

BMJ Open McGRATH MAC videolaryngoscope versus Macintosh laryngoscope for orotracheal intubation in intensive care patients: the randomised multicentre MACMAN trial study protocol

Arthur Bailly,¹ Jean Baptiste Lascarrou,¹ Aurelie Le Thuaut,^{2,3} Julie Boisrame-Helms,^{4,5} Toufik Kamel,⁶ Emmanuelle Mercier,⁷ Jean Damien Ricard,^{8,9} Virginie Lemiale,¹⁰ Benoit Champigneulle,¹¹ Jean Reignier,¹² for the Clinical Research in Intensive Care and Sepsis (CRICS) Group

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For numbered affiliations see end of article.

Correspondence to

Dr Jean Baptiste Lascarrou;
jean-baptiste.lascarrou@chd-
vendee.fr

ABSTRACT

Introduction: Critically ill patients with acute respiratory, neurological or cardiovascular failure requiring invasive mechanical ventilation are at high risk of difficult intubation and have organ dysfunctions associated with complications of intubation and anaesthesia such as hypotension and hypoxaemia. The complication rate increases with the number of intubation attempts. Videolaryngoscopy improves elective endotracheal intubation. McGRATH MAC is the lightest videolaryngoscope and the most similar to the Macintosh laryngoscope. The primary goal of this trial was to determine whether videolaryngoscopy increased the frequency of successful first-pass intubation in critically ill patients, compared to direct view Macintosh laryngoscopy.

Methods and analysis: MACMAN is a multicentre, open-label, randomised controlled superiority trial. Consecutive patients requiring intubation are randomly allocated to either the McGRATH MAC videolaryngoscope or the Macintosh laryngoscope, with stratification by centre and operator experience. The expected frequency of successful first-pass intubation is 65% in the Macintosh group and 80% in the videolaryngoscope group. With α set at 5%, to achieve 90% power for detecting this difference, 185 patients are needed in each group (370 in all). The primary outcome is the proportion of patients with successful first-pass orotracheal intubation, compared between the two groups using a generalised mixed model to take the stratification factors into account.

Ethics and dissemination: The study project has been approved by the appropriate ethics committee (CPP Ouest 2, # 2014-A00674-43). Informed consent is not required, as both laryngoscopy methods are considered standard care in France; information is provided before study inclusion. If videolaryngoscopy proves superior to Macintosh laryngoscopy, its use will become standard practice, thereby decreasing first-pass intubation failure rates and, potentially, the frequency of intubation-related complications.

Strengths and limitations of this study

- Multicentre, open-label, randomised controlled superiority trial.
- Use of successful first-pass intubation as the primary outcome.
- Powered to detect a 15% increase in the first-pass intubation success rate with videolaryngoscopy; therefore, a smaller but possibly clinically important true difference might be missed.

Thus, patient safety should benefit. Further studies would be warranted to determine whether videolaryngoscopy is also beneficial in the emergency room and for prehospital emergency care.

Trial registration number: NCT02413723; Pre-results.

INTRODUCTION

Background and rationale

This manuscript was written in accordance with the SPIRIT guidelines.¹

(A) Endotracheal intubation (ETI) is performed in intensive care units (ICUs) as an emergency procedure in patients with unstable critical illnesses. This setting is associated with an increased frequency of difficult intubation, compared to intubation for surgery (10% to 20% vs 3% to 5%).²⁻⁴ The combined presence in many ICU patients of multiple organ dysfunctions, a small physiological reserve and a high risk of difficult intubation translates into a high frequency of intubation-related complications, ranging from 25% to 40%.^{5 6} The risk of complications increases with the number of intubation attempts.^{7 8}

Several preventive measures are available for minimising the frequency and severity of intubation-related complications. Anaesthetic agents proven effective and safe for rapid sequence intubation (RSI)^{9–11} must be used if not contraindicated. RSI requires the concomitant administration of a fast-acting neuromuscular blocker, that is, succinylcholine or rocuronium, to facilitate the procedure and limit the risk of gastric content aspiration.¹² Also recommended is preoxygenation for 3 min at least, if needed using non-invasive ventilation (NIV).¹³ Finally, fluid resuscitation and vasopressor support must be started early to ensure haemodynamic stability during ETI. When used in combination as part of a standardised protocol, these measures considerably decrease the risk of complications.¹⁴ Many professional societies recommend the use of such a protocol, with training of all staff members and routine capnography before ETI.^{15 16}

The preventive measures described above decrease the risk of complications but fail to increase the frequency of successful first-pass ETI, a major determinant of intubation-related complications. Measures capable of increasing the frequency of successful first-pass ETI are needed. At present, use of a Macintosh laryngoscope with a metal blade is the reference standard for RSI.¹⁷ Over the past few years, however, videolaryngoscopes providing a full indirect view of the glottis have shown promise for facilitating ETI. Several studies compared various commercially available videolaryngoscopes, but most focused on ETI in the operating room for elective surgery. Their results suggest that benefits from videolaryngoscopy may be greatest in those patients at risk of difficult intubation.^{18–21} A 2014 meta-analysis suggested that videolaryngoscopy might be useful in the ICU.²² However, most of the studies had methodological weaknesses such as an observational^{23–25} or before/after^{26 27} design or a randomised design but a small sample size and/or single-centre patient recruitment.^{28 29} Studies performed more recently suggested benefits from videolaryngoscopy but either failed to routinely use neuromuscular blockade,^{8 29} in contradiction of current guidelines, or included patients with highly specific characteristics.³⁰ Furthermore, most studies of videolaryngoscopy were performed in the specific setting of difficult intubation^{31 32} (table 1).

(B) We chose the McGRATH MAC videolaryngoscope as the comparator, because its curved blade resembles that of the Macintosh laryngoscope and provides a direct view of the glottis and an indirect view via the camera, a combination that is helpful in the event of oropharyngeal malalignment. More specifically, our choice of the McGRATH MAC videolaryngoscope was based on three considerations:

- ▶ Intubators with experience using the Macintosh laryngoscope should be able to use the McGRATH MAC videolaryngoscope easily, as the blade curves are similar;
- ▶ The video monitor of the McGRATH MAC videolaryngoscope allows continuous supervision by a senior

Table 1 Recapitulation of previous studies on ETI with videolaryngoscopy in the intensive care unit or emergency department

First author	Device	Operators	Centre	Design	Number of ETI procedures	First-pass success (DL vs VL)	p Value	Comments
Studies showing higher first-pass success rates with VL								
Lakticova	Glidescope	Fellow	Single-centre	Before/after	140	54% vs 79%	0.0001	
Kory	Glidescope	PCCM fellow	Single-centre	Retrospective	138	68% vs 91%	<0.01	
Silverberg	Glidescope	PCCM fellow	Single-centre	Randomised	117	40% vs 74%	<0.01	
Mosier	Glidescope/CMAC	PCCM/CCM fellow	Single-centre	Retrospective	290	60.7% vs 78.6%	0.009	
Vassiliadis	CMAC	Mixed	Single-centre	Retrospective	619	85% vs 81.6%	0.023	
Griesdale	Glidescope	Non-anaesthesiology residents	Single-centre	Randomised	40	95% vs 58%	0.03	
Studies showing similar or higher first-pass success rates with DL								
Michailidou	Glidescope/CMAC	PGY	Single-centre	Prospective observational	709	71% vs 76%	0.17	Trauma centre
Ural	Glidescope	Residents in various fields	Single-centre	Before/after	103	73% vs 76%	0.66	
De Jong	McGRATH MAC	Mixed	Single-centre	Before/after	210	69% vs 79%	0.09	
Noppens	CMAC	Mixed	Single-centre	Before/after	274	79% vs 88%	0.08	
Platts-Mills	Glidescope	Residents	Single-centre	Prospective observational	280	84% vs 81%	0.59	Trauma centre
Yeatts	Glidescope	Residents	Single-centre	Randomised	623	81% vs 80%	0.46	Trauma centre

CCM, critical care medicine; DL, direct laryngoscopy; ETI, endotracheal intubation; PCCM, pulmonary critical care medicine; PGY, post-graduate year physicians; VL, videolaryngoscopy.

intubator when ETI is performed by a junior intubator; and

- ▶ The McGRATH MAC videolaryngoscope is the lightest weight videolaryngoscope available and can be stored in a small prehospital-care ambulance.

The main purpose of this study is to evaluate whether using videolaryngoscopy for ETI decreases the frequencies of ETI failure and complications, by increasing the first-pass ETI success rate via better visualisation of the glottis, for all ETI procedures performed in ICU patients.

Objectives

Primary objective: To determine whether McGRATH MAC videolaryngoscopy improves the frequency of successful first-pass ETI compared to Macintosh laryngoscopy in patients admitted to the ICU and requiring orotracheal intubation.

Secondary objectives: To determine whether McGRATH MAC videolaryngoscopy for ETI decreases mortality and morbidity and to assess the safety of McGRATH MAC videolaryngoscopy.

Trial design

MACMAN is a multicentre, open-label, randomised controlled superiority trial.

METHODS: PARTICIPANTS, INTERVENTIONS AND OUTCOMES

Study setting

The MACMAN trial is taking place in seven ICUs in seven hospitals (five university and two general hospitals) in France.

Eligibility criteria

Inclusion criteria

Patients must be admitted to an ICU and require mechanical ventilation through an endotracheal tube.

Exclusion criteria

Patients are excluded if they meet one or more of the following criteria:

- ▶ Contraindication to orotracheal intubation (eg, unstable spinal lesion);
- ▶ Insufficient time to include and randomise the patient (eg, because of cardiac arrest);
- ▶ Age <18 years;
- ▶ Pregnant or breastfeeding woman;
- ▶ Correctional facility inmate;
- ▶ Patient under guardianship;
- ▶ Patient without health insurance;
- ▶ Refusal of the patient or next of kin to participate in the study;
- ▶ Previous enrolment in a clinical randomised trial with intubation as the primary end point (including previous inclusion in the present trial).

Interventions

Concomitant treatments in both groups

Patients are evaluated for factors known to predict difficult intubation and/or difficult ventilation (body mass index, mouth opening, thyromental distance, Mallampati score, history of snoring, missing teeth, sleep apnoea syndrome).³³ The results of this evaluation are recorded in the electronic case report form (eCRF).

ETI is performed in both groups according to the protocol outlined below (figure 1).

(A) Preoxygenation is achieved using the device chosen by the doctor in charge of the patient:

- ▶ Bag valve mask delivering oxygen at a minimum flow of 15 L/min for at least 3 min.^{34 35}
- ▶ Non-rebreathing (high concentration) mask delivering oxygen at a minimum flow of 15 L/min for at least 3 min.³⁶
- ▶ Ventilator in NIV mode providing 100% FiO₂ for at least 3 min;
- ▶ High-flow nasal oxygen device (eg, Optiflow) delivering oxygen at a minimum flow of 60 L/min, with 100% FiO₂, for at least 3 min.³⁷

(B) Anaesthesia is then induced by injecting a hypnotic agent and a neuromuscular blocking agent. The type and dosage of these drugs are at the discretion of the intubating physician. Nevertheless, in agreement with international³⁸ and French guidelines,³⁹ the following two principles are applied:

- ▶ The preferred neuromuscular blocking agent in the absence of contraindications (eg, hyperkalaemia, burn injury more than 24 h earlier, spinal lesion or allergy) is succinylcholine in a dosage of 1 mg/kg. The alternative is rocuronium 1 mg/kg, provided the antidote sugammadex (16 mg/kg) is available.
- ▶ If possible, the hypnotic agent is either hypnomidate 0.2–0.3 mg/kg or ketamine 1–2 mg/kg.

(C) Laryngoscopy is performed using the device allocated at random:

- ▶ McGRATH MAC videolaryngoscope or
- ▶ Macintosh laryngoscope.

The first attempt with the McGRATH MAC videolaryngoscope is performed using the monitor. The final visualisation method (direct or indirect via the monitor) is recorded in the eCRF. The size of the endotracheal tube and the size of the Macintosh laryngoscope are chosen by the intubating physician.

(D) ETI is then performed. The cuff of the endotracheal tube is inflated and the tube is connected to the ventilator. If this first ETI attempt fails, the physician chooses between repeating the same laryngoscopy technique or switching to an alternative ETI technique. The choice of the alternative ETI technique is at the physician's discretion and in accordance with French guidelines.⁴⁰ Each introduction of the laryngoscope into the oral cavity of the patient is considered a separate laryngoscopy attempt. Use of Sellick's manoeuvre (pressure applied to the cricoid cartilage) during ETI is at the discretion of the intubating physician and is recorded in

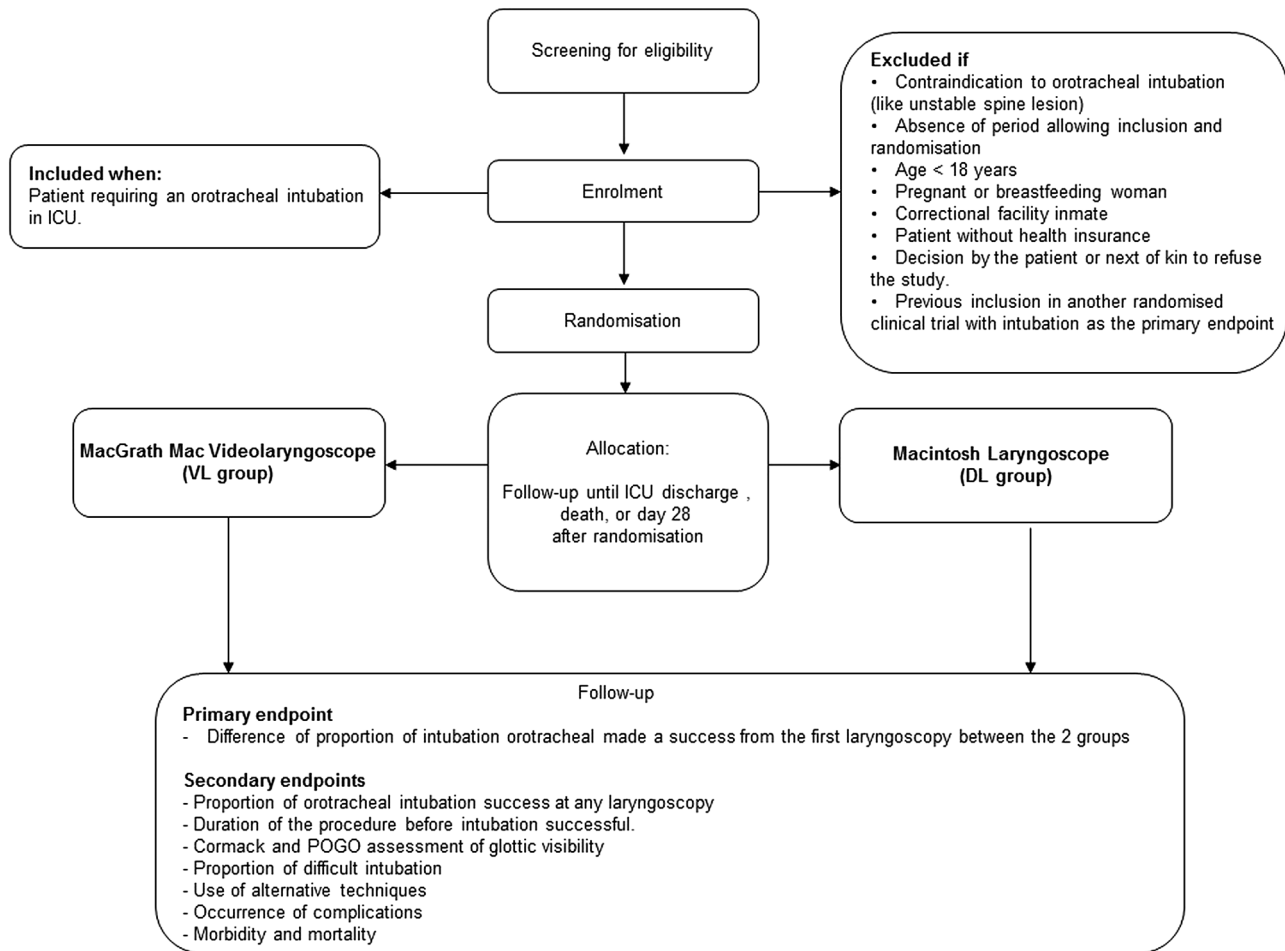


Figure 1 Study flow chart. DL, direct laryngoscopy; ICU, intensive care unit; POGO, percentage of glottic opening; VL, videolaryngoscopy.

the eCRF. The intratracheal tube position is confirmed by analysing the capnography curve over four or more breathing cycles. Total ETI duration is defined as the time from anaesthesia induction initiation to observation of the first inflection on the expired capnography curve (confirming the intratracheal tube position). All items in the eCRF are analysed in real time by a person not involved in patient care. Offline analysis of laryngoscopic intubation is not performed.

All investigators attended a meeting about the trial before inclusion of the first patient. The investigators and coinvestigators received hands-on training in the use of the McGRATH MAC videolaryngoscope and Macintosh laryngoscope.

Outcomes

Primary outcome measure

The primary outcome measure is the proportion of successful first-pass ETIs.

Secondary outcome measures

► Proportion of successful ETIs at any laryngoscopy attempt;

- Total time to successful ETI, defined as the time from anaesthesia induction initiation to confirmation of intratracheal endotracheal tube position based on the partial pressure of end-tidal exhaled carbon dioxide (PetCO₂);
- Cormack-Lehane grade of glottis visibility;
- Percentage of glottic opening scale score;
- Proportion of patients with difficult intubation;
- Proportion of patients intubated using alternative techniques, namely,
 - Gum elastic bougie,
 - Laryngeal mask airway (eg, Fastrach),
 - Videolaryngoscope proven to be helpful in difficult orotracheal intubation (Airtraq or GlideScope),
 - Fibre-optic endoscopy,
 - Rescue percutaneous or surgical transtracheal oxygenation.
- Occurrence of complications:
 - Broken teeth,
 - Aspiration of gastric content,
 - Oesophageal intubation,
 - Severe desaturation (SpO₂<90%),

- Severe hypotension (systolic blood pressure <90 mm Hg),
- Cardiac arrest.
- ▶ Variables reflecting morbidity:
 - Duration of mechanical ventilation,
 - Duration of ICU stay,
 - Duration of hospital stay,
 - ICU mortality,
 - Day-28 mortality.

Participant timeline

The participant timeline is described in [table 2](#).

Sample size

On the basis of previous data,^{26 41 42} we expect first-pass ETI to be successful in 65% of patients in the Macintosh group. Assuming that using McGRATH MAC increases this proportion to 80%, with α set at 5% and β at 10%, 185 patients are needed in each group, that is, 370 patients in all.

Recruitment

Patient inclusion started in June 2015 in seven French ICUs. Enrolment is ongoing. As of 11 August 2015, 111 patients had been included. Recruitment-rate enhancing strategies were deemed unnecessary, an opinion borne out by the higher-than-anticipated recruitment rate so far.

METHODS: ASSIGNMENT OF INTERVENTIONS

Allocation

Randomisation is centralised, web-based and accessible 24 h a day. The randomization scheme is balanced (1:1) and stratified by centre and intubator status, characterised as expert or non-expert. An expert intubator is defined as a doctor who has either worked in ICUs for at least 5 years or has worked in ICUs for at least 1 year after receiving at least 2 years of training in anaesthesia. All intubators who do not meet these criteria are classified as non-experts.⁴³ Details on the intubators will be

recorded in the eCRF, notably resident/junior/fellow/senior status and specialty of residency training if appropriate (anaesthesia; emergency department; other).

Sequence generation

The randomisation sequence was generated by a statistician working at the Clinical Research Unit and not involved in patient recruitment. Randomisation was performed in blocks. The software used to collect the data in the eCRFs automatically allocates the patients, thereby ensuring concealment. In each ICU, the physicians and a clinical research nurse and/or clinical research assistant screen the patients around the clock and include those who are eligible for the study.

Blinding

Blinding of healthcare workers and patients (despite the sedation) to the type of laryngoscopy device is not feasible. However, the primary outcome is assessed on the basis of an objective capnography criterion.

METHODS: DATA COLLECTION, MANAGEMENT AND ANALYSIS

Data collection and management

The study data are recorded in a web-based eCRF. They are extracted from the medical records of each patient (source data) by the ICU staff. The data manager, in cooperation with the coordinating investigator, establishes the trial database by exporting data from the eCRFs. Any protocol deviations are recorded in either the eCRF or the medical records; both are checked by a clinical research assistant to ensure that all protocol deviations and adverse events are in the database.

Statistical methods

Statistical analysis

A predefined statistical analysis plan will be followed, using SAS software V.9.3 (Cary, North Carolina, USA), with the intent-to-treat approach. The statistical analysis will incorporate all the elements required by the

Table 2 Participant timeline

	D0 Inclusion	D0 Preoxygenation	D0 Intubation	D1 to D2	End of ICU stay	D28
Eligibility: check inclusion and exclusion criteria	X					
Informed consent	X					
Demographic data	X					
Randomisation	X					
Patient characteristics	X					
Physical examination	X	X	X	X		
Laboratory tests	X	X	X	X		
Treatments	X	X	X			
Final extubation					X	
Vital status			X	X	X	X

D, day; ICU, intensive care unit.

CONSORT statement for non-pharmacological interventions.

Description of the patient groups at baseline

The baseline features of the overall population and of each group will be described, using n (%) for categorical variables and the minimum, maximum, mean, SD and quartiles for quantitative variables. No statistical test will be performed to compare the two groups at baseline.

Analysis of the primary outcome

The proportion of patients with successful first-pass ETI will be compared between the two groups using a generalised mixed model to take the stratification factors into account. A sensitivity analysis based on the MACOCHA score for predicting difficult intubation³³ will be carried out.

Analysis of secondary outcomes

Secondary outcomes will be analysed using generalised mixed models (linear or logistic depending on the variable type). These models will allow us to take into account the stratification of the randomisation scheme on centre (considered to have random effects) and operator experience (considered to have a fixed effect).

For all statistical tests, p values of 0.05 or less will be taken to indicate a significant difference.

Subgroup analysis

We will perform a separate analysis of patients with difficult intubation, defined as three or more laryngoscopies and/or a total ETI duration longer than 10 min.

METHODS: MONITORING

Data monitoring

Before the start of patient recruitment, all physicians and other healthcare workers in the seven participating ICUs attended formal training sessions on the study protocol and data collection in the eCRF. All documents required for the study are available in each ICU. The eCRF is a secure, interactive, web-response system available at each study centre, provided and managed by the biometrics unit of the Nantes University Hospital (Nantes, France). In each participating ICU, the physicians and a clinical research nurse and/or clinical research assistant are in charge of daily patient screening and inclusion, ensuring compliance with the study protocol and collecting the study data in the eCRFs.

The principal investigators meet with the ICU teams to discuss any problems with data collection and protocol compliance and to evaluate study progress.

According to French law, the eCRF and creation of the database were approved by the appropriate committees (CCTIRS, *Comité Consultatif sur le Traitement de l'Information en matière de Recherche dans le domaine de la Santé*, N 14 779, on 23 December 2014; and CNIL,

Commission Nationale de l'Informatique et des Libertés, N° MMS/VCS/AR1412251, on 16 February 2015).

Harms

The trial may be temporarily stopped for an individual patient, at the discretion of the attending physician, in case of major serious adverse events suspected to be associated with the type of laryngoscope used. According to French law, since the strategies used in both study arms are classified as standard care, no specific reporting procedure for unexpected serious adverse events is planned.

Auditing

The Clinical Research Unit of the La Roche-sur-Yon Hospital reviews the screening forms and clinical data at regular intervals.

ETHICS AND DISSEMINATION

Research ethics approval

The trial is conducted in compliance with the current version of the Declaration of Helsinki and Good Clinical Practice guidelines. The research project was approved by the appropriate Ethics Committee for the Protection of Patients (CPP Ouest 2) in Angers, France, on 18 July 2014 (registration number 2014-A00674-43).

Consent or assent

According to French law, since the strategies used in both study groups are considered components of standard care, there is no requirement for *consent*. Nevertheless, *information* of the patient or next of kin is required. The patient or next of kin confirms in writing that he/she has received this information. If no next of kin can be contacted during the screening for the study, trial inclusion is conducted as an emergency procedure by the ICU physician, in compliance with French law. Patients who regain consciousness are informed about the trial as soon as possible.

A patient may leave the trial at any time if the person informed about the study (patient or next of kin) is unwilling to continue in the trial. Data from patients who request full withdrawal will not be taken into account in the analysis.

Confidentiality

The study data will be handled as requested by the French Data Protection Authority (CNIL, *Commission Nationale de l'Informatique et des Libertés*). 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

None of the authors has any financial or other competing interests in relation to this study.

Aircraft Medical Limited, which produces the McGRATH MAC videolaryngoscope, had no role in the design of this study and will have no role in its conduct; data collection, analysis or interpretation; or decision to submit the results for publication.

DISCUSSION

To the best of our knowledge, the MACMAN trial is the first randomised multicentre study of videolaryngoscopy for ETI in ICU patients. Previous studies of this strategy had several weaknesses, including the use of a before-after design²⁶ or patient recruitment at a single centre.^{28–30} Moreover, most of these studies had no formal ETI protocol designed to limit bias due to variations in anaesthesia induction and/or preoxygenation.²⁴ Also, operator experience was not usually taken into account.

The MACMAN trial has an open-label design, as blinding to the type of laryngoscope used is not feasible. However, the main outcome measure is objective: it is the presence of an inflection on the expired capnography curve, indicating that the tube is in the trachea. ETI duration was the primary outcome measure in many studies. However, ETI duration measurement may lack reliability, as the start and end may be challenging to pinpoint. Other studies used the glottis view quality. However, obtaining a good view does not necessarily translate into successful ETI, and scoring of the view of the glottis is somewhat subjective. In addition, given the low frequency of serious complications, detecting a statistically significant difference in this variable would have required a very large sample size. Moreover, several studies showed a strong correlation between the frequency of complications and the number of laryngoscopy attempts.⁷ A larger number of attempts translates into a longer duration of ETI and therefore into a higher risk of aspiration and a greater degree of laryngeal oedema, which decreases the effectiveness of face-mask ventilation and increases the risk of desaturation during ETI.

In conclusion, if the main hypothesis is confirmed, videolaryngoscopy will become the reference standard for ETI in ICU patients. Expected benefits of this practice are improved patient safety, via decreases in ETI duration and in the frequency of serious complications (episodes of profound hypoxaemia and cardiac arrest). Videolaryngoscopy would also deserve consideration for use outside the ICU, in settings where emergent ETI is often required (emergency rooms and prehospital emergency-care units) and is a source of substantial morbidity.

Author affiliations

¹Medical-Surgical Intensive Care Unit, District Hospital Centre, La Roche-sur-Yon, France

²Clinical Research Unit, District Hospital Centre, La Roche-sur-Yon, France

³Delegation a la Recherche Clinique et a l'Innovation-CHU Hotel Dieu, Nantes, France

⁴Service de Réanimation Médicale, Nouvel Hôpital Civil, Hôpitaux Universitaires de Strasbourg, Strasbourg, France

⁵EA 7293, Fédération de Médecine Translationnelle de Strasbourg (FMTS), Faculté de médecine, Université de Strasbourg, Strasbourg, France

⁶Medical Intensive Care Unit, Regional Hospital Centre, Orleans, France

⁷Medical Intensive Care Unit, University Hospital Centre, Tours, France

⁸AP-HP, Service de Réanimation Médico-Chirurgicale, Hôpital Louis Mourier, Colombes, France

⁹Univ Paris Diderot, IAME 1137, Paris, France

¹⁰Medical Intensive Care Unit, Saint Louis University Hospital Centre, Paris, France

¹¹Medical Intensive Care Unit, Cochin University Hospital Centre, Paris, France

¹²Medical Intensive Care Unit, Nantes university Hospital Center, Nantes, France

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Contributors AB prepared the first draft of the manuscript. AB, JBL and JR wrote the manuscript. JBL and JR participated in designing the MACMAN study. ALT wrote the statistical analysis plan and estimated the sample size. JBL obtained funding for the study. All authors contributed to the acquisition of the study data. All authors revised the manuscript for important intellectual content and read and approved the final version of the manuscript.

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Competing interests None declared.

Patient consent Obtained.

Ethics approval CPP Ouest 2.

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement The steering committee will be happy to share data from this trial with researchers after analysis of requests.

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