or screen view of the McG. If McGrath fails after two attempts, the clinician is advised to proceed with a preferred rescue technique (eg, VL with a hyperangulated blade, SGA and flexible or rigid endoscope). The limitation of two intubation attempts and choice of an alternative technique is recommended by the study protocol and is in accordance with the clinical standard.[16–19] If ELM techniques, such as Backward Upwards Rightwards Pressure (BURP) (specific pressure applied to the cricoid cartilage), are required during laryngoscopy, they are recorded in the CRF. In all cases, an additional individual who is not involved in patient care (either a postgraduate student or a study nurse) is present during induction of anaesthesia to record the study parameters.

Outcome measures

Primary outcome measure

The primary outcome measure is the successful tracheal intubation within 120 s (time to ventilation) with the first-pass attempt.

Secondary outcome measure

- Laryngoscopy technique: whether direct or indirect glottic visualisation was used in the McG group is recorded.
- Incidence of loading and lifting of the epiglottis when using the McG.
- Different times for successful tracheal intubation.
- Time to view (defined as the time from insertion of the device until glottic view).
- Time to intubation defined as the time from insertion of the device until the first carbon dioxide wave on the anaesthesia respirator).
- Number of laryngoscopy attempts.
- Failures/crossovers to other rescue techniques (eg, hyperangulated blade).
- ELM (eg, BURP, CP or adjustment of participant's head and neck position).
- Glottic view with the C&L and Percentage Of Glottic Opening Score.
- Intubation Difficulty Score (IDS): 0 (degree of difficulty=easy); >5 (degree of difficulty: moderate to major).[42]
- If McGrath is used, occurrence of fogging is recorded.
- Comparing the level of training with intubation success.
- Complications (eg, desaturation<90% SpO_2, regurgitation, dental or soft tissue trauma).

Subgroup analysis

- Demographics.
- Patient (age, gender, body mass index (BMI) and American Society of Anesthesiologists (ASA) class).
- ADS.[38]
- Provider analysis (clinical experience, education status and experience in direct and indirect laryngoscopy).
- Type of neuromuscular blocking agent.
- Indication for RSII.
- TOF count when inserting the laryngoscope.
- Type of surgery (eg, bariatric surgery).

Data collection and management

The study data are recorded on a specific CRF. Prior to measurement, the data from each patient is collected by study personnel. All outcome measurements are recorded during and after the evaluation on the CRF. Any protocol deviations are recorded either on the CRF or in the medical records; a clinical research assistant ensures that all protocol deviations and adverse events are recorded in the database. If serious adverse events are observed, the ethics committee will be informed in writing.

Every allocated subject will be coded with a specific patient number. After measurement is completed, the study data will be entered into a premade computer-based table (Microsoft Excel V.14.0, Microsoft Corporation, Redmond, Washington, DC, USA).

Access to data

Data safety, data quality and statistical analysis will be managed by the two principal investigators, who are responsible for notifying any issues that may arise during the whole prospective study. Data are collected and stored according to good clinical practice (GCP) guidelines and is available to all participating study sites. Any issue occurring during the clinical trial will be reported to the principal investigators.

Statistics

For statistical analysis, GraphPad Prism (V.9.0 for MAC; GraphPad Software, La Jolla, California, USA) will be used. Data are expressed as the median (IQR) for non-Gaussian variables. The statistical analysis is consistent

with the Consolidated Standards of Reporting Trials statement for non-pharmacological interventions.

Description of the patient groups at baseline

The baseline features of the patients will be described using absolute numbers (n) and percentages for categorical variables and the minimum, maximum, mean, SD and quartiles for quantitative variables.

Analysis of the primary outcome

A χ^2 test will be used to compare the success rate between the two groups. The differences will be considered statistically significant if the p value is less than 0.05. Multiple logistic regression analysis of subgroup factors will allow to assess the factors affecting FPS comparing DL with McG such as age, sex, ASA, BMI, ADS and experience of provider. Kaplan-Meier curves and log-rank test will be used to compare time to intubation between methods. The joint effect of method and further explanatory variables can be assessed using Cox regression.

Analysis of the secondary outcomes

Comparison of the view of the glottis will be analysed by the Wilcoxon's rank sum test. Overall intubation time will be analysed with Kaplan-Meier curves and log-rank test. The effect of further explanatory variables will be explored using logistic regression and Cox regression, respectively.

Subgroup analysis

We will perform a separate analysis by specific type of surgery (eg, bariatric surgery), by use of neuromuscular agents, or patients with difficult intubation, defined as more than two attempts or an IDS score >5.

Sample size

The sample size calculation was based on achieving successful tracheal intubation on the first attempt. In recent trials, the VL showed a first attempt success rate of 97%. We determined the power of the study by assuming a first-pass success rate of 92% (DL)[20 30] and 97% (McG).[43] We chose this study for the sample size calculation because the purpose was to compare VL and DL, including anaesthesia trainees in the operating room. On the basis of the current first-pass success rate, we hypothesised that an increase of 5% by skilled laryngoscopists in the McGrath group compared with the DL group would be a relevant improvement in airway management. We determined that the inclusion of 474 patients per group would show relevant differences. Assuming a drop-out rate of about 5%, 500 patients per group will be included. With 1000 patients, an increase from 92% (DL) to 97% (McG) in the first-pass success rate can be observed with a power of 96% at the 5% significance level.

METHODS: MONITORING

Data monitoring

Prior to the start of patient enrolment, the study physicians and the clinical research assistants were involved in the study protocol and data collection in CRFs. All documents required for the study (eg, informed consent, CRF baseline and perioperative) are available in the operating room, where the study measurement begins. The CRF is prepared and managed by the investigator. Because this is an investigator initiated trial, the principal investigator meets with clinical research assistants to discuss any problems in data collection and protocol compliance and to evaluate study progress. This study is proposed, is managed and will be analysed in accordance with the ICH Guideline for GCP E6 (R2) and following the requirements of German law. All persons (eg, investigator and study assistants) are obliged to follow these rules.

Harms

The study may be temporarily stopped for an individual patient, at the discretion of the attending physician, in case of serious adverse events suspected to be associated with the type of laryngoscope used. An adverse event or suspected adverse reaction is considered 'serious' if, in the view of either the investigator or sponsor, it results in any of the following outcomes: death, a life-threatening adverse event, inpatient hospitalisation or prolongation of existing hospitalisation, and a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions.

Reporting of severe adverse events (SAE) will be per local research ethics committee (REC) standard operating procedures. SAEs will include the following when occurring as a result of airway manipulation (eg, cardiac arrest, acute circulatory failure, death, vocal cord injury and oesophageal rupture). The principal investigator informs the REC about the SAE. No specific reporting procedure for unexpected serious adverse events is planned.

Auditing

The Clinical Research Unit of the Department of Anaesthesiology, University Medical Centre of the Johannes Gutenberg University Mainz, reviews the screening form and clinical data at regular intervals.

Patient and public involvement

No formal patient advisory committee was set up and there was no patient or public involvement in the design and planning of the study.

ETHICS AND DISSEMINATION

Research ethics approval

This study is conducted in adherence with the current version of the Declaration of Helsinki and GCP guidelines. The initial research project was approved by the ethics committee (Medical Association of the State of Rhineland Palatine, Germany) in February 2021 (registration number: 2020–15502). It was also approved by the Medical Ethics Committee of the University of Freiburg (registration number: 21–1303).

Consent or assent

Prior to the trial, patients must consent orally and in writing after the possible consequences of the clinical study are explained in an understandable way. All documents must be written in German and comprehensible. According to German law, only a physician can have the conversation with the participant. The patient receives a copy of the signed patient information and informed consent. A patient may withdraw from the study at any time if he is unwilling to continue in the trial. In this case, the data from a patient who requests full withdrawal will not be considered in the data analysis.

Confidentiality

All original documents will be kept in the Clinical Research Unit for the next 15 years.

The study data will be handled as requested by the German Federal Data Protection Act, which implements the Directive 95/46/EC on data protection (Data Protection Directive). All original records will be kept on file at the trial sites or coordinating data managing centre for 15 years. The cleaned electronic trial database file will be anonymised and kept on file for 15 years.

Declaration of interests

Neither the Department of Anaesthesiology of the University Medical Centre of the Johannes Gutenberg University Mainz, Germany, nor any of its employees received any compensation for this work. No funding or competing interests are declared. None of the authors have financial interests or received honoraria or paid expert testimony. None of the authors have any personal relationships with people or organisations that could inappropriately influence (bias) this work. Medtronic, which produces the McG VL, had no role in the study design and will have no role in its conduct, data collection, analysis or interpretation, or the decision to submit the results for publication. The findings of this study will be presented at conferences and disseminated through publication in a peer-reviewed journal.

DISCUSSION

To the best of our knowledge, the LARA trial is one of the largest randomised, multicentre trials comparing VL to DL in anaesthetised patients undergoing RSII in the operating room. Several studies have suggested that videolaryngoscopy and DL using a Macintosh blade had similar intubation success rates.[11] The weaknesses of the existing research include the study setting (eg, predicted difficult airway or patients in the emergency department)[7–9 11 27–32 44] and study design (eg, inadequate sample size).[8 13] Furthermore, the clinical experience of the user was not usually taken into account.[11 28 36] In this trial, blinding of the operator is not feasible. However, the primary outcome measure is the presence of the inflection on the expired capnography curve to ensure that the ETT is in the tracheal position. The main outcome of other studies was the duration of the intubation attempt.[43] For detailed information about the intubation process, we divide the overall time into two time periods: time from insertion of the device until glottic view and the time from glottic view until the first ventilation. The visualisation of the glottis is another preferred outcome parameter in several airway studies, but a good view of the glottis cannot be associated with successful or faster tracheal intubation.[8–10] Furthermore, the number of attempts constitutes a relevant factor for increased airway complications (eg, risk of aspiration and tissue/mucosal damage) and desaturation during the intubation process.[8 12 22 23 44]

In conclusion, if our main hypothesis is confirmed, videolaryngoscopy might become the reference standard in the operating room for patients undergoing RSII. The expected benefits of this practice may include improved education of airway management and influence of neuromuscular agents for the intubation procedure as well as improved patient safety in terms of decreased airway management associated morbidity (eg, hypoxaemia and aspiration).

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Contributors MK designed the trial and prepared the manuscript. IS was involved with study design and estimated the sample size. MK, IS and AS drafted the manuscript. CJ, WS, JJ and OK contributed conceptualisation of the study design. MS, PL, CL, NP, E-VG, EW and FH are members of the study team that have contributed to specify the study design. All authors have revised the manuscript critically for important intellectual content and approved the final manuscript, and alone are responsible for the content and writing of the paper. None of the authors have financial interests or received honoraria or paid expert testimony, and have any personal relationships with people or organisations that could inappropriately influence (bias) this work.

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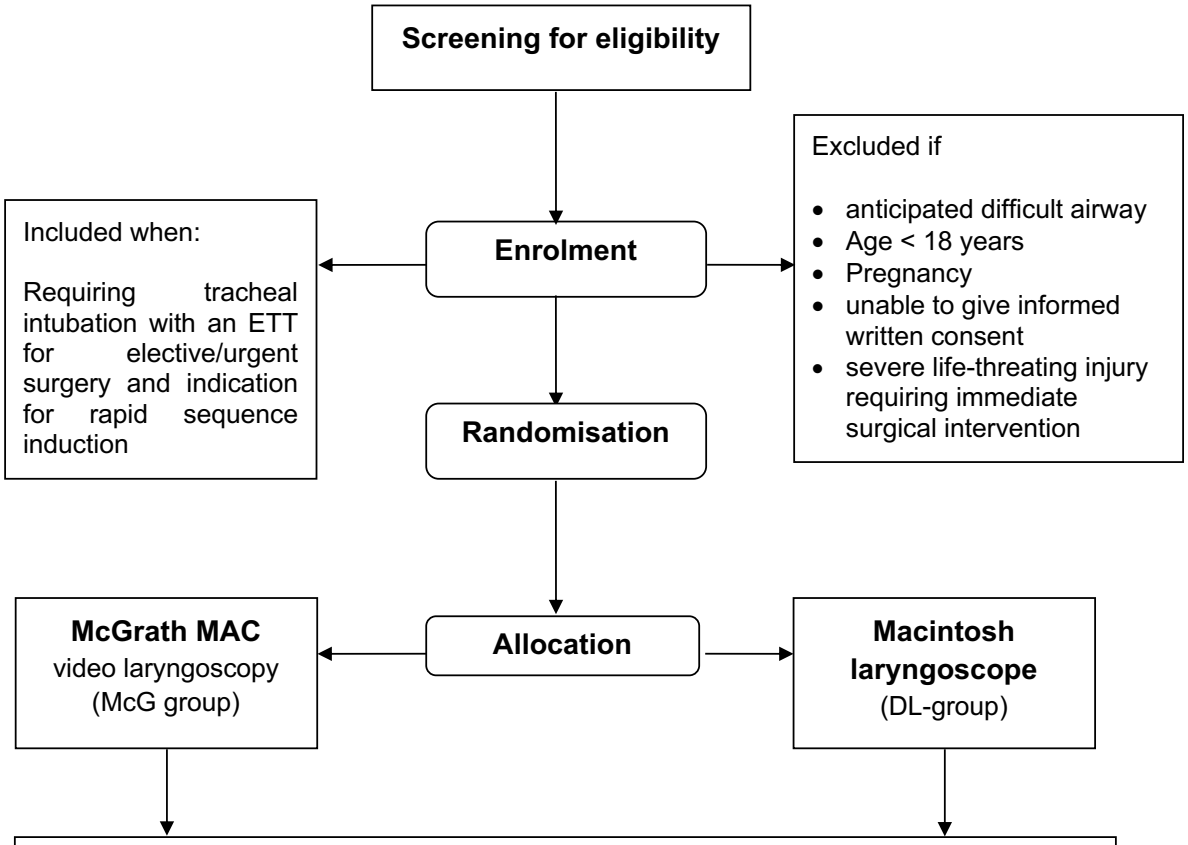
Supplementary Figure 1: CONSORT Diagram - Study flow-chart



Follow-up

Primary outcome measure

The primary outcome measure is the successful intubation with first intubation attempt.

Secondary outcome measure

- Demographic (e.g Age, Gender, BMI, ASA class, Airway difficult score)
- Different times to successful tracheal intubation
  - Time to view (defined from insert the device until glottic view)
  - Total time to successful placement (defined from insert the device until the first carbon dioxide wave on the anaesthesia respirator)
- Number of attempts for laryngoscopy
- Failures/ crossovers to other rescue techniques (e.g. SGA, Hyperangulated blade)
- Glottic view with the C&L grade and POGO score
- Incidence of loading and lifting of the epiglottis when using the McG
- Intubation Difficult Score (IDS)
- If McG are used: direct or indirect laryngoscopy technique and fogging
- Complications (e.g., Desaturation < 90% SpO_2, regurgitation, dental or soft tissue trauma)
- Comparing the level of training with intubation success
- External laryngeal manipulations (e.g., BURP, cricoid pressure)
- Indication for RSII (e.g. Paralysis of the intestine)
- Train-of-four (TOF) count when inserting the laryngoscope