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Influence of videolaryngoscopy using McGrath Mac™ on the need for a helper to perform intubation during general anaesthesia:

A multicentre randomised Video - No-Video trial

Running Title: Randomised Videolaryngoscopy trial for patients with normal airways

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Abstract

Objective: We hypothesized was that use of a videolaryngoscope modifies the practice of tracheal intubation.

Design: Randomized single-blinded study.

Setting: Three institutions: one academic, one non-profit and one profit.

Participants: Inclusion criteria were patients aged 18 years minimum, requiring orotracheal intubation, without a predicted difficult intubation (Arne score <11). Non-inclusion criteria was patients requiring a rapid-sequence intubation. 300 patients were included, 271 randomised, 256 analysed: 123 in the No-Video group and 133 in the Video group.

Intervention: Tracheal intubation uses a McGrath Mac™ videolaryngoscope. Patients were randomised into two groups: a Video group (screen activated) and a No-Video group (screen hidden).

Primary and secondary outcome measures: The main outcome was the need for help for the anaesthesiologist or the nurse anaesthetist in performing tracheal intubation, the sequence being video recorded. Secondary outcomes included the ease of intubation (intubation difficulty scale, Cormack and Lehane grade, percentage of glottic opening scale score, use of alternative techniques, duration, oxygen desaturation, especially). Other outcomes included the cooperation between members of the anaesthesiology team, the proportion of patients suffering from postoperative hoarseness or sore throat, and other adverse events.

Results:. Requirement for assistance was not decreased in the Video group: 36.1% [95% CI 27.9 to 44.9] versus 45.5% [95% 36.5 to 54.7] in the No-Video group (p=0.124). Intubation difficulty scale was lower in the Video group (p=0.009); glottis visualization (Cormack and Lehane score and glottic opening score) was better in the Video group (p<0.001). Duration of intubation was similar between groups. Oxygen desaturation or hypotension requiring treatment during the intubation period and postoperative complications (hoarseness or sore throat) were observed similarly in both groups. No other adverse event occurred.

Conclusion: In patients without risk of difficulty in airway management, videolaryngoscopy did not decrease the requirement for assistance to perform intubation.

Trial registration: Clinicaltrials.gov identifier: NCT02926144

Strengths and limitations of this study

- This study aimed to assess if the use of a videolaryngoscope modifies the practice of tracheal intubation in real life conditions.
- A major strength of this study performed on patients without a predicted difficult intubation was the choice of the main outcome: the need for help for the anaesthesiologist or the nurse anaesthetist in performing tracheal intubation.
- Permanent presence of a two-person team may have induced a bias because it facilitates the practice of an alternative technique.
- Another weakness comes from the choice of the McGrath MAC videolaryngoscope and, consequently, results cannot be generalized to other videolaryngoscopes which differ by the shape of the blade, and the existence or not of a channel.

Introduction

Airway management remains a major concern for anaesthesiologists while related morbimortality is determinant for anaesthesia.[1-3] Securing the patient's airway is a critical step in providing general anaesthesia and several recommendations have been published regarding the practice of intubation in anaesthesia.[4, 5] Direct laryngoscopy using the original Macintosh laryngoscope has been the rule for the past half century; however a wide range of videolaryngoscopes has been developed in recent years to provide an indirect visualization of the glottis via a camera. In patients with a suspected difficult airway, there is no doubt that videolaryngoscopy is associated with a significantly better view of the glottis, increases the first-attempt success and reduces mucosal trauma.[6]

In patients with no predicted difficult airway, no difference in failed intubation has been reported when comparing a videolaryngoscope and Macintosh laryngoscope.[7] Nevertheless some authors consider that the use of videolaryngoscopes is obvious for all patients, even for those in whom preoperative assessment has not found evidence of a particular risk of access to the airways.[8-10]

In their analysis of the literature, Lewis *et al.*[7] emphasize the importance of the choice of the evaluation criteria used to compare the techniques: glottic view, time required for intubation, successful intubation particularly at the first-attempt, risks of complications like hypoxia or other respiratory complications, laryngeal or airway traumas, and sore throat in the post-anaesthesia care unit. Another question that needs to be asked when a new technology is proposed is: does this technology change the practice?

This randomised multicentre study realized in real-life conditions, presence of an anaesthesiologist and of a nurse anaesthetist during the induction-intubation period, compared two scenarios, both using the same videolaryngoscope, one using the video function and the other not, for orotracheal intubation of surgical patients without particular risk of access to the airways. The hypothesis was that the use of the videolaryngoscope modifies the practice of tracheal intubation, the main outcome being the need for help for the anaesthesiologist or the nurse anaesthetist in performing tracheal intubation.

Methods

Study Design, Ethics approval and Setting

The McGrath Mac Videolaryngoscope versus McGrath Mac No-Video Laryngoscope for Orotracheal Intubation in Operating Room (Video - No-Video study) trial was an institutionally sponsored, single-blinded, multicentre, two parallel-groups randomised clinical trial (RCT) conducted at three Health Institutions in France (one academic, one non-profit and one profit). After approval by the Ethics Committee (Comité de Protection des Personnes Ile de France VIII, Boulogne Billancourt, France, n°160108, 19 February 2016, Chairman Bertrand MUSSETTA) and by the French Regulatory Office, and after registration on the web site ClinicalTrials.gov (NCT02926144, first Posted on October 6, 2016), patients were enrolled in the study after they gave their written informed consent including videorecording and blurring of patients faces if necessary.

Patient and public were not involved in the design, or conduct, or reporting, or dissemination plans of the research.

Patient population

Inclusion criteria were patients aged 18 years minimum, requiring general anaesthesia and orotracheal intubation with a single lumen tube, without a predicted difficult intubation (Arne score <11).[11]

Non-inclusion criteria were currently pregnant or breastfeeding woman, out-patients who could not be contacted within 24 hours following surgery, patients requiring a rapid-sequence intubation, and patients for whom general anaesthesia using sufentanil, propofol, atracurium or rocuronium was not suitable.

Inclusion and exclusion criteria were assessed by an investigator who could be different from the one who was to perform the intubation. Once in the operating room, inclusion criteria were confirmed by the anaesthesiologist in charge and randomisation was managed online.

Randomisation, Allocation Concealment

Centralized randomisation using fixed-size blocks had been performed by an independent biostatistician not involved in the trial. The randomisation scheme was balanced 1:1 and stratified by centre. Each patient received a unique patient number and a randomisation number (patient code) when the investigator connected to an Interactive Web Response System managed by an independent Contract Research Organization (Epiconcept Company, 75012, Paris, France) using a protected password just before the induction of anaesthesia. Thus, patients were randomised into two groups: a Video group, in which intubation is performed using a McGrath Mac videolaryngoscope with its screen activated, and a No-Video group, in which intubation is performed using a McGrath Mac videolaryngoscope with its screen hidden. The software used to allocate the patients to their group also was in-live fulfilled to collect data by the investigator in an electronic report form, ensuring concealment.

Study Protocol

Patients received care during the induction and intubation periods from an anaesthesiologist and a nurse anaesthetist as is usual in the hospitals where the protocol takes place. All anaesthesiologists and nurse anaesthetists working at the participating hospitals were experienced in orotracheal intubations using the McGrath Mac or had performed at least ten intubations with the device for training. They received a specific training pertaining to the study procedures prior to the beginning of the trial including the fact that they must rely on the video screen in the Video group and use the direct view in the No-Video group.

Upon arrival in the operating room, a dedicated peripheral intravenous cannula for the administration of IV anaesthetics was placed on the forearm, and routine monitoring was performed including bispectral index monitoring and quantitative measurement of neuromuscular block at the adductor

pollicis. Patients were positioned in dorsal decubitus with the head on a 7cm high pillow. Preoxygenation was achieved using a face mask, and oxygen at a flow of 15 L/min or greater for at least 3 minutes to achieve an end-tidal oxygen fraction of at least 90%.

General anaesthesia was then induced by injecting sufentanil, propofol and a neuromuscular blocking agent (atracurium or rocuronium) once the patient was unconsciousness. Laryngoscopy was performed by the anaesthesiologist or the nurse anaesthetist using the device allocated at random when bispectral index was under 60 and when there was no more muscle response to the train of four stimulation.

Intubation was performed using the video screen of the device in the McGrath Mac Videolaryngoscope group (Video group) while the video screen was hidden with an opaque cover in the McGrath Mac No-Video Laryngoscope group (No-Video group). Endotracheal tube size was 7 for women and 7.5 for men with blades size 3 or 4 according the practitioner's preference.

Asking for help from the other member of the anaesthetic team was at the discretion of the individual performing intubation if he/she deemed it necessary to perform an atraumatic intubation. Complementary techniques consisted in (a) backward, upward and rightward pressure (BURP) manoeuvre; (b) rail-roading the tube over a gum elastic bougie; (c) removing the opaque cover on the video screen in the No-Video group or change in the operator. If all these techniques failed, other manoeuvres could be used: (a) insertion of a stylet into the tube; (b) changing the blade; (c) removal of the pillow. Rescue techniques (insertion of an Intubating Laryngeal Mask Airway, transtracheal oxygenation, fiberoptic intubation, awakening) were considered if necessary according to the national recommendations.[12]

After intubation, the cuff was inflated, the tube was connected to the ventilator, and intratracheal tube position was confirmed by analysing the capnography curve.

Anaesthesia was conducted according to good practices.

Patients were reviewed the following day. Sore throat and hoarseness were evaluated, and adverse events collected by investigators not knowing the group to which the patient has been assigned.

Data collection

All cases were video recorded by a person not involved in the study which followed a mandatory script. This person, placed at the feet of the patient, was unable to see whether the screen of the videolaryngoscope was activated. Video recording began with preoxygenation and ended with the capnographic confirmation of successful tracheal intubation.

The framing of the videos was done in such a way that the patient's anonymity was respected. Otherwise, the patient's face was blurred before analysis.

Analysis of each video was performed by two anaesthesiologists blinded to the study group since the screen, transparent or opaque, of the videolaryngoscope was not apparent. The videos were reviewed by both anaesthesiologists in case of discordance.

All the variables used for the study were retrieved from the video apart from the glottis exposure which was recorded in real time by the person who performed the intubation using the Cormack and Lehane modified score and the percentage of glottis opening scale (POGO) score.[13, 14]

Primary and secondary outcomes

The primary outcome was the proportion of orotracheal intubations where assistance is necessary upon request of the operator.

Secondary outcomes included during the intubation period (1) the intubation difficulty scale,[15] (2) the Cormack and Lehane grade of glottis visibility, (3) the percentage of glottic opening scale score (POGO) score,[14] (4) the proportion of patients intubated using alternative techniques: (backward, upward and rightward pressure (BURP), rail-roading the tube over a gum elastic bougie, insertion of a stylet in the tube, laryngeal mask airway, fiberoptic endoscopy, or rescue percutaneous or surgical transtracheal oxygenation …), anaesthesia discontinuation, (5) the time from introduction of the McGrath videolaryngoscope in the mouth to the confirmation of tracheal tube position based on partial pressure of end-tidal exhaled carbon dioxide (third capnogram), (6) the proportion of patients having

had an oesophageal intubation, (7), the ease of intubation evaluated by the anaesthesiologist using a 11-level numeric scale from 0 (very easy) to 10 (very difficult), (8) the requirement of an abnormal traction force to intubate, (9) the heart rate and mean arterial pressure measured just before and after intubation, (10) complications such as oxygen desaturation (peripheral oxygen saturation < 92%) or hypotension having required treatment. The cooperation between members of the anaesthesiology team during intubation was graded using a 4-point scale (0=no cooperation at all, 3=a great deal of cooperation).[16]

The postoperative secondary outcomes included the proportion of patient suffering from hoarseness[17] or sore throat[18] on postoperative day 1. Other adverse events will be also collected.

Sample Size calculation

Adnet *et al.* published in 2001 a survey of tracheal intubation difficulty among 1171 surgical patients and found that the Intubation Difficulty Scale was > 0 in 522 cases (45%) and that external laryngeal pressure, requiring an assistant to help, was used in 271 of these cases (23% of all patients).[19] Based on this previous data, the expected rate of the assistance of another person for intubation was 25 % for patients in the No-Video group. Presuming that the video function would decrease this proportion to 12.5 %, with type 1 error set at 5 % and power set at 80 %, 131 patients were needed in each group (i.e., 262 patients total). It is was planned to recruit 300 patients to mitigate an attrition of the sample or the absence of values.

Statistical Analyses

Results are presented as number (proportion) [Confidence Interval 95 of the percentage] for categorical variables and compared by the Chi-square test when the number of observations was greater than five, and by the exact Fischer test when one of the numbers was less than five. For continuous variables, results are presented as median (Interquartile Range) [Confidence Interval 95 of

the median] and compared by a Wilcoxon test, after verification of the normality with a Shapiro-Wilk test. All tests were two-sided.

P values of less than 0.05 were considered significant. The statistics were generated using SAS 9.4 software.

Dataset is available from the Dryad repository (DOI: 10.5061/dryad.280gb5mp6).

Results

Patients were recruited between the 29th November 2016 and the 1st April 2019. Of 300 included patients, 271 were randomised and 256 analysed with 123 patients in the No-Video group and 133 in the Video group (**Figure 1**).

Baseline features were well balanced between groups (**Table 1**).

The requirement for assistance was not statistically significantly decreased in the Video group: 36.1% versus 45.5% in the No-Video group (p=0.124). The difference between groups was also similar when considering each centre separately; p=0.22 for centre 1, p=0.41 for centre 2, and p=0.62 for centre 3.

The Intubation Difficulty Scale was lower in the Video group (p=0.009) (**Table 2**).

Glottis visualization was significantly better in the Video group with a lower Cormack and Lehane score (p<0.001), and higher percentage of glottic opening score (p<0.001). There was no difference between groups considering other outcomes, in particular for duration of intubation, number of attempts, use of complementary techniques (BURP and railroading), except for ease of intubation, better in the Video group (p=0.001), and for requirement of an abnormal traction force, lower in the Video group (p=0.007) (**Table 2**). The opaque cover was withdrawn in 7.3% of the cases in the No-Video group.

Bispectral index increased after intubation only in the Video group (p=0.04). Heart rate and mean arterial pressure increased in both groups after intubation with a smaller increase in mean arterial pressure in the Video group (p=0.04) (**Table 3**).

Communication and behaviour within the anaesthesia team was appropriate in all cases (values of 3).

Oxygen desaturation, hypotension or hypertension requiring treatment during the intubation period and postoperative complications (hoarseness or sore throat) were observed similarly in both groups (**Table 4**).

No other adverse event occurred.

Discussion

In this Video-No Video trial performed in surgical patients without particular risk of difficulty in airway management, videolaryngoscopy did not decrease the requirement for assistance to perform intubation.

This result corroborates studies which consider that the use of a videolaryngoscope is of little interest in the management of such patients. Advantages of videolaryngoscopy seem to be secondary, especially better glottic visualization[7] which does not translate directly into a higher success rate on the first attempt.[7, 20]

There is no universal rule regarding anaesthetic staffing neither for qualifications, anaesthesiologists, or registered nurse anaesthetists nor for the required number during the whole procedure or during the induction-intubation sequence. In our study, patients received care during the induction and intubation periods from an anaesthesiologist and a nurse anaesthetist as is usual in the hospitals where the protocol takes place. This probably explains the high percentage of recourse to a second person since he or she is available without delay. Such incidence is not reported per se in studies contrary to the use of alternative techniques. Except for cases where tracheal intubation is easy, help is needed to perform a BURP manoeuvre or give a gum elastic bougie or a stylet for example.

Interestingly, Jones *et al.* studied the impact of the use the C-MAC® videolaryngoscope (Karl Storz Endoscopy, Slough, Berkshire, UK) on nurse anaesthetist working practices and training which has not previously been reported.[21] Most respondents claimed that the videolaryngoscope improved team work with the anaesthesiologist and allow anticipation of the required alternative technique by observing the view at laryngoscopy on a screen. Laryngoscopy is thus moving from an individual process to a shared procedure. Therefore, it is better to use a screen separate from the videolaryngoscope. The participation of the nurse facilitated by the glottic visualization is particularly

valuable when he or she performs a BURP to quickly find the most efficient gesture avoiding also a worsening of the glottic visualization.[22]

Alternative techniques were used at a similar incidence in both groups, mainly the backward, upward, and rightward pressure (BURP) in around 40% of the patients and the use of a gum elastic bougie (railroading technique) in around 10% of the patients. Such incidence of use of BURP is not surprising in that incidences of 23%[19] and 36%[23] have been reported previously. High incidence of their use is probably explained by the fear of dental breakage, with an incidence up to 0.2% of all general anaesthesia procedures, is responsible for 40% of the complaints against anaesthesiologists in France.[24]

The BURP manoeuvre improves laryngoscopic visualization more easily than simple back pressure on the larynx[25] and limits the forces exerted during laryngoscopy.[26, 27] However, the best condition is represented when the assistant can view the laryngeal view in real time on a remote screen during intubation to adapt the BURP to have the best glottic view.[28] The McGrath MAC videolaryngoscope has not this possibility contrary to other videolaryngoscopes which have the possibility to have a remote screen and thus be accessible to all participants (Airtraq®, Glidescope®, and King Vision® for example). This is important because poor BURP practice is counterproductive and aggravates glottic vision.[29]

The secondly alternative technique used is tube rail-roading over a gum elastic bougie.[30] This technique of choice when BURP does not align the oral, pharyngeal and laryngeal axes is more complex since it requires good coordination between the members of the team.

It should also be noted that the anaesthesiologist chose to remove the screen cover to benefit from the video function of the videolaryngoscope in 7% of the cases.

Finally, complications noticed during the induction-intubation sequence and after it up to the next day were similar in both groups. Contrary to others who used a Glide Scope, we did not find that the use of a videolaryngoscope decreased the incidence and severity of sore throat and hoarseness after tracheal intubation.[31]

The strengths of the study come from the usual practice of the centres which were used, including especially the staffing ratio with one anaesthesiologist and one nurse anaesthetist (1 to 1) in each case. But this permanent presence of a two-person team may have induced a bias because it facilitates the practice of an alternative technique. Another strength is the use of the same laryngoscope in both groups, the only difference being the use or not of the video screen. The last strength is that the present study is the first single blinded study since most of the criteria of judgment, in particular the main criterion, are obtained from a video recording of the intubation sequence without the possibility for the evaluator to know if the video function of the McGrath MAC videolaryngoscope was used.

One weakness comes from the choice of the McGrath MAC videolaryngoscope. We chose this device since it requires limited training because of its similarity to the Macintosh laryngoscope with especially a similar blade. Another reason for its choice was its small size and low cost compared with other videolaryngoscopes, those with a swivelling or remote screen which may optimize the help, especially for the application of BURP. Consequently, our results cannot be generalized to other videolaryngoscopes which differ by the shape of the blade, and the existence or not of a channel. Another point explaining why generalization is not possible is that our procedure includes the simultaneous presence of an anaesthesiologist and a nurse anaesthetist as is the rule in the health care institutions that participated in the study, but this practice is far from being the rule. In these institutions, anaesthesiologists and nurse anaesthetists have an identical practice when intubation concerns patients with no particular risk of access to the airways. Other weakness are the risk of 7% misclassification when using the Arné score to predict difficult intubation[11] and the large number of patients who were not seen the day after the operation, which makes the postoperative data very questionable.

Conclusion

The Difficult Airway Society (DAS) guidelines for unanticipated difficult intubation recommend that all anaesthesiologists are trained to use a videolaryngoscope and that they have immediate access to one[5] and several authors have called for videolaryngoscopes to be used for all intubations.[9] One would have expected that the use of a videolaryngoscope, i.e. the introduction of a new technology, would have changed the practice of intubation. In patients at low risk of intubation difficulty, the expected benefit should have been greater autonomy for the person performing the procedure. Our results do not confirm this hypothesis.

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Presentation: None.

Authors contribution

OB, XP, JMD, MF and MLG have contribute substantially to conception and design of the study.

OB, ZC, JO, LAT, XP, SM, MLG have contribute substantially to acquisition of data.

All authors have participated to the analysis and interpretation of data.

TK performed the statistical analysis.

MF has written the first draft.

MF has taken responsibility for the integrity of the work as a whole, from inception to published article.

All authors have revised it critically for important intellectual content.

All authors approve the final version.

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Legend of Figure 1

Flow chart

No-Video Group: intubation was performed using a McGrath Mac videolaryngoscope with its screen deactivated

Video group: intubation was performed using a McGrath Mac videolaryngoscope with its screen activated

No VR: No video recording

Table 1. Patient characteristics

	Video group (n=133)	No-Video group (n=123)
Male patients	61 (45.9)	58 (47.1)
	[37.2 - 54.7]	[38.3 - 56.4]
Age, years	58 (23)	60 (26)
	[54 - 62]	[52 - 64]
Body mass index, kg/m^{-2}	25.1 (6.3)	24.7 (5.8)
	[24.2 - 26.1]	[23.7 - 25.4]
Arné score [11]	2 (5)	2 (4)
	[2 - 3]	[2 - 2]
Previous knowledge of difficult intubation	1 (0.8) [0.0 - 4.1]	1 (0.8) [0.0 - 4.4]
Pathologies associated with difficult intubation	1 (0.8) [0.0 - 4.1]	0
Clinical symptoms of airway pathology	6 (4.5) [1.7 - 9.6]	6 (4.9) [1.8 - 10.3]
Interincisor gap (<25 mm) and limited mandible luxation	0	0
Thyromental distance < 65 mm	4 (3.0) [0.8 - 7.5]	2 (1.6) [0.2 - 5.7]
Maximum range of head and neck movement ≤ 80°	4 (3.0) [0.8 - 7.5]	1 (0.8) [0.0 - 4.4]
Mallampati score		
1	71 (53.4) [44.5 - 62.1]	69 (56.1) [46.9 - 65.0]
2	51 (38.3) [30.0 - 47.2]	42 (34.1) [25.8 - 43.2]
3	10 (7.5) [3.7 - 13.4]	12 (9.7) [5.1 - 16.4]
4	1 (0.8) [0.0 - 4.1]	0

The results are presented as number (proportion) [95% CI of the percentage] for categorical variables and as median (interquartile range) [95% CI of the median] for continuous variables.

Table 2. Intubation variables

	Video group (n=133)	No-Video group (n=123)	P value
Required assistance by the additional person	48 (36.1) [27.9 - 44.9]	56 (45.5) [95% 36.5 - 54.7]	0.12
Intubation Difficulty Scale (IDS)			**0.009**
IDS = 0	77 (57.9) [49.0 - 66.4]	50 (40.6) [31.9 - 49.9]	
0 < IDS ≤ 5	55 (41.3) [32.9 - 50.2]	68 (55.3) [46.1 - 64.2]	
> 5	1 (0.8) [0.0 - 4.1]	5 (4.1) [1.3 - 9.2]	
Number of attempts			0.24
1	122 (91.7) [87.0 - 96.4]	112 (91.1) [86.0 - 96.1]	
2	10 (7.5) [3.0 - 12.0]	6 (4.9) [1.1 - 8.7]	
3	1 (0.8) [0.0 - 2.2]	4 (3.2) [0.1 - 6.4]	
4	0 (0.0) [0.0 - 0.0]	1 (0.8) [0.0 - 2.4]	
Complementary techniques			
BURP	46 (34.6) [26.6 - 43.3]	53 (43.1) [34.2 - 52.3]	0.16
Railroading the tube over a gum elastic bougie	16 (12.0) [7.0 - 18.8]	13 (10.6) [5.7 - 17.4]	0.71

Table 2. Intubation variables (continued)

	Video group (n=133)	No-Video group (n=123)	P value
Cormack and Lehane grade			**<0.001**
1	111 (83.5) [76.0 - 89.3]	63 (51.2) [42.0 - 60.3]	
2a	19 (14.3) [8.8 - 21.4]	33 (26.8) [19.2 - 35.6]	
2b	1 (0.8) [0.0 - 4.1]	18 (14.6) [8.9 - 22.1]	
3	2 (1.5) [0.2 - 5.3]	9 (7.3) [3.4 - 13.4]	
Percentage of glottic opening score	100 (10) [100 - 100]	80 (40) [80 - 90]	**<0.001**
Vocal cord position, abduction	133 (100) [100 - 100]	123 (100) [100 - 100]	
Abnormal traction force	13 (9.8) [5.3 - 16.1]	27 (21.9) [15.0 - 30.3]	**0.007**
Oesophageal Intubation	4 (3.1) [0.8 - 7.5]	2 (1.6) [0.2 - 5.7]	0.68
Removing the cover		9 (7.3) [2.7 - 11.9]	
Time between the introduction of the McGrath and the third capnogram, sec	50 (31) [46 - 57] {113}	49 (31) [42 - 53] {104}	0.13
Ease of intubation, 0 (very easy) - 10 (very difficult)	0 (2) [0 - 0]	2 (4) [1 - 2]	**<0.001**

The results are presented as number (proportion) [95% CI of the percentage] for categorical variables and as median (interquartile range) [95% CI of the median] for continuous variables.

In cases in which the data are incomplete, the number of available data points is indicated between curly brackets {}.

Table 3. Bispectral index, heart rate and arterial pressure measurements

	Group	Before induction	Before intubation	After intubation	Difference between before and after intubation	Before intubation vs. after intubation	Video vs. No-Video group
						P-value	
BIS	Video group	94 (8) [93 – 97] {74}	40 (19) [37 – 45] {88}	44 (18) [40 – 47] {102}	2 (15) (0 – 5) {85}	0.11	0.20
	No-Video group	96 (6) [94 – 97] {75}	46 (21) (42 – 48) {84}	50 (17) [46 – 53] {89}	5 (17) (2 – 9) {79}	**0.04**	
HR	Video group	74 (20) [71 - 78] {129}	67 (16) [63 - 70] {130}	79 (27) [75 - 82] {131}	9 (17) (7 - 14) {129}	**<0.001**	0.103
	No-Video group	72 (22) [68 - 76] {115}	65 (16) [61 - 69] {121}	83 (23) [78 - 86] {121}	13 (19) (10 - 19) {120}	**<0.001**	
MAP	Video group	98 (20) [93 - 100] {128}	74 (24) [72 - 81] {125}	82 (28) [78 - 87] {125}	4 (25) (0 - 7) {121}	**0.007**	**0.04**
	No-Video group	99 (22) [97 - 104] {114}	77 (22) (74 - 84) {118}	87 (41) [82 - 93] {113}	12 (39) (5 - 20) {110}	**<0.001**	

The results are presented as median (interquartile range) [95% CI of the median].

Number of available data points is indicated between curly brackets {}.

BIS = Bispectral index, HR = heart rate (beats per minute), PAM = mean blood pressure (mmHg)

Table 4. Intra- and postoperative complications

	Video group (n=133)	No-Video group (n=123)	P value
Intraoperative complications			
Oxygen desaturation (peripheral oxygen saturation < 92%)	2 (1.5) [0.2 - 5.3]	0	0.50
Hypotension having required treatment	4 (3.0) [0.1 - 5.9]	3 (2.4) [0.0 - 5.2]	0.99
Hypertension having required treatment	0 (0.0) [0.0 - 0.0]	1 (0.0) [0.0 - 2.4]	0.48
Dental injury	0	0	
Postoperative complications			
Hoarseness	{n=34}	{n=37}	0.99
Grade 1	23 (68) [49.5 - 82.6]	25 (68) [50.2 - 82.0]	
Grade 2	11 (32) [17.4 - 50.5]	12 (32) [18.0 - 49.8]	
Grade 3	0	0	
Sore throat	{n=42}	{n=33}	0.41
Grade 1	33 (78.6) [63.2 - 89.7]	23 (69.7) [51.3 - 84.4]	
Grade 2	8 (19.0) [8.6 - 34.1]	10 (30.3) [15.6 - 48.7]	
Grade 3	1 (2.4) [0.1 - 12.6]	0	

The results are presented as number (proportion) [95% CI of the percentage].

When the data were incomplete, the number of available data points is indicated between curly brackets {}.

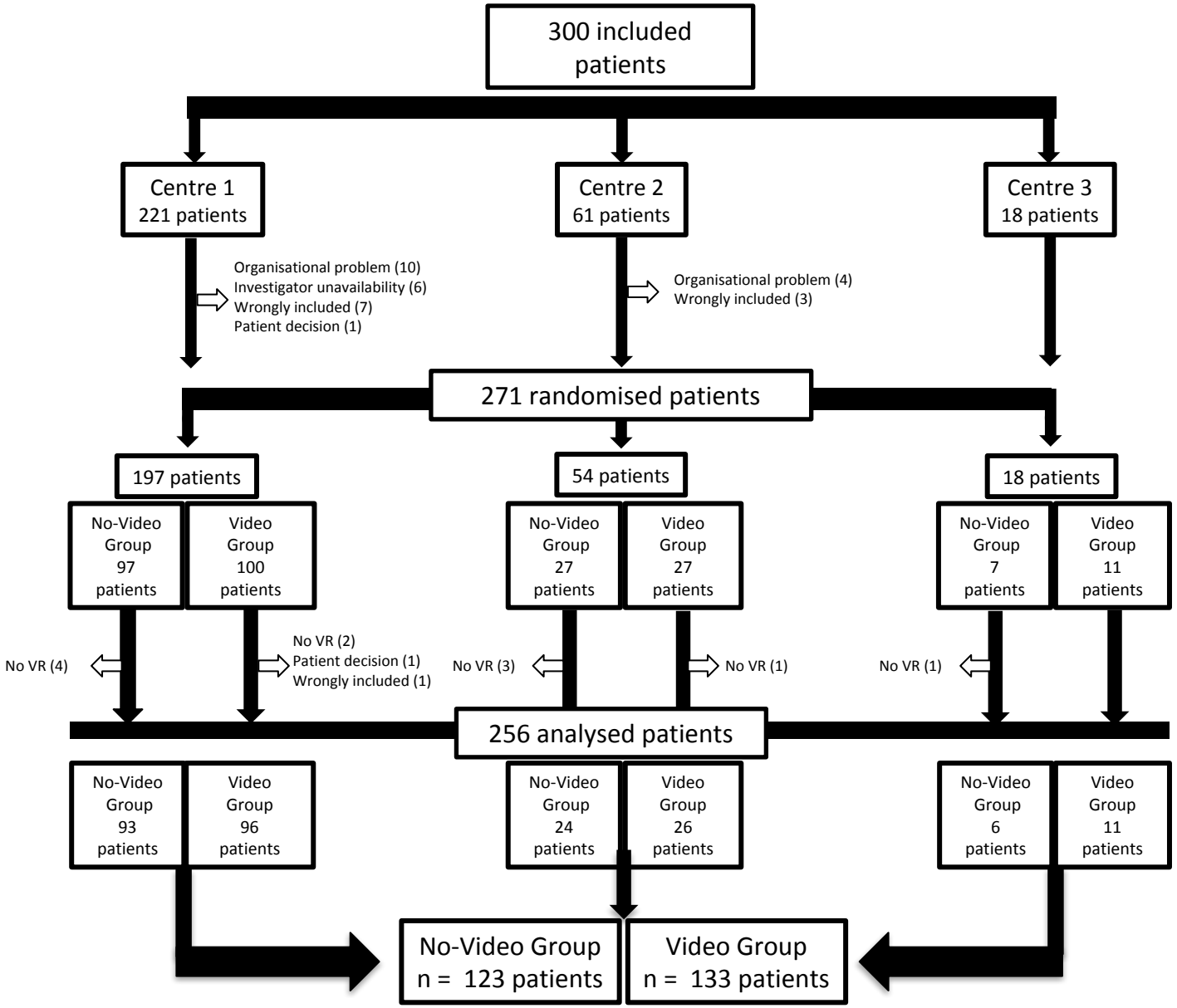
300 included patients
Centre 1 221 patients
Centre 2 61 patients
Centre 3 18 patients
Organisational problem (10)
Investigator unavailability (6)
Wrongly included (7)
Patient decision (1)
Organisational problem (4)
Wrongly included (3)
271 randomised patients
197 patients
54 patients
18 patients
No-Video Group 97 patients
Video Group 100 patients
No-Video Group 27 patients
Video Group 27 patients
No-Video Group 7 patients
Video Group 11 patients
No VR (4)
No VR (2)
Patient decision (1)
Wrongly included (1)
No VR (3)
No VR (1)
No VR (1)
256 analysed patients
No-Video Group 93 patients
Video Group 96 patients
No-Video Group 24 patients
Video Group 26 patients
No-Video Group 6 patients
Video Group 11 patients
No-Video Group n = 123 patients
Video Group n = 133 patients

Figure 1

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	5
	2b	Specific objectives or hypotheses	5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	6
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	6 and Figure 1
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	7
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	9
	6b	Any changes to trial outcomes after the trial commenced, with reasons	NA
Sample size	7a	How sample size was determined	10
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	6-7
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	6-7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	9

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	7
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	10
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	NA
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	12
	14b	Why the trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Tables
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Tables
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	--
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	NA
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	13 – Table 4
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	16
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	16
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	14
Other information			
Registration	23	Registration number and name of trial registry	3
Protocol	24	Where the full trial protocol can be accessed, if available	On request
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	18

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

BMJ Open

Influence of videolaryngoscopy using McGrath Mac™ on the need for a helper to perform intubation during general anaesthesia: A multicentre randomised Video - No-Video trial

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Influence of videolaryngoscopy using McGrath MacTM on the need for a helper to perform intubation during general anaesthesia:

A multicentre randomised Video - No-Video trial

Running Title: Randomised Videolaryngoscopy trial for patients with normal airways

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Abstract

Objective: We hypothesised that videolaryngoscopy modifies practice of tracheal intubation.

Design: Randomised single-blinded study (Video and No-Video groups).

Setting: Three institutions: One academic, one non-profit and one profit.

Participants: Patients >18 years, requiring orotracheal intubation, without predicted difficult intubation. Non-inclusion criterion was patients requiring a rapid-sequence intubation. 300 patients were included, 271 randomised, 256 analysed: 123 in the No-Video and 133 in the Video groups.

Intervention: Tracheal intubation using a McGrath Mac™ videolaryngoscope, the sequence being video recorded.

Primary and secondary outcome measures: The primary outcome was the proportion of intubations where assistance is necessary upon request of the operator. Secondary outcomes included intraoperative variables (intubation difficulty scale and its components, percentage of glottic opening score, oesophageal Intubation, duration of intubation, removal of the screen cover in the No-Video group, global evaluation of the ease of intubation, bispectral index, heart rate and blood pressure), intraoperative and postoperative complications (hoarseness or sore throat), and cooperation of the anaesthesiology team.

Results: Requirement for assistance was not decreased in the Video group: 36.1% [95% CI 27.9-44.9] versus 45.5% [95%CI 36.5-54.7] in the No-Video group, p=0.74; Odds Ratio: 0.7 [0.4-1.1] and Absolute Risk: 0.10 [-0.03-0.22]. Intubation difficulty scale was similar in both groups (p=0.05). Percentage of glottic opening score was better in the Video group (median of 100 [95% CI [100-100] and 80 [95%CI [80-90] in the no-Video group; p<0.001) as Cormack and Lehane grade (p=0001). Ease of intubation was considered better in the Video group (p<0.001). Other secondary outcomes were similar between groups. Screen cover was removed in 7.3% (95%CI [2.7-11.9]) of the cases in the Video group. No serious adverse event occurred. Communication and behaviour within the anaesthesia team were appropriate in all cases.

Conclusion: In patients without predicted difficult intubation, videolaryngoscopy did not decrease the requirement for assistance to perform intubation.

Trial registration: Clinicaltrials.gov identifier: NCT02926144

Strengths and limitations of this study

- This study aimed to assess if the use of a videolaryngoscope modifies the practice of tracheal intubation in real life conditions.
- A major strength of this study performed on patients without a predicted difficult intubation was the choice of the main outcome: the need for help for the anaesthesiologist or the nurse anaesthetist in performing tracheal intubation.
- Permanent presence of a two-person team may have induced a bias because it facilitates the practice of an alternative technique.
- Another weakness comes from the choice of the McGrath MAC videolaryngoscope and, consequently, results cannot be generalized to other videolaryngoscopes which differ by the shape of the blade, and the existence or not of a channel.

Introduction

Airway management remains a major concern for anaesthesiologists while related morbimortality is determinant for anaesthesia.[1-3] Securing the patient's airway is a critical step in providing general anaesthesia and several recommendations have been published regarding the practice of intubation in anaesthesia.[4, 5] Direct laryngoscopy using the original Macintosh laryngoscope has been the rule for the past half century; however a wide range of videolaryngoscopes has been developed in recent years to provide an indirect visualisation of the glottis via a camera. In patients with a suspected difficult airway, there is no doubt that videolaryngoscopy is associated with a significantly better view of the glottis, increases the first-attempt success and reduces mucosal trauma.[6]

In patients with no predicted difficult airway, no difference in failed intubation has been reported when comparing a videolaryngoscope and Macintosh laryngoscope.[7] Nevertheless some authors consider that the use of videolaryngoscopes must be generalised for all patients, even for those in whom preoperative assessment has not found evidence of a particular risk of access to the airways.[8-10]

In their analysis of the literature, Lewis *et al.*[7] emphasize the importance of the choice of the evaluation criteria used to compare the techniques: glottic view, time required for intubation, successful intubation particularly at the first-attempt, risks of complications like hypoxia or other respiratory complications, laryngeal or airway traumas, and sore throat in the post-anaesthesia care unit. Another question that needs to be asked when a new technology is proposed is: does this technology change the practice?

This randomised multicentre study done in our real-life conditions, presence of an anaesthesiologist and of a nurse anaesthetist during the induction-intubation period, compared two scenarios, both using the same videolaryngoscope, one using the video function and the other not, for orotracheal intubation of surgical patients without particular risk of access to the airways. The hypothesis was that the use of the videolaryngoscope modifies the practice of tracheal intubation, the main outcome being the need for help for the anaesthesiologist or the nurse anaesthetist in performing tracheal intubation.

Methods

Ethics approval

After approval by the Ethics Committee (Comité de Protection des Personnes Ile de France VIII, Boulogne Billancourt, France, n°160108, 19 February 2016, Chairman Bertrand MUSSETTA) and by the French Regulatory Office, and after registration on the web site ClinicalTrials.gov (NCT02926144, first Posted on October 6, 2016), patients were enrolled in the study after they gave their written informed consent including videorecording and blurring of patients faces if necessary. The complete protocol, registered with the competent authorities under the N° ID-RCP 2013-A01307-38, can be obtained on request. Patient and public were not involved in the design, or conduct, or reporting, or dissemination plans of the research.

Study Design, and Setting

The McGrath Mac Videolaryngoscope versus McGrath Mac No-Video Laryngoscope for Orotracheal Intubation in Operating Room (Video - No-Video study) trial was an institutionally sponsored, single-blinded, multicentre, two parallel-groups randomised clinical trial (RCT) conducted at three Health Institutions in France (one academic, one non-profit and one profit).

Patient population

Inclusion criteria were patients aged 18 years minimum, requiring general anaesthesia and orotracheal intubation with a single lumen tube, without a predicted difficult intubation (Arne score <11).[11] Non-inclusion criteria were currently pregnant or breastfeeding woman, out-patients who could not be contacted within 24 hours following surgery, patients requiring a rapid-sequence intubation, and patients for whom general anaesthesia using sufentanil, propofol, atracurium or rocuronium was not suitable.

Inclusion and exclusion criteria were assessed by an investigator who could be different from the one who was to perform the intubation. Once in the operating room, inclusion criteria were confirmed by the anaesthesiologist in charge and randomisation was managed online.

Randomisation, Allocation Concealment

Centralized randomisation using fixed-size blocks had been performed by an independent biostatistician not involved in the trial. The randomisation scheme was balanced 1:1 and stratified by centre. Each patient received a unique patient number and a randomisation number (patient code) when the investigator connected to an Interactive Web Response System managed by an independent Contract Research Organization (Epiconcept Company, 75012, Paris, France) using a protected password just before the induction of anaesthesia. Thus, patients were randomised into two groups: a Video group, in which intubation is performed using a McGrath Mac videolaryngoscope with its screen activated, and a No-Video group, in which intubation is performed using a McGrath Mac videolaryngoscope with its screen hidden. The software used to allocate the patients to their group also was in-live fulfilled to collect data by the investigator in an electronic report form, ensuring concealment.

Study Protocol

Patients received care during the induction and intubation periods from an anaesthesiologist and a nurse anaesthetist as is usual in the hospitals where the protocol took place. All anaesthesiologists and nurse anaesthetists had performed at least ten intubations with the McGrath Mac Videolaryngoscope. This experience seems sufficient since the learning curve is steep especially among this population[12] especially since the professionals received specific training pertaining to the study procedures prior to the beginning of the trial including the fact that they must rely on the video screen in the Video group and use the direct view in the No-Video group.

Upon arrival in the operating room, a dedicated peripheral intravenous cannula for the administration of IV anaesthetics was placed on the forearm, and routine monitoring was performed including bispectral index monitoring and quantitative measurement of neuromuscular block at the adductor pollicis. Patients were positioned in dorsal decubitus with the head on a 7cm high pillow. Preoxygenation was achieved using a face mask, and oxygen at a flow of 15 L/min or greater for at least 3 minutes to achieve an end-tidal oxygen fraction of at least 90%.

General anaesthesia was then induced by injecting sufentanil, propofol and a neuromuscular blocking agent (atracurium or rocuronium) once the patient was unconsciousness. Intubation was performed by the anaesthesiologist or the nurse anaesthetist using the device allocated at random when bispectral index was under 60 and when there was no more muscle response to the train of four stimulation.

Intubation was performed using the video screen of the device in the McGrath Mac Videolaryngoscope group (Video group) while the video screen was hidden with an opaque cover in the McGrath Mac No-Video Laryngoscope group (No-Video group). Endotracheal tube size was 7 for women and 7.5 for men with blades size 3 or 4 according the practitioner's preference.

Asking for help from the other member of the anaesthetic team was at the discretion of the individual performing intubation if he/she deemed it necessary to perform an easy and atraumatic intubation. Complementary techniques consisted in (a) backward, upward and rightward pressure (BURP) manoeuvre; (b) rail-roading the tube over a gum elastic bougie; (c) removing the opaque cover on the video screen in the No-Video group or change in the operator. If all these techniques failed, other manoeuvres could be used: (a) insertion of a stylet into the tube; (b) changing the blade; (c) removal of the pillow. Rescue techniques (insertion of an Intubating Laryngeal Mask Airway, transtracheal oxygenation, fiberoptic intubation, awakening) were considered if necessary according to the national recommendations.[13] Number of intubation attempts, time to intubate or number of alternative techniques were not limited by the protocol.

After intubation, the cuff was inflated, the tube was connected to the ventilator, and intratracheal tube position was confirmed by analysing the capnography curve.

Anaesthesia was conducted according to good practices.

Patients were reviewed the following day. Sore throat and hoarseness were evaluated, and adverse events collected by investigators not knowing the group to which the patient has been assigned.

Data collection

All cases were video recorded by a person not involved in the study which followed a mandatory script. This person, placed at the feet of the patient, was unable to see whether the screen of the videolaryngoscope was activated. Video recording began with preoxygenation and ended with the capnographic confirmation of successful tracheal intubation.

The framing of the videos was done in such a way that the patient's anonymity was respected. Otherwise, the patient's face was blurred before analysis.

Analysis of each video was performed by two anaesthesiologists blinded to the study group since the screen, transparent or opaque, of the videolaryngoscope was not apparent. The videos were reviewed by both anaesthesiologists in case of discordance.

All the variables used for the study were retrieved from the video apart from the glottis exposure which was recorded in real time by the person who performed the intubation using the Cormack and Lehane modified score and the percentage of glottis opening scale (POGO) score.[14,15]

Timeline of measurement of each variable is summarised in a Supplementary Table.

Primary and secondary outcomes

The primary outcome, the proportion of orotracheal intubations where assistance was necessary upon request of the operator, was obtained from the video of the intubation sequence.

Secondary outcomes included during the intubation period (1) the intubation difficulty scale,[16] (2) the Cormack and Lehane grade of glottis visibility,[14] (3) the percentage of glottic opening scale score (POGO)

score,[15] (4) the proportion of patients intubated using alternative techniques: (backward, upward and rightward pressure (BURP), rail-roading the tube over a gum elastic bougie, insertion of a stylet in the tube, laryngeal mask airway, fiberoptic endoscopy, or rescue percutaneous or surgical transtracheal oxygenation ...), anaesthesia discontinuation, (5) the time from introduction of the McGrath videolaryngoscope in the mouth to the confirmation of tracheal tube position based on partial pressure of end-tidal exhaled carbon dioxide (third capnogram), (6) the proportion of patients having had an oesophageal intubation, (7), the ease of intubation evaluated by the anaesthesiologist using a 11-level numeric scale from 0 (very easy) to 10 (very difficult), (8) the requirement of an abnormal traction force to intubate, (9) the heart rate and mean arterial pressure measured just before and after intubation, (10) complications such as oxygen desaturation (peripheral oxygen saturation < 92%) or hypotension having required treatment. The cooperation between members of the anaesthesiology team during intubation was graded using a 4-point scale (0=no cooperation at all, 3=a great deal of cooperation).[17]

The postoperative secondary outcomes included the proportion of patient suffering from hoarseness[18] or sore throat[19] on postoperative day 1. Other adverse events will be also collected.

Sample Size calculation

The number of patients to be included took into consideration the frequency with which external laryngeal pressure is used. Adnet et al. published in 2001 a survey of tracheal intubation difficulty among 1171 surgical patients and found that the Intubation Difficulty Scale was > 0 in 522 cases (45%) and that external laryngeal pressure, requiring an assistant to help, was used in 271 of these cases (23% of all patients).[20] Based on this data, the expected rate for the assistance of another person for intubation was 25 % for patients in the No-Video group. Presuming that the video function would decrease this proportion to 12.5 %, with type 1 error set at 5 % and power set at 80 %, 131 patients were needed in each group (i.e., 262 patients total). We planned to recruit 300 patients to mitigate an attrition of the sample or the absence of values.

Statistical Analyses

Statistical analysis was conducted using the principle of the intention-to-treat analysis. Results are presented as number (proportion) [Confidence Interval 95 of the percentage] for categorical variables and compared by the Chi-square test when the number of observations was greater than five, and by the exact Fischer test when one of the numbers was less than five. For continuous variables, results are presented as median (Interquartile Range) [Confidence Interval 95 of the median] and compared by a Wilcoxon test, after verification of the normality with a Shapiro-Wilk test. All tests were two-sided. The types of all variables, categorical or continuous, are summarised in a Supplementary Table.

P values of less than 0.05 were considered significant. Bonferroni correction was used to correct p values of the comparison between groups of the Intubation Difficulty Scale and of its parameters.

The statistics were generated using SAS 9.4 software.

Data sharing

Dataset is available from the Dryad repository (DOI: 10.5061/dryad.280gb5mp6).

Results

Patients were recruited between the 29th November 2016 and the 1st April 2019. Of 300 included patients, 271 were randomised and 256 analysed with 123 patients in the No-Video group and 133 in the Video group (**Figure 1**).

Baseline features were well balanced between groups (**Table 1**).

Requirement for assistance was not decreased in the Video group (36.1% [95% CI 27.9-44.9] versus 45.5% [95%CI 36.5-54.7] in the No-Video group, p=0.74 after Bonferroni correction; Odds Ratio: 0.7 [0.4-1.1] and Absolute Risk: 0.10 [-0.03-0.22] (**Table 2**). Requirement for assistance was similar between groups when considering each centre separately (p=0.99).

The Intubation Difficulty Scale was similar between groups (p=0.05; Table 2); its parameters are presented in Table 3.

Glottis visualization was significantly better in the Video group with a lower Cormack and Lehane score (p<0.001), and higher percentage of glottic opening score (p<0.001). There was no difference between groups considering other outcomes, in particular for duration of intubation, number of attempts, use of complementary techniques (BURP and railroading), except for ease of intubation, better in the Video group (p=0.001), and for requirement of an abnormal traction force, lower in the Video group (p=0.007). The opaque cover was withdrawn in 7.3% of the cases in the No-Video group (**Tables 2 and 3**).

Bispectral index increased after intubation only in the Video group (p=0.04). Heart rate and mean arterial pressure increased in both groups after intubation with a smaller increase in mean arterial pressure in the Video group (p=0.04) (**Table 4**).

Communication and behaviour within the anaesthesia team was appropriate in all cases (values of 3).

Oxygen desaturation, hypotension or hypertension requiring treatment during the intubation period

and postoperative complications (hoarseness or sore throat) were observed similarly in both groups (**Table 5**).

No serious adverse event occurred.

Discussion

In this Video-No Video trial performed in surgical patients without particular risk of difficulty in airway management, videolaryngoscopy did not decrease the requirement for assistance to perform intubation.

This result corroborates studies which consider that the use of a videolaryngoscope is of little interest in the management of such patients. Advantages of videolaryngoscopy seem to be secondary, especially better glottic visualization[7] which does not translate directly into a higher success rate on the first attempt.[7,21]

There is no universal rule regarding anaesthetic staffing neither for qualifications, anaesthesiologists, or registered nurse anaesthetists nor for the required number during the whole procedure or during the induction-intubation sequence. In our study, patients received care during the induction and intubation periods from an anaesthesiologist and a nurse anaesthetist as is usual in the hospitals where the protocol takes place. This probably explains the high percentage of recourse to a second person since he or she is available without delay. Such incidence is not reported per se in studies contrary to the use of alternative techniques. Except for cases where tracheal intubation is easy, help is needed to perform a BURP manoeuvre or give a gum elastic bougie or a stylet for example.

Interestingly, Jones *et al.* studied the impact of the use the C-MAC videolaryngoscope (Karl Storz Endoscopy, Slough, Berkshire, UK) on nurse anaesthetist working practices and training which has not previously been reported.[22] Most respondents claimed that the videolaryngoscope improved team work with the anaesthesiologist and allow anticipation of the required alternative technique by observing the view at laryngoscopy on a screen. Laryngoscopy is thus moving from an individual process to a shared procedure. Therefore, it is better to use a screen separate from the videolaryngoscope. The participation of the nurse facilitated by the glottic visualization is particularly

valuable when he or she performs a BURP to quickly find the most efficient gesture avoiding also a worsening of the glottic visualization.[23]

Alternative techniques were used at a similar incidence in both groups, mainly the backward, upward, and rightward pressure (BURP) in around 40% of the patients and the use of a gum elastic bougie (railroading technique) in around 10% of the patients. Such incidence of use of BURP is not surprising in that incidences of 23%[20] and 36%[24] have been reported previously. High incidence of their use is probably explained by the fear of dental breakage, with an incidence up to 0.2% of all general anaesthesia procedures, is responsible for 40% of the complaints against anaesthesiologists in France.[25]

The BURP manoeuvre improves laryngoscopic visualization more easily than simple back pressure on the larynx[26] and limits the forces exerted during laryngoscopy.[27,28] However, the best condition is represented when the assistant can view the laryngeal view in real time on a remote screen during intubation to adapt the BURP to have the best glottic view.[29] The McGrath MAC videolaryngoscope has not this possibility contrary to other videolaryngoscopes which have the possibility to have a remote screen and thus be accessible to all participants (Airtraq®, Glidescope®, and King Vision® for example). This is important because poor BURP practice is counterproductive and aggravates glottic vision.[30] The secondly alternative technique used is tube rail-roading over a gum elastic bougie.[31] This technique of choice when BURP does not align the oral, pharyngeal and laryngeal axes is more complex since it requires good coordination between the members of the team.

It should also be noted that the anaesthesiologist chose to remove the screen cover to benefit from the video function of the videolaryngoscope in 7% of the cases.

Finally, complications noticed during the induction-intubation sequence and after it up to the next day were similar in both groups. Contrary to others who used a Glide Scope, we did not find that the use of a videolaryngoscope decreased the incidence and severity of sore throat and hoarseness after tracheal intubation.[32]

The strengths of the study come from the usual practice of the centres which were used, including especially the staffing ratio with one anaesthesiologist and one nurse anaesthetist (1 to 1) in each case. But this permanent presence of a two-person team may have induced a bias because it facilitates the practice of an alternative technique. Another strength is the use of the same laryngoscope in both groups, the only difference being the use or not of the video screen. The last strength is that the present study is the first single blinded study since most of the criteria of judgment, in particular the main criterion, are obtained from a video recording of the intubation sequence without the possibility for the evaluator to know if the video function of the McGrath MAC videolaryngoscope was used.

One weakness comes from the choice of the McGrath MAC videolaryngoscope. We chose this device since it requires limited training because of its similarity to the Macintosh laryngoscope with especially a similar blade, a small size, and a low cost. Consequently, our results could be valid for other videolaryngoscopes having a blade-shape like the Macintosh laryngoscope (C-MAC or APA for example), but not acutely angled videolaryngoscopes (McGrath and GlideScope for example) or with an integrated channel videolaryngoscope (KingVision, AWS-S200, and Airtraq). Another point explaining why generalization is not possible is that our procedure includes the simultaneous presence of an anaesthesiologist, and a nurse anaesthetist as is the rule in the health care institutions that participated in the study, but this practice is far from being the rule. In these institutions, anaesthesiologists and nurse anaesthetists have an identical practice when intubation concerns patients with no particular risk of access to the airways. Other weakness are the risk of 7% misclassification when using the Arné score to predict difficult intubation[11] and the large number of patients who were not seen the day after the operation, which makes the postoperative data very questionable. Another major point is that we used the need for assistance from a member of the anaesthetic team as the primary outcome. This choice is not usual, but it seemed to us more interesting than the time to successful tracheal intubation or the number of attempts, outcomes that have little interest in a population without risk of difficult intubation. On the other hand, we felt it was important to evaluate the possible benefit of a new technology on the ergonomics of the work of

anaesthesiologists. However, one of the limitations of our primary outcome is its personal nature and we could have been more specific in the need for assistance and possibly create a score combining for example force exerted and POGO. We sought to have this primary outcome assessed blind to the randomisation arm. As noted, the person recording the video sequence was positioned at the foot of the patient, making it impossible to see if there was an opaque cover on the videolaryngoscope screen. It is possible, however, that the persons who was watching the video could see, or thought they could see, if the video function was being used. Finally, eight patients were missing in the video-group since the calculation of the number to be included resulted in a minimum number of 131 patients in each group. However, it is highly unlikely that this would change the results significantly.

Conclusion

The Difficult Airway Society (DAS) guidelines for unanticipated difficult intubation recommend that all anaesthesiologists are trained to use a videolaryngoscope and that they have immediate access to one[5] and several authors have called for videolaryngoscopes to be used for all intubations.[9] One would have expected that the use of a videolaryngoscope, i.e. the introduction of a new technology, would have changed the practice of intubation. In patients at low risk of intubation difficulty, the expected benefit should have been greater autonomy for the person performing the procedure. Our results do not confirm this hypothesis.

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Authors contribution

OB, XP, JMD, MF and MLG have contribute substantially to conception and design of the study.

OB, ZC, JO, LAT, XP, SM, MLG have contribute substantially to acquisition of data.

All authors have participated to the analysis and interpretation of data.

TK performed the statistical analysis.

MF has written the first draft.

MF has taken responsibility for the integrity of the work as a whole, from inception to published article.

All authors have revised it critically for important intellectual content.

All authors approve the final version.

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Legend of Figure 1

Flow chart

No-Video Group: intubation was performed using a McGrath Mac videolaryngoscope with its screen deactivated

Video group: intubation was performed using a McGrath Mac videolaryngoscope with its screen activated

No VR: No video recording

Supplementary Table

Outcomes (type of variable and timeline of measurements)

Table 1. Patient characteristics

	Video group (n=133)	No-Video group (n=123)
Male patients, number (%) [95% CI of %]	61 (45.9) [37.2 - 54.7]	58 (47.1) [38.3 - 56.4]
Age, years, median (IQR) [95% CI of median]	58 (23) [54 - 62]	60 (26) [52 - 64]
Body mass index, kg/m^{-2}, median (IQR) [95% CI of median]	25.1 (6.3) [24.2 - 26.1]	24.7 (5.8) [23.7 - 25.4]
Arné score[11], number (%) [95% CI of %]	2 (5) [2 - 3]	2 (4) [2 - 2]
Previous knowledge of difficult intubation	1 (0.8) [0.0 - 4.1]	1 (0.8) [0.0 - 4.4]
Pathologies associated with difficult intubation	1 (0.8) [0.0 - 4.1]	0
Clinical symptoms of airway pathology	6 (4.5) [1.7 - 9.6]	6 (4.9) [1.8 - 10.3]
Interincisor gap (<25 mm) and limited mandible luxation	0	0
Thyromental distance < 65 mm	4 (3.0) [0.8 - 7.5]	2 (1.6) [0.2 - 5.7]
Maximum range of head and neck movement ≤ 80°	4 (3.0) [0.8 - 7.5]	1 (0.8) [0.0 - 4.4]
Mallampati score		
1	71 (53.4) [44.5 - 62.1]	69 (56.1) [46.9 - 65.0]
2	51 (38.3) [30.0 - 47.2]	42 (34.1) [25.8 - 43.2]
3	10 (7.5) [3.7 - 13.4]	12 (9.7) [5.1 - 16.4]
4	1 (0.8) [0.0 - 4.1]	0

Table 2. Intubation variables (final values)

	Video group (n=133)	**No-Video group** (n=123)	**P value**
Required assistance by the additional person, yes, number (%) [95% CI of %]	48 (36.1) [27.9 - 44.9]	56 (45.5) [36.5 --54.7]	0.74*
Intubation Difficulty Scale (IDS), classes, number (%) [95% CI of %]			0.05*
IDS = 0	77 (57.9) [49.0 - 66.4]	50 (40.6) [31.9 - 49.9]	
0 < IDS ≤ 5	55 (41.3) [32.9 - 50.2]	68 (55.3) [46.1 - 64.2]	
> 5	1 (0.8) [0.0 - 4.1]	5 (4.1) [1.3 - 9.2]	
Railroading the tube over a gum elastic bougie, yes, number (%) [95% CI of %]	16 (12.0)[7.0 - 18.8]	13 (10.6) [5.7 - 17.4]	0.71
Percentage of glottic opening score, median (IQR) [95% CI of median]	100 (10) [100 - 100]	80 (40) [80 - 90]	**<0.001**
Oesophageal Intubation, yes, number (%) [95% CI of %]	4 (3.1) [0.8 - 7.5]	2 (1.6) [0.2 - 5.7]	0.68
BURP, yes, number (%) [95% CI of %]	46 (34.6)[26.6 - 43.3]	53 (43.1) [34.2 - 52.3]	0.16
Removing the cover, yes, number (%) [95% CI of %]		9 (7.3) [2.7 - 11.9]	
Time between the introduction of the McGrath and the third capnogram, sec, median (IQR) [95% CI of median]	50 (31) [46 - 57] {113}	49 (31) [42 - 53] {104}	0.13
Ease of intubation, 0 (very easy) - 10 (very difficult), median (IQR) [95% CI of median]	0 (2) [0 - 0]	2 (4) [1 - 2]	**<0.001**

In cases in which the data are incomplete, the number of available data points is indicated between curly brackets {}

* P value with Bonferroni correction

Table 3. Parameters of the Intubation Difficulty Scale, (final values)

	Video group (n=133)	**No-Video group** (n=123)	**P value***
Number of attempts, classes, number (%) [95% CI of %]			0.99
1	122 (91.7) [87.0 - 96.4]	112 (91.1)[86.0 - 96.1]	
2	10 (7.5)[3.0 - 12.0]	6 (4.9)[1.1 - 8.7]	
3	1 (0.8)[0.0 - 2.2]	4 (3.2)[0.1 - 6.4]	
4	0 (0.0)[0.0 - 0.0]	1 (0.8)[0.0 - 2.4]	
Required assistance by the additional person, yes, number (%) [95% CI of %]	48 (36.1) [27.9 - 44.9]	56 (45.5) [36.5 - 54.7]	0.74
Number of alternatives techniques, number (%) [95% CI of %]			0.99
None	85 (63.9) [55.7 - 72.1]	69 (56.1) [47.3 - 64.8]	
1	34 (25.6) [18.1 - 33.0]	42 (34.1) [25.8 - 42.6]	
2	14 (10.5) [5.3 - 15.7]	12 (9.8) [4.5 - 15.0]	
Cormack and Lehane grade, number (%) [95% CI of %]			**0.001**
1	111 (83.5) [76.0 - 89.3]	63 (51.2) [42.0 - 60.3]	
2a	19 (14.3) [8.8 - 21.4]	33 (26.8) [19.2 - 35.6]	
2b	1 (0.8) [0.0 - 4.1]	18 (14.6) [8.9 - 22.1]	
3	2 (1.5) [0.2 - 5.3]	9 (7.3) [3.4 - 13.4]	
Abnormal traction force, yes, number (%) [95% CI of %]	13 (9.8) [5.3 - 16.1]	27 (21.9) [15.0 - 30.3]	**0.04**
Vocal cord position, abduction, yes, number (%) [95% CI of %]	133 (100) [100 - 100]	123 (100) [100 - 100]	NA

In cases in which the data are incomplete, the number of available data points is indicated between curly brackets {}.

*: P values were calculated using Bonferroni correction

Table 4. Bispectral index, heart rate and arterial pressure measurements (change from baseline and from preintubation period)

	Group	Before induction	Before intubation	After intubation	Difference between before and after intubation	Before intubation vs. after intubation P-value	Video vs. No-Video group
BIS, number (%) [95% CI of %]	Video group	94 (8) [93 – 97] {74}	40 (19) [37 – 45] {88}	44 (18) [40 – 47] {102}	2 (15) (0 – 5) {85}	0.11	0.20
	No-Video group	96 (6) [94 – 97] {75}	46 (21) (42 – 48) {84}	50 (17) [46 – 53] {89}	5 (17) (2 – 9) {79}	**0.04**	
HR, beats/min, number (%) [95% CI of %]	Video group	74 (20) [71 - 78] {129}	67 (16) [63 - 70] {130}	79 (27) [75 - 82] {131}	9 (17) (7 - 14) {129}	**<0.001**	0.103
	No-Video group	72 (22) [68 - 76] {115}	65 (16) [61 - 69] {121}	83 (23) [78 - 86] {121}	13 (19) (10 - 19) {120}	**<0.001**	
MAP, mmHg, number (%) [95% CI of %]	Video group	98 (20) [93 - 100] {128}	74 (24) [72 - 81] {125}	82 (28) [78 - 87] {125}	4 (25) (0 - 7) {121}	**0.007**	**0.04**
	No-Video group	99 (22) [97 - 104] {114}	77 (22) (74 - 84) {118}	87 (41) [82 - 93] {113}	12 (39) (5 - 20) {110}	**<0.001**	

The results are presented as median (interquartile range) [95% CI of the median]. Number of available data points is indicated between curly brackets {}.

BIS = Bispectral index, HR = heart rate (beats per minute), PAM = mean blood pressure (mmHg)

Table 5. Intra- and postoperative complications

	Video group (n=133)	No-Video group (n=123)	P value
Intraoperative complications			
Oxygen desaturation (peripheral oxygen saturation < 92%), number (%) [95% CI of %]	2 (1.5) [0.2 - 5.3]	0	0.50
Hypotension having required treatment, number (%) [95% CI of %]	4 (3.0) [0.1 - 5.9]	3 (2.4) [0.0 - 5.2]	0.99
Hypertension having required treatment, number (%) [95% CI of %]	0 (0.0) [0.0 - 0.0]	1 (0.0) [0.0 - 2.4]	0.48
Dental injury, number (%) [95% CI of %]	0	0	
Postoperative complications			
Hoarseness, number (%) [95% CI of %]	{n=34}	{n=37}	0.99
Grade 1	23 (68) [49.5 - 82.6]	25 (68) [50.2 - 82.0]	
Grade 2	11 (32) [17.4 - 50.5]	12 (32) [18.0 - 49.8]	
Grade 3	0	0	
Sore throat, number (%) [95% CI of %]	{n=42}	{n=33}	0.41
Grade 1	33 (78.6) [63.2 - 89.7]	23 (69.7) [51.3 - 84.4]	
Grade 2	8 (19.0) [8.6 - 34.1]	10 (30.3) [15.6 - 48.7]	
Grade 3	1 (2.4) [0.1 - 12.6]	0	

When the data were incomplete, the number of available data points is indicated between curly brackets {}.

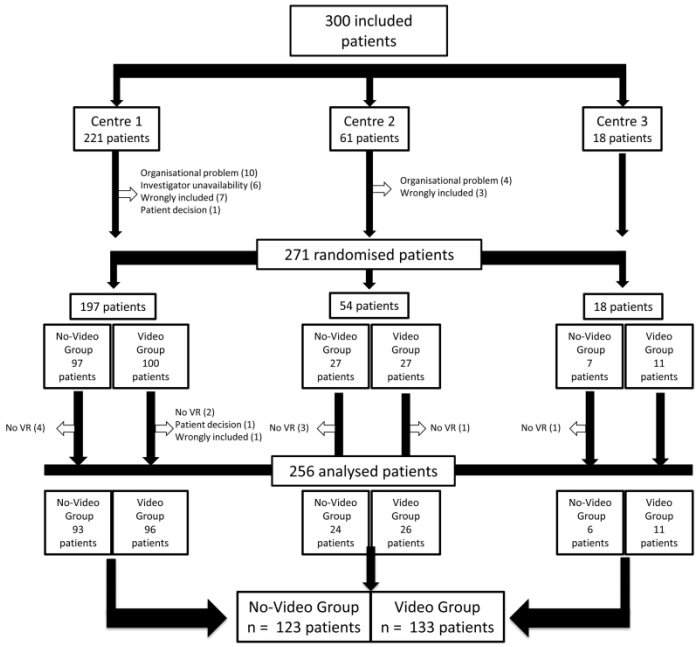

Figure 1

Figure 1

297x209mm (300 x 300 DPI)

Supplementary Table. Outcomes (type of variable and timeline of measurements)

	Type of variable	Timeline of the measurement
Primary outcome		
Required assistance by the additional person, yes	Categorical	Off line
Secondary outcomes		
Intubation		
Intubation Difficulty Scale, three classes	Categorical	
Number of attempts, four classes	Categorical	Off line
Number of operators, one/two	Categorical	Off line
Number of alternative techniques, none/one/two	Categorical	Off line
Cormack and Lehane grade, four classes	Categorical	On line
Abnormal traction force, yes	Categorical	On line
BURP, yes	Categorical	Off line
Vocal cord position (abduction), yes	Categorical	On line
Railroading the tube over a gum elastic bougie, yes	Categorical	Off line
Percentage of glottic opening score	Continuous	On line
Oesophageal Intubation, yes	Categorical	On line
Removing the cover, yes	Categorical	Off line
Time between the introduction of the McGrath and the third capnogram, seconds	Continuous	Off line
Ease of intubation, 0 (very easy) to 10 (very difficult),	Continuous	On line
BIS and haemodynamic variables		
BIS, absolute values,	Continuous	On line
Heart rate and arterial pressure, absolute values,	Continuous	On line
Intraoperative complications		
Oxygen desaturation (peripheral oxygen saturation < 92%), yes	Categorical	On line
Hypotension having required treatment, yes	Categorical	On line
Hypertension having required treatment, yes	Categorical	On line
Dental injury, yes	Categorical	On line
Postoperative complications		
Hoarseness, three grades	Categorical	Day1
Sore throat, three grades	Categorical	Day1
Serious adverse event, yes	Categorical	Day1

On line: variable recorded during the procedure

Off line: variable recorded a posteriori from the lecture of the video of the intubation sequence

Day1: postoperative visit at day1

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	2/56
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	3/56
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	6/56
	2b	Specific objectives or hypotheses	6/56
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	7/56
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	7/56
	4b	Settings and locations where the data were collected	7/56
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	8/56
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	10/56
	6b	Any changes to trial outcomes after the trial commenced, with reasons	NA
Sample size	7a	How sample size was determined	11/56
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	8/56
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	8/56
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	8/56
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	8/56
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	10/56

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	NA
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	11/56
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	NA
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	13/56
	14b	Why the trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Figure 1
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	13/56
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Tables
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	NA
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	14/56
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	17/56
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	17/56
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	15/56
Other information			
Registration	23	Registration number and name of trial registry	7/56
Protocol	24	Where the full trial protocol can be accessed, if available	On request
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	20/56

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

BMJ Open

Influence of videolaryngoscopy using McGrath Mac™ on the need for a helper to perform intubation during general anaesthesia: A multicentre randomised Video - No-Video trial

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Influence of videolaryngoscopy using McGrath MacTM on the need for a helper to perform intubation during general anaesthesia:

A multicentre randomised Video - No-Video trial

Running Title: Randomised Videolaryngoscopy trial for patients with normal airways

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Abstract

Objective: We hypothesised that videolaryngoscopy modifies practice of tracheal intubation.

Design: Randomised single-blinded study (Video and No-Video groups).

Setting: Three institutions: One academic, one non-profit and one profit.

Participants: Patients >18 years, requiring orotracheal intubation, without predicted difficult intubation. Non-inclusion criterion was patients requiring a rapid-sequence intubation. 300 patients were included, 271 randomised, 256 analysed: 123 in the No-Video and 133 in the Video groups.

Intervention: Tracheal intubation using a McGrath Mac™ videolaryngoscope, the sequence being video recorded.

Primary and secondary outcome measures: The primary outcome was the proportion of intubations where assistance is necessary upon request of the operator. Secondary outcomes included intraoperative variables (intubation difficulty scale and its components, percentage of glottic opening score, oesophageal Intubation, duration of intubation, removal of the screen cover in the No-Video group, global evaluation of the ease of intubation, bispectral index, heart rate and blood pressure), intraoperative and postoperative complications (hoarseness or sore throat), and cooperation of the anaesthesiology team.

Results: Requirement for assistance was not decreased in the Video group: 36.1% [95% CI 27.9-44.9] versus 45.5% [95%CI 36.5-54.7] in the No-Video group, p=0.74; Odds Ratio: 0.7 [0.4-1.1] and Absolute Risk: 0.10 [-0.03-0.22]. Intubation difficulty scale was similar in both groups (p=0.05). Percentage of glottic opening score was better in the Video group (median of 100 [95% CI [100-100] and 80 [95%CI [80-90] in the no-Video group; p<0.001) as Cormack and Lehane grade (p=0001). Ease of intubation was considered better in the Video group (p<0.001). Other secondary outcomes were similar between groups. Screen cover was removed in 7.3% (95%CI [2.7-11.9]) of the cases in the Video group. No serious adverse event occurred. Communication and behaviour within the anaesthesia team were appropriate in all cases.

Conclusion: In patients without predicted difficult intubation, videolaryngoscopy did not decrease the requirement for assistance to perform intubation.

Trial registration: Clinicaltrials.gov identifier: NCT02926144

Strengths and limitations of this study

- This study aimed to assess if the use of a videolaryngoscope modifies the practice of tracheal intubation in real life conditions.
- A major strength of this study performed on patients without a predicted difficult intubation was the choice of the main outcome: the need for help for the anaesthesiologist or the nurse anaesthetist in performing tracheal intubation.
- Permanent presence of a two-person team may have induced a bias because it facilitates the practice of an alternative technique.
- Another weakness comes from the choice of the McGrath MAC videolaryngoscope and, consequently, results cannot be generalized to other videolaryngoscopes which differ by the shape of the blade, and the existence or not of a channel.

Introduction

Airway management remains a major concern for anaesthesiologists while related morbimortality is determinant for anaesthesia.[1-3] Securing the patient's airway is a critical step in providing general anaesthesia and several recommendations have been published regarding the practice of intubation in anaesthesia.[4, 5] Direct laryngoscopy using the original Macintosh laryngoscope has been the rule for the past half century; however a wide range of videolaryngoscopes has been developed in recent years to provide an indirect visualisation of the glottis via a camera. In patients with a suspected difficult airway, there is no doubt that videolaryngoscopy is associated with a significantly better view of the glottis, increases the first-attempt success and reduces mucosal trauma.[6]

In patients with no predicted difficult airway, no difference in failed intubation has been reported when comparing a videolaryngoscope and Macintosh laryngoscope.[7] Nevertheless some authors consider that the use of videolaryngoscopes must be generalised for all patients, even for those in whom preoperative assessment has not found evidence of a particular risk of access to the airways.[8-10]

In their analysis of the literature, Lewis *et al.*[7] emphasize the importance of the choice of the evaluation criteria used to compare the techniques: glottic view, time required for intubation, successful intubation particularly at the first-attempt, risks of complications like hypoxia or other respiratory complications, laryngeal or airway traumas, and sore throat in the post-anaesthesia care unit. Another question that needs to be asked when a new technology is proposed is: does this technology change the practice?

This randomised multicentre study done in our real-life conditions, presence of an anaesthesiologist and of a nurse anaesthetist during the induction-intubation period, compared two scenarios, both using the same videolaryngoscope, one using the video function and the other not, for orotracheal intubation of surgical patients without particular risk of access to the airways. The hypothesis was that the use of the videolaryngoscope modifies the practice of tracheal intubation, the main outcome being the need for help for the anaesthesiologist or the nurse anaesthetist in performing tracheal intubation.

Methods

Ethics approval

After approval by the Ethics Committee (Comité de Protection des Personnes Ile de France VIII, Boulogne Billancourt, France, n°160108, 19 February 2016, Chairman Bertrand MUSSETTA) and by the French Regulatory Office, and after registration on the web site ClinicalTrials.gov (NCT02926144, first Posted on October 6, 2016), patients were enrolled in the study after they gave their written informed consent including videorecording and blurring of patients faces if necessary. The complete protocol, registered with the competent authorities under the N° ID-RCP 2013-A01307-38, can be obtained on request.

Patient and public involvement

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

Study Design, and Setting

The McGrath Mac Videolaryngoscope versus McGrath Mac No-Video Laryngoscope for Orotracheal Intubation in Operating Room (Video - No-Video study) trial was an institutionally sponsored, single-blinded, multicentre, two parallel-groups randomised clinical trial (RCT) conducted at three Health Institutions in France (one academic, one non-profit and one profit).

Patient population

Inclusion criteria were patients aged 18 years minimum, requiring general anaesthesia and orotracheal intubation with a single lumen tube, without a predicted difficult intubation (Arne score <11).[11] Non-inclusion criteria were currently pregnant or breastfeeding woman, out-patients who could not be contacted within 24 hours following surgery, patients requiring a rapid-sequence intubation, and

patients for whom general anaesthesia using sufentanil, propofol, atracurium or rocuronium was not suitable.

Inclusion and exclusion criteria were assessed by an investigator who could be different from the one who was to perform the intubation. Once in the operating room, inclusion criteria were confirmed by the anaesthesiologist in charge and randomisation was managed online.

Randomisation, Allocation Concealment

Centralized randomisation using fixed-size blocks had been performed by an independent biostatistician not involved in the trial. The randomisation scheme was balanced 1:1 and stratified by centre. Each patient received a unique patient number and a randomisation number (patient code) when the investigator connected to an Interactive Web Response System managed by an independent Contract Research Organization (Epiconcept Company, 75012, Paris, France) using a protected password just before the induction of anaesthesia. Thus, patients were randomised into two groups: a Video group, in which intubation is performed using a McGrath Mac videolaryngoscope with its screen activated, and a No-Video group, in which intubation is performed using a McGrath Mac videolaryngoscope with its screen hidden. The software used to allocate the patients to their group also was in-live fulfilled to collect data by the investigator in an electronic report form, ensuring concealment.

Study Protocol

Patients received care during the induction and intubation periods from an anaesthesiologist and a nurse anaesthetist as is usual in the hospitals where the protocol took place. All anaesthesiologists and nurse anaesthetists had performed at least ten intubations with the McGrath Mac Videolaryngoscope. This experience seems sufficient since the learning curve is steep especially among this population[12] especially since the professionals received specific training pertaining to the study procedures prior to

the beginning of the trial including the fact that they must rely on the video screen in the Video group and use the direct view in the No-Video group.

Upon arrival in the operating room, a dedicated peripheral intravenous cannula for the administration of IV anaesthetics was placed on the forearm, and routine monitoring was performed including bispectral index monitoring and quantitative measurement of neuromuscular block at the adductor pollicis. Patients were positioned in dorsal decubitus with the head on a 7cm high pillow. Preoxygenation was achieved using a face mask, and oxygen at a flow of 15 L/min or greater for at least 3 minutes to achieve an end-tidal oxygen fraction of at least 90%.

General anaesthesia was then induced by injecting sufentanil, propofol and a neuromuscular blocking agent (atracurium or rocuronium) once the patient was unconsciousness. Intubation was performed by the anaesthesiologist or the nurse anaesthetist using the device allocated at random when bispectral index was under 60 and when there was no more muscle response to the train of four stimulation.

Intubation was performed using the video screen of the device in the McGrath Mac Videolaryngoscope group (Video group) while the video screen was hidden with an opaque cover in the McGrath Mac No-Video Laryngoscope group (No-Video group). Endotracheal tube size was 7 for women and 7.5 for men with blades size 3 or 4 according the practitioner's preference.

Asking for help from the other member of the anaesthetic team was at the discretion of the individual performing intubation if he/she deemed it necessary to perform an easy and atraumatic intubation. Complementary techniques consisted in (a) backward, upward and rightward pressure (BURP) manoeuvre; (b) rail-roading the tube over a gum elastic bougie; (c) removing the opaque cover on the video screen in the No-Video group or change in the operator. If all these techniques failed, other manoeuvres could be used: (a) insertion of a stylet into the tube; (b) changing the blade; (c) removal of the pillow. Rescue techniques (insertion of an Intubating Laryngeal Mask Airway, transtracheal oxygenation, fiberoptic intubation, awakening) were considered if necessary according to the national

recommendations.[13] Number of intubation attempts, time to intubate or number of alternative techniques were not limited by the protocol.

After intubation, the cuff was inflated, the tube was connected to the ventilator, and intratracheal tube position was confirmed by analysing the capnography curve.

Anaesthesia was conducted according to good practices.

Patients were reviewed the following day. Sore throat and hoarseness were evaluated, and adverse events collected by investigators not knowing the group to which the patient has been assigned.

Data collection

All cases were video recorded by a person not involved in the study which followed a mandatory script. This person, placed at the feet of the patient, was unable to see whether the screen of the videolaryngoscope was activated. Video recording began with preoxygenation and ended with the capnographic confirmation of successful tracheal intubation.

The framing of the videos was done in such a way that the patient's anonymity was respected. Otherwise, the patient's face was blurred before analysis.

Analysis of each video was performed by two anaesthesiologists blinded to the study group since the screen, transparent or opaque, of the videolaryngoscope was not apparent. The videos were reviewed by both anaesthesiologists in case of discordance.

All the variables used for the study were retrieved from the video apart from the glottis exposure which was recorded in real time by the person who performed the intubation using the Cormack and Lehane modified score and the percentage of glottis opening scale (POGO) score.[14,15]

Timeline of measurement of each variable is summarised in a Supplementary Table.

Primary and secondary outcomes

The primary outcome, the proportion of orotracheal intubations where assistance was necessary upon request of the operator, was obtained from the video of the intubation sequence.

Secondary outcomes included during the intubation period (1) the intubation difficulty scale,[16] (2) the Cormack and Lehane grade of glottis visibility,[14] (3) the percentage of glottic opening scale score (POGO) score,[15] (4) the proportion of patients intubated using alternative techniques: (backward, upward and rightward pressure (BURP), rail-roading the tube over a gum elastic bougie, insertion of a stylet in the tube, laryngeal mask airway, fiberoptic endoscopy, or rescue percutaneous or surgical transtracheal oxygenation ...), anaesthesia discontinuation, (5) the time from introduction of the McGrath videolaryngoscope in the mouth to the confirmation of tracheal tube position based on partial pressure of end-tidal exhaled carbon dioxide (third capnogram), (6) the proportion of patients having had an oesophageal intubation, (7), the ease of intubation evaluated by the anaesthesiologist using a 11-level numeric scale from 0 (very easy) to 10 (very difficult), (8) the requirement of an abnormal traction force to intubate, (9) the heart rate and mean arterial pressure measured just before and after intubation, (10) complications such as oxygen desaturation (peripheral oxygen saturation < 92%) or hypotension having required treatment. The cooperation between members of the anaesthesiology team during intubation was graded using a 4-point scale (0=no cooperation at all, 3=a great deal of cooperation).[17]

The postoperative secondary outcomes included the proportion of patient suffering from hoarseness[18] or sore throat[19] on postoperative day 1. Other adverse events will be also collected.

Sample Size calculation

The number of patients to be included took into consideration the frequency with which external laryngeal pressure is used. Adnet et al. published in 2001 a survey of tracheal intubation difficulty among 1171 surgical patients and found that the Intubation Difficulty Scale was > 0 in 522 cases (45%) and that external laryngeal pressure, requiring an assistant to help, was used in 271 of these cases (23% of all patients).[20] Based on this data, the expected rate for the assistance of another person for intubation was 25 % for patients in the No-Video group. Presuming that the video function would decrease this proportion to 12.5 %, with type 1 error set at 5 % and power set at 80 %, 131

patients were needed in each group (i.e., 262 patients total). We planned to recruit 300 patients to mitigate an attrition of the sample or the absence of values.

Statistical Analyses

Statistical analysis was conducted using the principle of the intention-to-treat analysis. Results are presented as number (proportion) [Confidence Interval 95 of the percentage] for categorical variables and compared by the Chi-square test when the number of observations was greater than five, and by the exact Fischer test when one of the numbers was less than five. For continuous variables, results are presented as median (Interquartile Range) [Confidence Interval 95 of the median] and compared by a Wilcoxon test, after verification of the normality with a Shapiro-Wilk test. All tests were two-sided. The types of all variables, categorical or continuous, are summarised in a Supplementary Table.

P values of less than 0.05 were considered significant. Bonferroni correction was used to correct p values of the comparison between groups of the Intubation Difficulty Scale and of its parameters.

The statistics were generated using SAS 9.4 software.

Results

Patients were recruited between the 29th November 2016 and the 1st April 2019. Of 300 included patients, 271 were randomised and 256 analysed with 123 patients in the No-Video group and 133 in the Video group (**Figure 1**).

Baseline features were well balanced between groups (**Table 1**).

Requirement for assistance was not decreased in the Video group (36.1% [95% CI 27.9-44.9] versus 45.5% [95%CI 36.5-54.7] in the No-Video group, p=0.74 after Bonferroni correction; Odds Ratio: 0.7 [0.4-1.1] and Absolute Risk: 0.10 [-0.03-0.22] (**Table 2**). Requirement for assistance was similar between groups when considering each centre separately (p=0.99).

The Intubation Difficulty Scale was similar between groups (p=0.05; Table 2); its parameters are presented in Table 3.

Glottis visualization was significantly better in the Video group with a lower Cormack and Lehane score (p<0.001), and higher percentage of glottic opening score (p<0.001). There was no difference between groups considering other outcomes, in particular for duration of intubation, number of attempts, use of complementary techniques (BURP and railroading), except for ease of intubation, better in the Video group (p=0.001), and for requirement of an abnormal traction force, lower in the Video group (p=0.007). The opaque cover was withdrawn in 7.3% of the cases in the No-Video group (**Tables 2 and 3**).

Bispectral index increased after intubation only in the Video group (p=0.04). Heart rate and mean arterial pressure increased in both groups after intubation with a smaller increase in mean arterial pressure in the Video group (p=0.04) (**Table 4**).

Communication and behaviour within the anaesthesia team was appropriate in all cases (values of 3).

Oxygen desaturation, hypotension or hypertension requiring treatment during the intubation period

and postoperative complications (hoarseness or sore throat) were observed similarly in both groups (**Table 5**).

No serious adverse event occurred.

Discussion

In this Video-No Video trial performed in surgical patients without particular risk of difficulty in airway management, videolaryngoscopy did not decrease the requirement for assistance to perform intubation.

This result corroborates studies which consider that the use of a videolaryngoscope is of little interest in the management of such patients. Advantages of videolaryngoscopy seem to be secondary, especially better glottic visualization[7] which does not translate directly into a higher success rate on the first attempt.[7,21]

There is no universal rule regarding anaesthetic staffing neither for qualifications, anaesthesiologists, or registered nurse anaesthetists nor for the required number during the whole procedure or during the induction-intubation sequence. In our study, patients received care during the induction and intubation periods from an anaesthesiologist and a nurse anaesthetist as is usual in the hospitals where the protocol takes place. This probably explains the high percentage of recourse to a second person since he or she is available without delay. Such incidence is not reported per se in studies contrary to the use of alternative techniques. Except for cases where tracheal intubation is easy, help is needed to perform a BURP manoeuvre or give a gum elastic bougie or a stylet for example.

Interestingly, Jones *et al.* studied the impact of the use the C-MAC videolaryngoscope (Karl Storz Endoscopy, Slough, Berkshire, UK) on nurse anaesthetist working practices and training which has not previously been reported.[22] Most respondents claimed that the videolaryngoscope improved team work with the anaesthesiologist and allow anticipation of the required alternative technique by observing the view at laryngoscopy on a screen. Laryngoscopy is thus moving from an individual process to a shared procedure. Therefore, it is better to use a screen separate from the videolaryngoscope. The participation of the nurse facilitated by the glottic visualization is particularly

valuable when he or she performs a BURP to quickly find the most efficient gesture avoiding also a worsening of the glottic visualization.[23]

Alternative techniques were used at a similar incidence in both groups, mainly the backward, upward, and rightward pressure (BURP) in around 40% of the patients and the use of a gum elastic bougie (railroading technique) in around 10% of the patients. Such incidence of use of BURP is not surprising in that incidences of 23%[20] and 36%[24] have been reported previously. High incidence of their use is probably explained by the fear of dental breakage, with an incidence up to 0.2% of all general anaesthesia procedures, is responsible for 40% of the complaints against anaesthesiologists in France.[25]

The BURP manoeuvre improves laryngoscopic visualization more easily than simple back pressure on the larynx[26] and limits the forces exerted during laryngoscopy.[27,28] However, the best condition is represented when the assistant can view the laryngeal view in real time on a remote screen during intubation to adapt the BURP to have the best glottic view.[29] The McGrath MAC videolaryngoscope has not this possibility contrary to other videolaryngoscopes which have the possibility to have a remote screen and thus be accessible to all participants (Airtraq®, Glidescope®, and King Vision® for example). This is important because poor BURP practice is counterproductive and aggravates glottic vision.[30] The secondly alternative technique used is tube rail-roading over a gum elastic bougie.[31] This technique of choice when BURP does not align the oral, pharyngeal and laryngeal axes is more complex since it requires good coordination between the members of the team.

It should also be noted that the anaesthesiologist chose to remove the screen cover to benefit from the video function of the videolaryngoscope in 7% of the cases.

Finally, complications noticed during the induction-intubation sequence and after it up to the next day were similar in both groups. Contrary to others who used a Glide Scope, we did not find that the use of a videolaryngoscope decreased the incidence and severity of sore throat and hoarseness after tracheal intubation.[32]

The strengths of the study come from the usual practice of the centres which were used, including especially the staffing ratio with one anaesthesiologist and one nurse anaesthetist (1 to 1) in each case. But this permanent presence of a two-person team may have induced a bias because it facilitates the practice of an alternative technique. Another strength is the use of the same laryngoscope in both groups, the only difference being the use or not of the video screen. The last strength is that the present study is the first single blinded study since most of the criteria of judgment, in particular the main criterion, are obtained from a video recording of the intubation sequence without the possibility for the evaluator to know if the video function of the McGrath MAC videolaryngoscope was used.

One weakness comes from the choice of the McGrath MAC videolaryngoscope. We chose this device since it requires limited training because of its similarity to the Macintosh laryngoscope with especially a similar blade, a small size, and a low cost. Consequently, our results could be valid for other videolaryngoscopes having a blade-shape like the Macintosh laryngoscope (C-MAC or APA for example), but not acutely angled videolaryngoscopes (McGrath and GlideScope for example) or with an integrated channel videolaryngoscope (KingVision, AWS-S200, and Airtraq). Another point explaining why generalization is not possible is that our procedure includes the simultaneous presence of an anaesthesiologist, and a nurse anaesthetist as is the rule in the health care institutions that participated in the study, but this practice is far from being the rule. In these institutions, anaesthesiologists and nurse anaesthetists have an identical practice when intubation concerns patients with no particular risk of access to the airways. Other weakness are the risk of 7% misclassification when using the Arné score to predict difficult intubation[11] and the large number of patients who were not seen the day after the operation, which makes the postoperative data very questionable. Another major point is that we used the need for assistance from a member of the anaesthetic team as the primary outcome. This choice is not usual, but it seemed to us more interesting than the time to successful tracheal intubation or the number of attempts, outcomes that have little interest in a population without risk of difficult intubation. On the other hand, we felt it was important to evaluate the possible benefit of a new technology on the ergonomics of the work of

anaesthesiologists. However, one of the limitations of our primary outcome is its personal nature and we could have been more specific in the need for assistance and possibly create a score combining for example force exerted and POGO. We sought to have this primary outcome assessed blind to the randomisation arm. As noted, the person recording the video sequence was positioned at the foot of the patient, making it impossible to see if there was an opaque cover on the videolaryngoscope screen. It is possible, however, that the persons who was watching the video could see, or thought they could see, if the video function was being used. Finally, eight patients were missing in the video-group since the calculation of the number to be included resulted in a minimum number of 131 patients in each group. However, it is highly unlikely that this would change the results significantly.

Conclusion

The Difficult Airway Society (DAS) guidelines for unanticipated difficult intubation recommend that all anaesthesiologists are trained to use a videolaryngoscope and that they have immediate access to one[5] and several authors have called for videolaryngoscopes to be used for all intubations.[9] One would have expected that the use of a videolaryngoscope, i.e. the introduction of a new technology, would have changed the practice of intubation. In patients at low risk of intubation difficulty, the expected benefit should have been greater autonomy for the person performing the procedure. Our results do not confirm this hypothesis.

Data availability statement

[dataset] [33]. Fischler M. Influence of videolaryngoscopy using McGrath Mac™ on the need for a helper to perform intubation during general anaesthesia: A multicentre randomised Video - No-Video trial. Dryad Digital Repository. January 25, 2021. https://datadryad.org/stash/dataset/doi:10.5061%2Fdryad.280gb5mp6. This dataset contains patients characteristics, variables related to intubation, and postoperative variables.

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Conflicts of interest: None.

Presentation: None.

Authors contribution

OB, XP, JMD, MF and MLG have contribute substantially to conception and design of the study.

OB, ZC, JO, LAT, XP, SM, MLG have contribute substantially to acquisition of data.

All authors have participated to the analysis and interpretation of data.

TK performed the statistical analysis.

MF has written the first draft.

MF has taken responsibility for the integrity of the work as a whole, from inception to published article.

All authors have revised it critically for important intellectual content.

All authors approve the final version.

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Legend of Figure 1

Flow chart

No-Video Group: intubation was performed using a McGrath Mac videolaryngoscope with its screen deactivated

Video group: intubation was performed using a McGrath Mac videolaryngoscope with its screen activated

No VR: No video recording

Supplementary Table

Outcomes (type of variable and timeline of measurements)

Table 1. Patient characteristics

	Video group (n=133)	No-Video group (n=123)
Male patients, number (%) [95% CI of %]	61 (45.9) [37.2 - 54.7]	58 (47.1) [38.3 - 56.4]
Age, years, median (IQR) [95% CI of median]	58 (23) [54 - 62]	60 (26) [52 - 64]
Body mass index, kg/m^{-2}, median (IQR) [95% CI of median]	25.1 (6.3) [24.2 - 26.1]	24.7 (5.8) [23.7 - 25.4]
Arné score[11], number (%) [95% CI of %]	2 (5) [2 - 3]	2 (4) [2 - 2]
Previous knowledge of difficult intubation	1 (0.8) [0.0 - 4.1]	1 (0.8) [0.0 - 4.4]
Pathologies associated with difficult intubation	1 (0.8) [0.0 - 4.1]	0
Clinical symptoms of airway pathology	6 (4.5) [1.7 - 9.6]	6 (4.9) [1.8 - 10.3]
Interincisor gap (<25 mm) and limited mandible luxation	0	0
Thyromental distance < 65 mm	4 (3.0) [0.8 - 7.5]	2 (1.6) [0.2 - 5.7]
Maximum range of head and neck movement ≤ 80°	4 (3.0) [0.8 - 7.5]	1 (0.8) [0.0 - 4.4]
Mallampati score		
1	71 (53.4) [44.5 - 62.1]	69 (56.1) [46.9 - 65.0]
2	51 (38.3) [30.0 - 47.2]	42 (34.1) [25.8 - 43.2]
3	10 (7.5) [3.7 - 13.4]	12 (9.7) [5.1 - 16.4]
4	1 (0.8) [0.0 - 4.1]	0

Table 2. Intubation variables (final values)

	Video group (n=133)	**No-Video group** (n=123)	**P value**
Required assistance by the additional person, yes, number (%) [95% CI of %]	48 (36.1) [27.9 - 44.9]	56 (45.5) [36.5 --54.7]	0.74*
Intubation Difficulty Scale (IDS), classes, number (%) [95% CI of %]			0.05*
IDS = 0	77 (57.9) [49.0 - 66.4]	50 (40.6) [31.9 - 49.9]	
0 < IDS ≤ 5	55 (41.3) [32.9 - 50.2]	68 (55.3) [46.1 - 64.2]	
> 5	1 (0.8) [0.0 - 4.1]	5 (4.1) [1.3 - 9.2]	
Railroading the tube over a gum elastic bougie, yes, number (%) [95% CI of %]	16 (12.0)[7.0 - 18.8]	13 (10.6) [5.7 - 17.4]	0.71
Percentage of glottic opening score, median (IQR) [95% CI of median]	100 (10) [100 - 100]	80 (40) [80 - 90]	**<0.001**
Oesophageal Intubation, yes, number (%) [95% CI of %]	4 (3.1) [0.8 - 7.5]	2 (1.6) [0.2 - 5.7]	0.68
BURP, yes, number (%) [95% CI of %]	46 (34.6)[26.6 - 43.3]	53 (43.1) [34.2 - 52.3]	0.16
Removing the cover, yes, number (%) [95% CI of %]		9 (7.3) [2.7 - 11.9]	
Time between the introduction of the McGrath and the third capnogram, sec, median (IQR) [95% CI of median]	50 (31) [46 - 57] {113}	49 (31) [42 - 53] {104}	0.13
Ease of intubation, 0 (very easy) - 10 (very difficult), median (IQR) [95% CI of median]	0 (2) [0 - 0]	2 (4) [1 - 2]	**<0.001**

In cases in which the data are incomplete, the number of available data points is indicated between curly brackets {}

* P value with Bonferroni correction

Table 3. Parameters of the Intubation Difficulty Scale, (final values)

	Video group (n=133)	**No-Video group** (n=123)	**P value***
Number of attempts, classes, number (%) [95% CI of %]			0.99
1	122 (91.7) [87.0 - 96.4]	112 (91.1)[86.0 - 96.1]	
2	10 (7.5)[3.0 - 12.0]	6 (4.9)[1.1 - 8.7]	
3	1 (0.8)[0.0 - 2.2]	4 (3.2)[0.1 - 6.4]	
4	0 (0.0)[0.0 - 0.0]	1 (0.8)[0.0 - 2.4]	
Required assistance by the additional person, yes, number (%) [95% CI of %]	48 (36.1) [27.9 - 44.9]	56 (45.5) [36.5 - 54.7]	0.74
Number of alternatives techniques, number (%) [95% CI of %]			0.99
None	85 (63.9) [55.7 - 72.1]	69 (56.1) [47.3 - 64.8]	
1	34 (25.6) [18.1 - 33.0]	42 (34.1) [25.8 - 42.6]	
2	14 (10.5) [5.3 - 15.7]	12 (9.8) [4.5 - 15.0]	
Cormack and Lehane grade, number (%) [95% CI of %]			**0.001**
1	111 (83.5) [76.0 - 89.3]	63 (51.2) [42.0 - 60.3]	
2a	19 (14.3) [8.8 - 21.4]	33 (26.8) [19.2 - 35.6]	
2b	1 (0.8) [0.0 - 4.1]	18 (14.6) [8.9 - 22.1]	
3	2 (1.5) [0.2 - 5.3]	9 (7.3) [3.4 - 13.4]	
Abnormal traction force, yes, number (%) [95% CI of %]	13 (9.8) [5.3 - 16.1]	27 (21.9) [15.0 - 30.3]	**0.04**
Vocal cord position, abduction, yes, number (%) [95% CI of %]	133 (100) [100 - 100]	123 (100) [100 - 100]	NA

In cases in which the data are incomplete, the number of available data points is indicated between curly brackets {}.

*: P values were calculated using Bonferroni correction

Table 4. Bispectral index, heart rate and arterial pressure measurements (change from baseline and from preintubation period)

	Group	Before induction	Before intubation	After intubation	Difference between before and after intubation	Before intubation vs. after intubation P-value	Video vs. No-Video group
BIS, number (%) [95% CI of %]	Video group	94 (8) [93 – 97] {74}	40 (19) [37 – 45] {88}	44 (18) [40 – 47] {102}	2 (15) (0 – 5) {85}	0.11	0.20
	No-Video group	96 (6) [94 – 97] {75}	46 (21) (42 – 48) {84}	50 (17) [46 – 53] {89}	5 (17) (2 – 9) {79}	**0.04**	
HR, beats/min, number (%) [95% CI of %]	Video group	74 (20) [71 - 78] {129}	67 (16) [63 - 70] {130}	79 (27) [75 - 82] {131}	9 (17) (7 - 14) {129}	**<0.001**	0.103
	No-Video group	72 (22) [68 - 76] {115}	65 (16) [61 - 69] {121}	83 (23) [78 - 86] {121}	13 (19) (10 - 19) {120}	**<0.001**	
MAP, mmHg, number (%) [95% CI of %]	Video group	98 (20) [93 - 100] {128}	74 (24) [72 - 81] {125}	82 (28) [78 - 87] {125}	4 (25) (0 - 7) {121}	**0.007**	**0.04**
	No-Video group	99 (22) [97 - 104] {114}	77 (22) (74 - 84) {118}	87 (41) [82 - 93] {113}	12 (39) (5 - 20) {110}	**<0.001**	

The results are presented as median (interquartile range) [95% CI of the median]. Number of available data points is indicated between curly brackets {}.

BIS = Bispectral index, HR = heart rate (beats per minute), PAM = mean blood pressure (mmHg)

Table 5. Intra- and postoperative complications

	Video group (n=133)	No-Video group (n=123)	P value
Intraoperative complications			
Oxygen desaturation (peripheral oxygen saturation < 92%), number (%) [95% CI of %]	2 (1.5) [0.2 - 5.3]	0	0.50
Hypotension having required treatment, number (%) [95% CI of %]	4 (3.0) [0.1 - 5.9]	3 (2.4) [0.0 - 5.2]	0.99
Hypertension having required treatment, number (%) [95% CI of %]	0 (0.0) [0.0 - 0.0]	1 (0.0) [0.0 - 2.4]	0.48
Dental injury, number (%) [95% CI of %]	0	0	
Postoperative complications			
Hoarseness, number (%) [95% CI of %]	{n=34}	{n=37}	0.99
Grade 1	23 (68) [49.5 - 82.6]	25 (68) [50.2 - 82.0]	
Grade 2	11 (32) [17.4 - 50.5]	12 (32) [18.0 - 49.8]	
Grade 3	0	0	
Sore throat, number (%) [95% CI of %]	{n=42}	{n=33}	0.41
Grade 1	33 (78.6) [63.2 - 89.7]	23 (69.7) [51.3 - 84.4]	
Grade 2	8 (19.0) [8.6 - 34.1]	10 (30.3) [15.6 - 48.7]	
Grade 3	1 (2.4) [0.1 - 12.6]	0	

When the data were incomplete, the number of available data points is indicated between curly brackets {}.

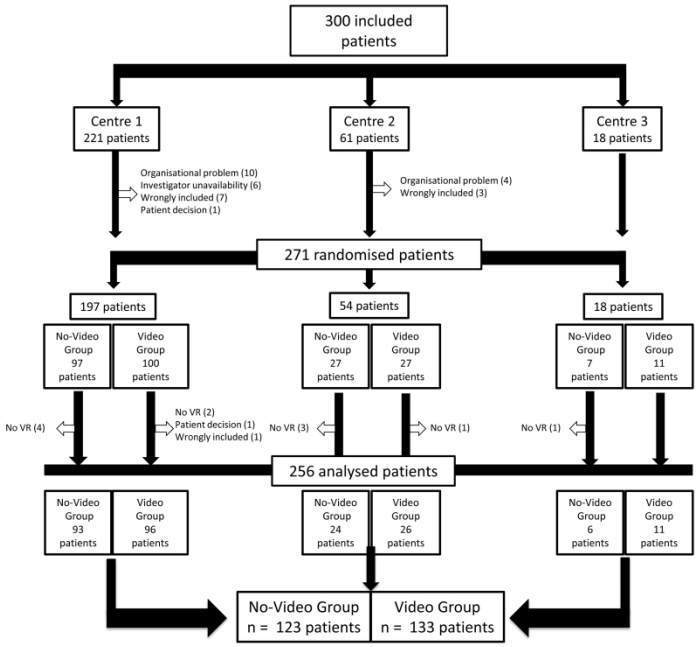

Figure 1

Figure 1

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Supplementary Table. Outcomes (type of variable and timeline of measurements)

	Type of variable	Timeline of the measurement
Primary outcome		
Required assistance by the additional person, yes	Categorical	Off line
Secondary outcomes		
Intubation		
Intubation Difficulty Scale, three classes	Categorical	
Number of attempts, four classes	Categorical	Off line
Number of operators, one/two	Categorical	Off line
Number of alternative techniques, none/one/two	Categorical	Off line
Cormack and Lehane grade, four classes	Categorical	On line
Abnormal traction force, yes	Categorical	On line
BURP, yes	Categorical	Off line
Vocal cord position (abduction), yes	Categorical	On line
Railroading the tube over a gum elastic bougie, yes	Categorical	Off line
Percentage of glottic opening score	Continuous	On line
Oesophageal Intubation, yes	Categorical	On line
Removing the cover, yes	Categorical	Off line
Time between the introduction of the McGrath and the third capnogram, seconds	Continuous	Off line
Ease of intubation, 0 (very easy) to 10 (very difficult),	Continuous	On line
BIS and haemodynamic variables		
BIS, absolute values,	Continuous	On line
Heart rate and arterial pressure, absolute values,	Continuous	On line
Intraoperative complications		
Oxygen desaturation (peripheral oxygen saturation < 92%), yes	Categorical	On line
Hypotension having required treatment, yes	Categorical	On line
Hypertension having required treatment, yes	Categorical	On line
Dental injury, yes	Categorical	On line
Postoperative complications		
Hoarseness, three grades	Categorical	Day1
Sore throat, three grades	Categorical	Day1
Serious adverse event, yes	Categorical	Day1

On line: variable recorded during the procedure

Off line: variable recorded a posteriori from the lecture of the video of the intubation sequence

Day1: postoperative visit at day1

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	2/56
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	3/56
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	6/56
	2b	Specific objectives or hypotheses	6/56
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	7/56
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	7/56
	4b	Settings and locations where the data were collected	7/56
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	8/56
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	10/56
	6b	Any changes to trial outcomes after the trial commenced, with reasons	NA
Sample size	7a	How sample size was determined	11/56
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	8/56
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	8/56
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	8/56
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	8/56
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	10/56

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	NA
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	11/56
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	NA
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	13/56
	14b	Why the trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Figure 1
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	13/56
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Tables
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	NA
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	14/56
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	17/56
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	17/56
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	15/56
Other information			
Registration	23	Registration number and name of trial registry	7/56
Protocol	24	Where the full trial protocol can be accessed, if available	On request
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	20/56

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.