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HELP-VDL: study protocol for a multicentre, open, randomised, controlled clinical trial comparing the use of the head-elevated laryngoscopy position and the use of a videolaryngoscope to facilitate orotracheal intubation in a patient population without predictable difficulty of intubation

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ABSTRACT

Introduction Tracheal intubation remains an everyday challenge for anaesthesiologists, even in patients without suspected difficult airways. The ideal positioning of the patient's head (flat, raised a few centimetres on a cushion in the sniffing position (SP), or raised to achieve horizontal alignment between the external acoustic meatus and the sternal angle) and the use of videolaryngoscopy remain controversial. This trial aims to compare the efficacy for orotracheal intubation of the SP or the head-elevated laryngoscopy position (HELP), which has been shown to improve laryngeal visualization and the intubation condition particularly in obese patients, in combination with a McGrath Mac videolaryngoscope whose video screen is either on or off (Video or NoVideo).

Methods and analysis The HELP-VDL factorial trial is a prospective, randomised, parallel, multicentre, open study of 240 adult patients undergoing tracheal intubation under general anaesthesia. Patients will be allocated into four groups: SP-NoVideo, HELP-NoVideo, SP-Video and HELP-Video. The primary outcome is the proportion of orotracheal intubations that requires the assistance of a nurse anaesthetist. The secondary outcomes include the intubation duration, the first intubation success rate, the quality of visualisation of the glottis, the glottis visualisation score, adjunctive manoeuvres and alternative techniques used, the occurrence of oesophageal intubation, failure of tracheal intubation, the incidence of arterial oxygen desaturation, the perception of a difficult intubation, the score on the Intubation Difficulty Scale, cooperation among the members of the anaesthesia team, the evolution of vital signs and the frequency and severity of intubation complications. Data will be analysed on the intention-to-treat principle and a per-protocol basis.

Ethics and dissemination Ethics approval was obtained from the Ethical Committee Ile de France V (Paris, France). Participant recruitment began on 3 July 2019. The results will be submitted for publication in peer-reviewed journals.

Trial registration number NCT03987009; Pre-results.

Strengths and limitations of this study

- The primary outcome was pragmatically selected to represent the clinical relevance of the difficulty of tracheal intubation.
- The risk of selection and allocation biases will be reduced through the use of computer-generated randomisation and allocation concealment.
- Only patients without predictable difficulty of intubation will be included since the indication for videolaryngoscopy is disputable in this population.
- The head-elevated position is not amenable to the blinding of patients or clinical or research staff; consequently, this is an open study.
- The study uses the McGrath Mac videolaryngoscope, and the results will not be readily extended to all videolaryngoscopes since major differences exist between them.

INTRODUCTION

Airway management remains an important determinant of morbidity and mortality in anaesthesia despite progress in recognising factors that are predictive of difficult mask ventilation and intubation.[1] Many

recommendations have been published regarding the practice of intubation in anaesthesia.[2 3] Our study focuses on two topics that remain under discussion: the position of the patient's head and the use of a videolaryngoscope.

Although the position with the head flat is used by some anaesthesiologists, most place the patient in the sniffing position (SP, a supine torso with the neck flexed forward and the head extended). However, this choice has been questioned since this position does not allow alignment of the three important axes (the mouth, pharynx and larynx) in awake volunteers with normal airways and anatomy as shown by MRI.[4] A more elevated head position with the back tilted at 25° by breaking the operating table at the hips has been proposed, which improves the laryngeal view,[5] facilitates tracheal intubation in surgical patients,[6 7] and decreases airway-related complications in patients undergoing emergent tracheal intubation outside of the operating room.[8] This proposed position led to a position called bed-up-head-elevated, which has been proposed as the standard intubation position for all patients.[9] A similar position with the head and neck raised, the 'head-elevated laryngoscopy position' (HELP), is specified by an anatomical marker—an imaginary horizontal line should connect the patient's sternal notch with the external auditory meatus.[10] The HELP has been proven to be a better position for intubation in obese[11–14] and lean patients.[14] In patients with an expected difficult intubation, positioning the patient in the HELP compared with the SP led to a higher rate of successful endotracheal intubation and an improved laryngeal view.[15] A similar result has been reported when novices perform intubation on a simulator configured to have a difficult airway.[16] However, a systematic review and meta-analysis of randomised clinical trials showed no favourable aspects of the ramped position compared with the SP,[17] while more favourable results have been reported in non-randomised clinical trials.[13 14] This contrast renders the effectiveness of the HELP controversial. The HELP can be achieved with a combination of hospital pillows and/or a stack of blankets[18] or by using a dedicated device such as the Troop Elevation Pillow (Mercury Medical, Clearwater, Florida, USA), Pi's Pillow (American Eagle Medical, Nw York, USA) and the Oxford Head Elevating Laryngoscopy Pillow (Alma Medical, Oxford, UK). The AirPal RAMP mattress was selected in this trial because it has two compartments: the first compartment steers the patient towards the SP, and the second compartment provides the HELP and allows adjustment of the height of the compartments to the patient's morphology.

Videolaryngoscopy represents a major advance in airway management. A recent Cochrane Systematic Review concluded that videolaryngoscopy eased laryngeal views and reduced difficult visualisation and intubation difficulty.[19] However, its role is still debated as a first-line method or a rescue strategy in cases of suspected airway difficulty. Systematic use of videolaryngoscopy entails discarding the standard Macintosh laryngoscope,[20] which has not been supported by clinical studies, especially those of Wallace *et al*[21] and Thion *et al*.[22] We selected the McGrath Mac videolaryngoscope (VDL, Covidien/Medtronic, Minneapolis, Minnesota, USA) for this trial since this apparatus has the advantage of being almost identical to the classic Macintosh laryngoscope, which still remains a reference for many anaesthesiologists. Conversely, this choice implies that the results of our study will not be readily generalisable to all videolaryngoscopes since major differences exist between videolaryngoscopes, such as hyperangulated-blade videolaryngoscopes, videolaryngoscopes with a guide channel, and Macintosh blade-geometry videolaryngoscopes.

The main purpose of this study, which will be carried out under real-world conditions, is to show whether combining the HELP and videolaryngoscopy reduces the need for a nurse anaesthetist to assist the anaesthesiologist in performing tracheal intubation. This main outcome is original since it reflects 'real life' much more than criteria usually used in studies on tracheal intubation, that is, time to intubate or number of attempts, etc., which have little clinical relevance. A few more seconds or two or even three attempts have a very limited clinical impact, and failure to intubate is too rare to be used as the principal criterion of evaluation when the study bears on patients with a 'normal' airway.

METHODS AND ANALYSIS

Trial design

The HELP-VDL trial is an investigator-initiated, multicentre, randomised, parallel-group, open factorial clinical trial with allocation of patients scheduled to undergo orotracheal intubation for general anaesthesia to groups subjected to a combination of two factors: position (sniffing or HELP) and a McGrath Mac videolaryngoscope (with or without using the video screen, with the latter corresponding to direct laryngoscopy). The trial will be conducted at five Parisian private nonprofit tertiary medical centres.

Participant eligibility and consent

Trial site investigators will identify consecutive eligible patients from the listed criteria. Eligible patients will receive written and oral information and will be included after investigators have obtained informed written consent.

Inclusion criteria

Patients with American Society of Anesthesiologists physical status classes of I–III who are 18–89 years old and scheduled for elective surgical procedures that require orotracheal intubation for general anaesthesia will be enrolled in the study.

Non-inclusion criteria

Pregnant or lactating women will be excluded as will patients with anticipated difficult mask ventilation[23] or anticipated difficult intubation (Arné score ≥11),[24]

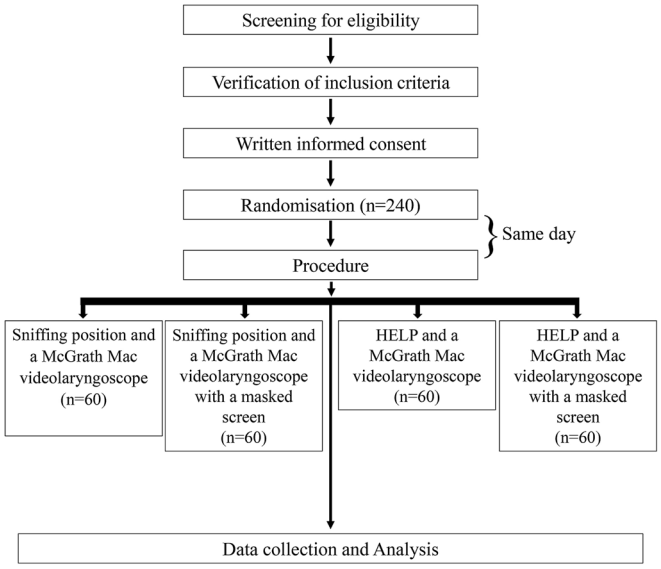

Figure 1 Trial procedures. HELP, head-elevated laryngoscopy position.

patients requiring a rapid sequence induction, patients requiring the use of a double-lumen tube, patients scheduled for a surgical procedure involving the mouth or the upper airway, and patients with a contraindication to one of the drugs required by the protocol.

Allocation

Patients will be randomised into four groups in this factorial trial at a 1:1:1:1 ratio:

- Group A: the SP plus a McGrath Mac videolaryngoscope with its screen deactivated to mimic a plain laryngoscope (SP-NoVideo).
- Group B: the HELP plus a McGrath Mac videolaryngoscope with a deactivated video screen (HELP-NoVideo).
- Group C: the SP plus a McGrath Mac videolaryngoscope with an activated video screen (SP-Video).
- Group D: the HELP plus a McGrath Mac videolaryngoscope with its video screen activated (HELP-Video).

To ensure group comparability, a plan of randomisation will be used. Centralised randomisation using fixed-size blocks will be performed by an independent biostatistician not involved in the trial, from the Research Unit of the Promotor using SAS V.9.4 (SAS France, 77 257 Brie Comte Robert, France). Each patient will be given a unique patient number and a randomisation number (patient code) when the investigator connects to an interactive web response system managed by an independent Contract Research Organisation (Clinfile, 78146 Vélizy-Villacoublay, France) using a protected password just before the induction of anaesthesia.

Blinding

Each procedure is recorded on videotape, with the recording person at the patient's feet. This video will be used to evaluate the primary outcome and some secondary outcomes. Thus, the patient's position, SP or HELP, cannot be blinded to the outcome assessors, unlike the activation or not of the videolaryngoscope screen. Similarly, the patient can remember the position in which he or she was placed. Under these conditions, this is an open study.

Interventions

Figure 1 outlines the trial procedures, and table 1 shows the schedule for enrolment, interventions and assessments.

Preoperative period

Inclusion and non-inclusion criteria will be verified during a pre-anaesthesia visit; the criteria will be confirmed by the anaesthesiologist in charge of the patient at the time of the anaesthesia.

Patients will receive complete, reliable information on the study at the time of the preanaesthetic visit. At this occasion, a written notice of information and a consent form will be handed over to the patient. This form should be completed by the patient (first and last names, signature and date) and the investigator or his/her representative (first and last names, signature, and date) before the beginning of any trial-specific procedure. Two originals will be signed: one for the patient and one for the investigator.

Three persons are required to run the procedure: an anaesthesiologist with a specific training pertaining to the study procedures prior to the beginning of the trial, a nurse anaesthetist who will help the anaesthesiologist in case of difficulty, and an observer at the feet of the patient who will be unable to see whether the screen of the videolaryngoscope is activated and will videotape the preoxygenation and intubation sequence. The recording will be terminated as soon as intubation is completed or when failure to intubate is declared. The patient's authorisation to use the recording will be obtained at the time of consent. In addition, an independent assistant will review all recordings ensuring proper blurring of the patients' face and removal of any spoken indication that could hinder the blindness of the outcome assessor.

Study-specific technical notes have been developed describing how the recordings should be made, downloaded, erased from the recorder, blurred and cleared of spoken indications prior to being transferred for outcome scoring.

Intraoperative period

In all cases, the patient will receive care during the induction and intubation periods from a physician anaesthetist and a nurse anaesthetist as is usual in the hospitals where the protocol takes place. Patients will have standard monitoring in the operating room, that is, heart rate, non-invasive blood pressure, pulse oximetry, capnography, bispectral index and quantitative measurement of neuromuscular block. A peripheral venous line will be established.

Table 1 Schedule for enrolment, interventions and assessments

	Study period				
	Enrolment	Intervention			
Time point	Preoperative visit*	Before anaesthesia	During anaesthesia	After anaesthesia	Completion visit†
Enrolment:					
Eligibility	X				
Informed consent	X				
Demographic characteristics	X				
Allocation		X			
Interventions:					
Sniffing position and McGrath Mac videolaryngoscope			X		
Sniffing position and McGrath Mac videolaryngoscope with a masked screen			X		
HELP and McGrath Mac videolaryngoscope			X		
HELP and McGrath Mac videolaryngoscope with a masked screen			X		
Assessments:					
Proportion of orotracheal intubations for which the assistance of a nurse anaesthetist is required by the operator (primary outcome)			X		
Intubation time			X		
First intubation success rate					
Visualisation of the glottis			X		
Adjunctive manoeuvres and alternative techniques			X		
Oesophageal intubation, failure and complications of tracheal intubation			X		
Arterial oxygen desaturation			X		
Difficulty with intubation (numerical scale and Intubation Difficulty Scale)			X		
Kraus-adapted scale of cooperation			X		
Evolution of vital signs			X		
Hoarseness					X
Sore throat					X
Adverse events			X		X

*Preoperative visits are performed within the 2 weeks before the day of anaesthesia.
†Completion visits are usually performed on the first postoperative day but no later than 3 days after surgery (if surgery was performed on a Friday).
HELP,head-elevated laryngoscopy position.

The proper functioning of the AirPal RAMP mattress (Rapid Airway Management Positioner, AirPal-Patient Transfer Systems, Pennsylvania, USA) will be checked before the patient enters the operating room; then, the AirPal RAMP will be deflated. The patient will be placed in the supine position and then positioned in either the SP or the HELP according to randomisation. The AirPal mattress has two distinct inflatable compartments; when inflated, the lower one corresponds to an 8-cm-high pillow (SP), while the upper one, when inflated, ensures that the patient is in the HELP with the external auditory meatus at the same level as the suprasternal notch.

Following adequate preoxygenation using 100% oxygen via a face mask for at least 3 min to reach an end-tidal oxygen fraction ≥90%, anaesthesia will be induced via an intravenous injection of propofol and sufentanil or remifentanil. Atracurium or rocuronium will be administered for neuromuscular blockade. Bag-mask

ventilation will be continued with 100% oxygen until muscle relaxation is confirmed (no response to a train of four nerve stimulations). The bispectral index should be less than 60; if not, an additional bolus dose of propofol will be administered. The anaesthesiologist will choose either a 3 or a 4 blade size for the McGrath Mac laryngoscope and will generally use a tracheal tube size with an internal diameter of 7 mm (women) or 7.5 mm (men). At any time and whatever the circumstances, the anaesthesiologist may ask the anaesthetist nurse to apply external laryngeal pressure, use a stylet, change the plastic blade or use a metal blade, change the intubation technique (insertion of a laryngeal mask or Fastrach LMA, fibroscopy, trans-tracheal oxygenation and even tracheostomy), activate the screen of the videolaryngoscope, or interrupt anaesthesia.

After tracheal intubation, the upper cushion is deflated, which leaves the patients in the R+ groups in the same position (the head raised 8 cm above the table level) as those in the R– groups. The deflation of the pillow is not video recorded. Anaesthesia is then continued according to the routine procedures of the anaesthesia department.

Postoperative period

The research completion visit will take place no more than 3 days after surgery, if surgery was performed on a Friday, and usually on the first postoperative day. Two questions are asked with four possible answers. To the question 'Are you hoarse?', four responses are possible: no hoarseness; hoarseness noticed only by the patient; hoarseness obvious for the observer; and aphonia.[25] To the question 'Do you have a sore throat?', four responses are possible: no; mild (pain when swallowing); moderate (permanent pain increasing with swallowing) and severe (pain interfering with diet and requiring analgesia).[26]

Outcomes measures

Primary outcome measure

The primary outcome is the proportion of orotracheal intubations for which the assistance of a third party (a nurse anaesthetist) is necessary on request of the operator.

Secondary outcomes measures

Secondary outcomes include the intubation duration (from passage of the incisors to the first capnogram), the first intubation success rate, the quality of visualisation of the glottis (Cormak and Lehane's score modified by Yentis),[27] the percentage of glottic opening,[28] the use of adjunctive manoeuvres and alternative techniques, the occurrence of oesophageal intubation, failure of tracheal intubation, the incidence of arterial oxygen desaturation (<92%), the perception of a difficult intubation (using a numerical scale ranging from 0 for 'no difficulty' to 10 for 'extreme difficulty'), the Intubation Difficulty Scale score,[29] cooperation among the various members of the anaesthesia team (using a scale adapted by Kraus from Ellyson and Dovidio,[30] the evolution of vital signs (heart rate and blood pressure), the frequency and severity of intubation complications (especially lip or dental injury, sore throat and hoarseness as recorded by a blinded observer during the scheduled postoperative visit).

Statistical analysis and sample size calculation

The intention-to-treat approach is considered the primary analysis. However, if more than 10% of the cases are considered to suffer from major protocol violations (eg, failure to comply with the inclusion criteria or shifting a patient from the right randomisation arm to another arm), a secondary per-protocol analysis will be performed on the cases with no or minor protocol violations.

Global scores and subscores for scales will be calculated according to the results of the French validation of these scales. Since the cooperation scale adapted by Kraus has not been validated in France, it will be validated using our study data prior to starting the statistical analysis proper.

For the primary outcome, the comparison between groups will be performed using a X^2 test or the Fisher's exact test depending on the validity. Then, a logistic multivariate regression will be performed as follows: the need for nurse anaesthetist help (primary outcome) will be considered the dependent variable, and position (SP or HELP) and videolaryngoscope (video function on or off) will serve as the independent variables. We will add an interaction term between position and videolaryngoscope in the model to measure the influence of the synergy. As the centre will be a potential cofounding factor, this variable will be tested as an independent variable in the model.

For the secondary outcomes, continuous variables will be compared between groups using a PERMANOVA + (permutational multivariate analysis of variance) procedure. Pseudoanalysis of variance uses a procedure to partition dissimilarity matrices that are calculated using Euclidean distances for continuous variables and simple matching for discrete ones. The PERMANOVA + procedure provides a pseudo F ratio, which is tested using a permutation paradigm. Discrete variables will be compared between groups using the X^2 test or the Fisher's exact test.

Descriptive summaries will be provided for the overall group and for each group. Continuous variables will be presented as the mean±SD or as the median (IQR) according to their normal or non-normal distribution. Categorical variables will be presented as a number (percentage).

All statistical analyses will be performed using the Software SAS V.9.4 (SAS). A two-sided $p<0.05$ will be considered significant.

Missing values

Missing data will not be replaced.

Sample size calculation

Previous observations from our centre showed that the operator had to resort to the help of a nurse anaesthetist in 50% of the cases when intubation was performed without video function. We assume that the need for help could be reduced by 50% when the procedure is

performed using the video function turned on. Thus, to observe a 50% reduction in the main outcome with an alpha risk of 0.05 and a beta risk of 0.8, and an attrition rate below 10%, 60 patients are required per group, resulting in a total of 240 patients.

Data registration

The study data presented in table 1 will be recorded in an electronic database from three sources:

- Direct entry by the staff in an electronic case report form (eCRF) available in the operating room or at the operator's desk.
- Entry by an independent scorer reviewing the videotapes once blurred and edited from cues that could break the blindness of the scorer; a predefined scoring sheet has been developed that will be used as a source document.
- Direct entry in the eCRF of the scores obtained on the postoperative visit.

From the eCRF, the trial database will be established. Data collection will be monitored by trained research coordinators.

Patient withdrawal

A participant who no longer agrees to participate in the clinical trial can withdraw the informed consent at any time without need of further explanation. Participants who will withdraw from the study will be followed up according to routine clinical practice in each participating centre. To conduct the intention-to-treat analyses with as little missing data as possible, the investigator may ask the participant which aspects of the trial from which he/she wishes to withdraw (participation in the remaining follow-up assessments, use of already collected data). Whenever possible, the participant will be asked for permission to obtain data for the primary outcome measure. All randomised patients will be reported, and all data available with consent will be used in the analyses.

Safety

All the investigators are aware of the French regulation rules and know how to record any adverse events regardless of the severity on the eCRF. This study is registered as class 2 Research according to French law. This class corresponds to research with minimal risks and constraints. In this case, in accordance with article L1123-10 of the Public Health Code, the safety of the research participants will be ensured in the same manner as usually ensured in the context of care. Adverse events and incidents occurring in the context of this research will thus be reported according to the usual channels for health vigilance, such as:

- The circuit of material vigilance in connection with the local correspondent of material vigilance of the investigator centre.
- The pharmacovigilance circuit in connection with the Pharmacovigilance Centre on which the investigating centre depends.
- The biovigilance circuit in connection with the local biovigilance correspondent of the investigating centre.

Finally, adverse events will not be reported to the ethical committee according to the law.

Data handling and retention

Data will be handled according to French law. All original records (including consent forms, reports of suspected unexpected serious adverse reactions and relevant correspondences) will be archived at trial sites for 15 years. The clean trial database file will be anonymised and maintained for 15 years.

Patient and public involvement

Patients and public are not involved in any of the phases of this study.

ETHICS AND DISSEMINATION

Ethics

Ethics approval was sought and obtained for the HELP-VDL trial from the Ethical Committee Ile de France V (Paris, France) on 6 November 2018, with the reference number 18.09.11.39700 CAT 2. Written informed consent is required from patients to enter the study.

Participant recruitment began on 3 July 2019. We expect to complete recruitment in 1 year.

Dissemination

The Consolidated Standards of Reporting Trials (CONSORT) to guide protocol and study design will be followed.[31 32] All dissemination will involve aggregate data only and be undertaken using the CONSORT 2010 statement: updated guidelines for reporting parallel-group randomised trials[33] and the template for intervention description and replication checklist.[34]

Publication plan

Scientific presentations and reports corresponding to the study will be written under the responsibility of the coordinating investigator of the study with the agreement of the principal investigators and the methodologist. The coauthors of the report and the publications will be the investigators and clinicians involved, on a pro rata basis of their contribution in the study, as well as the biostatistician and associated researchers. All trial sites will be acknowledged, and all investigators at these sites will appear with their names under 'the HELP-VDL investigators' in an appendix to the final manuscript. Rules on publication will follow international recommendations.[35]

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Contributors MLG, JT and MF contributed to the conception and design of the research protocol. ZC, GD, JO and MLG provided critical input pertaining to the design of the trial interventions and procedures and will make substantial contributions to the acquisition and interpretation of the data. MF wrote the first draft of the protocol and this manuscript. JT designed the statistical analysis plan. All authors (MLG, ZC, GD, JO, JT and MF) critically revised and modified the protocol and the article. They all approved the final version to be published and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work will be appropriately investigated and resolved.

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