British Journal of Anaesthesia **103 (3):** 440–5 (2009)
doi:10.1093/bja/aep191 Advance Access publication July 15, 2009

BJA

RESPIRATION AND THE AIRWAY

Randomized controlled trial of intubation with the McGrath® Series 5 videolaryngoscope by inexperienced anaesthetists

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Background. The McGrath® Series 5 videolaryngoscope might reduce the incidence of unexpected difficult tracheal intubation. If it also performs as well as a standard laryngoscope during uncomplicated intubations, there would be an argument for the McGrath® to become the laryngoscope of choice in higher risk settings, such as rapid sequence induction by inexperienced anaesthetists. Therefore, we compared the McGrath and the Macintosh laryngoscopes during routine tracheal intubation performed by inexperienced anaesthetists.

Methods. Single-blind randomized controlled trial with 120 adult patients allocated to intubation by first-year anaesthetic trainees, using a McGrath® or Macintosh laryngoscope. The primary outcome was time to intubation. Secondary outcomes were quality of view at laryngoscopy and evidence of differential learning between using the two laryngoscopes. A Cox proportional hazards model was used to determine the effect of the laryngoscopes on time to intubation.

Results. Duration of intubation was significantly longer ($P<0.001$) in the McGrath® group [median (IQR); 47.0 (39.0–60.0) *vs* 29.5 (23.0–36.8) s]. There were no significant differences in other outcomes, including grade of laryngoscopy view, visual confirmation of tube placement, number of laryngoscopies, or complications (oesophageal intubation, hypoxaemia, and airway trauma). There was no differential learning effect.

Conclusions. There were no advantages to using the McGrath® laryngoscope for uncomplicated tracheal intubation and duration of intubation was longer, so it should not be used as a first-line laryngoscope instrument by inexperienced anaesthetists.

Trials Registry: This trial was registered before onset of participation at ClinicalTrials.gov. Identification no. 08-so802-4. URL: http://www.clinicaltrials.gov/ct2/show/NCT00633867?term=08-so802-4&rank=1.

Br J Anaesth 2009; **103**: 440–5

Keywords: airway; equipment, laryngoscopes; larynx, laryngoscopy

Accepted for publication: June 2, 2009

Difficulty with or failure of tracheal intubation is more common among less experienced anaesthetists.[1 2] In addition, Confidential Enquiry data indicate that the inexperienced are more likely to encounter adverse outcomes (including patient death) as a result, particularly when working without direct supervision.[3]

A central part of using the Macintosh laryngoscope involves obtaining a direct view of the glottis, but newer, non-standard laryngoscopes permit a non-line-of-sight view of the glottis and could prove better devices for avoiding unexpected difficult intubation. If so, they would potentially be of most benefit in the hands of the least experienced. The McGrath® Series 5 is a self-contained videolaryngoscope (Aircraft Medical, Edinburgh, UK) which has been used successfully in the management of both normal and difficult airways.[4–7] It has functional simplicity and is intuitive to use for those trained in direct laryngoscopy. Therefore, we considered it potentially useful as a first-line laryngoscope by the inexperienced during a rapid sequence induction (RSI). However, a prerequisite

for any device that might be an alternative to or possible replacement for the Macintosh laryngoscope is that it must perform at least equally well during uncomplicated intubations. Otherwise, even if a difficult intubation was less likely, a large number of patients would be exposed to an increased risk in order to benefit only a few.

In this study, we examined the performance of the most current version of the McGrath® Series 5 compared with a Macintosh (Diamond Fibrelight, Penlon, Abingdon, UK) when used by inexperienced anaesthetists during routine laryngoscopy and tracheal intubation.

Methods

This was a pragmatic, single-blind, randomized controlled trial, approved by the North of Scotland Research Ethics Service, with written informed consent obtained from participating patients. Between February 2 and August 5, 2008, we studied 120 patients aged $\geq$18 yr, undergoing elective surgery, whose anaesthesia plan included routine oro-tracheal intubation under general anaesthesia performed by a first-year trainee anaesthetist and supervised by a senior colleague. Patients were excluded if other intubation techniques were planned or if RSI was indicated. Baseline data, including patient age, gender, weight, height, modified Mallampati score,[8] and arterial oxygen saturation while breathing air, were collected. Before each procedure, the capnograph gas sample delay time was measured (and this time was then subtracted from total recorded intubation time, to correct for the different sampling times between the capnographs used).

Patients were randomized to undergo intubation using either a McGrath® or a Macintosh laryngoscope. The randomization sequence was generated in advance by the study's statistical advisor. Each of the four participating anaesthetists (M.H., C.H., E.L., and I.S.) had their own sequence of 30 subjects equally allocated to the two laryngoscopes. Sequentially numbered opaque envelopes were used to conceal the sequence and were opened only on arrival of the patient in the anaesthetic room. Routine cardiorespiratory monitoring including pulse oximetry, non-invasive arterial pressure monitoring, ECG, and capnography was established before induction of anaesthesia as recommended by the Association of Anaesthetists of Great Britain and Ireland.[9] Being a pragmatic trial, other aspects of anaesthesia technique, including choice of drugs, were at the discretion of the anaesthetist providing patient care. All of the four anaesthetists who performed tracheal intubation had undergone between 6 and 12 months of anaesthesia training during the study. All had achieved the Royal College of Anaesthetists initial competency in general anaesthesia with tracheal intubation[10] and had also received training in use of the McGrath® laryngoscope. This followed a standard competency-based model, initially using a manikin followed by 10 successful intubations in clinical practice. A shaped stylet (Mallinckrodt satin slip intubating stylet) was inserted into the tracheal tube for intubations with the McGrath® laryngoscope because the view of the glottis is indirect. This practice is supported by the manufacturers and in the literature.[4 11] When a Macintosh laryngoscope was used, the use of a stylet or other intubation aid was at the discretion of the anaesthetist. Data during intubation were collected by an independent observer; the intubator was not informed of the time taken to achieve any intubations.

The primary endpoint was time to achieve tracheal intubation. This was defined as the time between the anaesthetist taking the laryngoscope in his hand until effective ventilation was initiated via the tracheal tube. Effective ventilation was taken as the first upward deflection on the capnograph after connection of the anaesthetic breathing system to the tracheal tube (corrected for the capnograph gas sample delay time). This definition was used because it was objective (particularly in the case of an obscured view of the glottis and uncertainty of tube placement), and it also reflects the duration of apnoea. If the trainee anaesthetist could not achieve tracheal intubation, the time taken until the procedure was abandoned or until taken over by a senior anaesthetist was recorded. Any decision to limit the attempts of the trainee anaesthetist to achieve tracheal intubation was at the discretion of the senior anaesthetist. An *a priori* definition of prolonged intubation was specified as one taking >70 s.

Other data collected were: best view during laryngoscopy (using Cormack and Lehane classification),[12] whether it was possible to see the tube pass through the vocal cords, the number of laryngoscopies required (defined as number of times the laryngoscope was removed from mouth then replaced), the initial location of the tube (either in trachea or in oesophagus), the incidence of hypoxaemia (defined as Sp_{O_2} <92%) between the start of intubation until 1 min after its completion, the presence and description of blood or trauma in the airway after intubation, and any deviations from the study protocol.

Sample size was based upon detecting a 15 s difference in mean time to intubation, which we considered the shortest to be clinically significant, in terms of risk of hypoxaemia. Using α=0.05 and β=0.2 for an experimental design incorporating two equal-sized groups and assuming an SD for time to intubate of 29 s (the longest found in the literature),[13] we estimated that 60 patients would be required per group. Categorical intubation variables were compared between the two groups using continuity corrected χ^2 tests or Fisher's exact tests. Intubation times were compared using the log-rank test, and the cumulative probability distribution was plotted. In order to examine whether the order in which the anaesthetists carried out the laryngoscopies had any effect on the time to completion by laryngoscope used, a Cox regression model was fitted adjusted for laryngoscope used and order of laryngoscopy. An interaction term was fitted between the laryngoscope and order

to see if order had an effect between the laryngoscopes used because this would indicate a differential learning effect between the two devices. SPSS 16.0 (SPSS Inc., Chicago, IL, USA) statistical software was used to perform statistical analysis.

Results

One hundred and twenty patients were randomized into the study, 30 by each of the four anaesthetists (Fig. 1). Both groups were comparable (Table 1), apart from a greater median age in the Macintosh group (60.5 *vs* 48.0 yr). All patients were successfully intubated by the anaesthetic trainee, as planned. All patients in the Macintosh group were intubated successfully, but in one patient in the McGrath® group, a Macintosh laryngoscope had to be used because of battery failure in the McGrath® during intubation. Time to intubation was also not recorded for this patient owing to an error with the stopwatch. The remaining 59 patients in this group were successfully intubated with the McGrath® laryngoscope and the times recorded.

Median time to achieve tracheal intubation was significantly longer in the McGrath® group (Table 2). Seven of the intubations using the McGrath® laryngoscope took longer than 70 s, compared with two with the Macintosh laryngoscope, but this was not statistically significant. The views obtained at laryngoscopy and outcome of intubation were similar between the groups (Table 2). Although more patients in the Macintosh group were found to have blood in their airway after extubation (Table 2), three of these patients had undergone surgery likely to account for this. There was a consistent delay in completion of tracheal intubation with the McGrath® laryngoscope compared with the Macintosh, as shown by the cumulative probability distribution (Fig. 2).

Using the Cox regression model, both type of laryngoscope and order of laryngoscopy were significant variables. The likelihood of finishing first using a McGrath was 0.28 times (95% CI 0.18, 0.42; $P<0.001$) that of the Macintosh. The hazard ratio for completion of intubation was 1.08 (95% CI 1.04, 1.13), meaning that the chance of completing intubation increased by 8% with each patient.

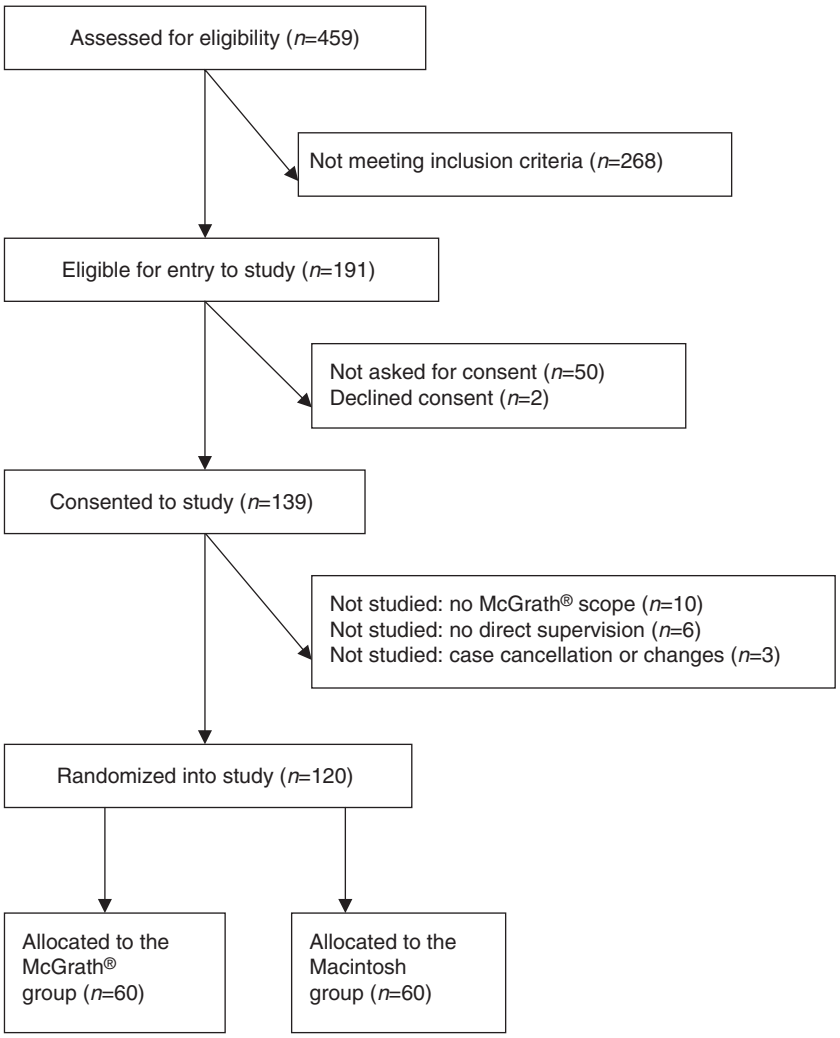

Fig 1 Flow diagram showing recruitment into study.

Table 1 Characteristics of patients entered into the study, by type of the laryngoscope used. Values are median (range) or number (%). *$P<0.05$

	Macintosh ($n=60$)	McGrath® ($n=60$)
Age (yr)	60.5 (21–84)	48.0 (21–84)*
Gender (M:F)	19:41	17:43
Body weight (kg)	69.8 (44.0–106.5)	71.0 (50.0–116.4)
Height (m)	1.64 (1.48–1.90)	1.66 (1.50–1.89)
BMI (kg m^{-2})	25.2 (17.3–47.2)	25.7 (16.1–39.5)
Mallampati score		
I	32 (53.3)	29 (48.3)
II	27 (45.0)	29 (48.3)
III	1 (1.7)	2 (3.3)
IV	0 (0.0)	0 (0.0)
Sp_{O_2} (breathing air) (%)	98.0 (94–100)	98.0 (92–100)

Table 2 Intubation variables. Values are median (range) or number (%). *$P<0.001$; †$P=0.07$. Grades 2–4 were combined to conduct continuity corrected χ^2 test. ‡One patient in the McGrath® group was intubated using a Macintosh laryngoscope because of equipment failure (see text). §$n=59$ because of failure in timing in the case where the McGrath® battery failed

	Macintosh ($n=60$)	McGrath® ($n=60$)
Intubations completed by trainee anaesthetist‡	60 (100)	60 (100)
Intubation time (s)	29.5 (15–121)	47.0 (25–202)*
Intubation time >70 s	2 (3.3)	7 (11.9)§
Cormack and Lehane grade		
1	47 (78)	55 (92)†
2	13 (22)	4 (7)
3	0 (0)	1 (1.7)
4	0 (0)	0 (0.0)
Tube seen to pass through cords	52 (93)	57 (95)
Requiring >1 laryngoscopy	1 (2)	3 (5)
Initial oesophageal intubation	0 (0)	0 (0)
Sp_{O_2} <92%	0 (0)	0 (0)
Trauma/blood in airway after intubation	8 (13.3)	3 (5.0)

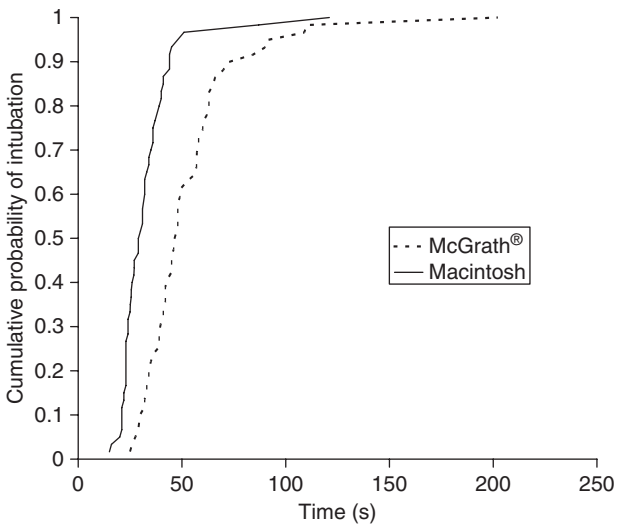

Fig 2 Cumulative probability of completion of tracheal intubation against time with the McGrath® and Macintosh laryngoscopes.

However, there was no significant interaction between type of laryngoscope used and order of laryngoscopy [hazard ratio 1.06 (95% CI 0.98, 1.15; $P=0.15$)], meaning that the order of laryngoscopy did not have a significant effect on the completion time between the two laryngoscopes. Any learning effect was therefore similar with either laryngoscope.

Several Macintosh laryngoscopes were used during the study, with no failures during use. Two McGrath® laryngoscopes were used and one failed once, because the operator had not replaced the battery as per manufacturer's instructions.

Discussion

Routine tracheal intubation with the McGrath® Series 5 videolaryngoscope by first-year trainee anaesthetists was slower than when using a Macintosh laryngoscope. The 17.5 s difference exceeded our *a priori* definition of a clinically significant delay of 15 s. The McGrath® would not therefore be an appropriate device to be used as a first-line instrument by this group during RSI. The cumulative probability of intubation curves for the two laryngoscopes are approximately parallel (Fig. 2), indicating that the difference in intubation was consistent across the different clinical cases encountered in the study.

As with all studies of this kind, it was impossible to blind the operator as to the laryngoscope being used. The study was designed in a deliberately pragmatic way to reflect clinical practice. Randomization was only performed after the patient was present in the anaesthetic room, and both laryngoscopes prepared for each patient in an effort to reduce risk of bias. This might have been reduced by delaying randomization to the last moment before intubation. We did not control induction technique or head position because these would vary in normal practice. We found a significant difference in intubation time, despite allowing for a wide variance in this in the power calculation, in order to reflect variation in clinical practice. Previous studies including intubation time as a variable have often defined this using time until the intubator declares the tracheal tube to be between the vocal cords,[14 15] whereas we used an upward deflection on the capnograph upon ventilation of the lungs via the tracheal tube. The advantage of our approach is that it removes some subjectivity and takes account of any occasion when the view of the glottis is obscured. It also accounts for any additional steps required before effective ventilation of the lungs. For example, because the McGrath® laryngoscope provides a non-line-of-sight view, the use of an intubation aid (stylet or bougie) is helpful to enable placement of the tracheal tube through the glottis[4] (we specified a stylet because this could be inserted and shaped before induction of anaesthesia). Removing the stylet increases the delay before ventilation can be established, but this will have been included by the use of this definition. When a Macintosh is used, the need for a stylet is variable; therefore, this decision was left to the individual performing intubation as would occur in

normal practice. This does lead to the possibility that the difference in time to achieve tracheal intubation between the two laryngoscopes is due to the extra time required to remove the stylet which was used routinely with the McGrath laryngoscope®. In an effort to quantify this time as a part of the intubation sequence, each of the trainee anaesthetists performed tracheal intubation with the McGrath laryngoscope® and a stylet 10 times upon an airway training manikin. Time taken to remove the stylet was recorded. This was defined as the time interval between releasing the tracheal tube with the intubating hand once the tube was placed within the trachea, and the stylet being free of the tube which was then free for connection to a breathing system. For all operators, this time was consistently <2.5 s. Therefore, it seems likely that the extra time incurred to remove the stylet does not account for the 17.5 s difference found in intubation times.

The trainee anaesthetists were more experienced with the Macintosh than the McGrath® at the start of the trial, which was a deliberate aspect of the design. The Macintosh is ubiquitously available and even if the McGrath® were to come into routine use for RSI, a trainee's experience with the Macintosh will still be highest during their early training. The training for the McGrath® followed a standard competency-based model, initially on a manikin, then in 10 successful uses in clinical practice. Under current training schemes, our experience is that each trainee encounters 10–12 supervised routine intubations per month, so the clinical experience specified was a realistic standard. If the difference in experience with the two laryngoscopes were significant, it would have been expected that a greater learning effect would be seen with one of the laryngoscopes. However, this was not the case.

Durability and reliability in repeated use are essential characteristics of clinical equipment. Although we found that the McGrath® laryngoscope generally performed well in this respect, our study was affected twice by inability to use it. On the first occasion, the screen image was lost during laryngoscopy. This was later found to be caused by failure to replace an exhausted battery. The manufacturer states a battery life of 2 h with a standard AA battery, and recommends replacement between each use. The second occasion was caused by damage to the rotating screen connection during cleaning by untrained personnel, despite it being designed to withstand significant stresses.[16] Although the McGrath® videolaryngoscope offers advantages as a stand-alone unit, without separate power units, screens, or cables, these events underline the importance of strictly following the manufacturer's guidance on handling, maintenance, and cleaning.

Videolaryngoscopy appears to have considerable promise in airway management[17] and also as a teaching tool.[18 19] This novel technology has been widely described, without finding a clear role in airway management strategies. In common with other videolaryngoscopes, the McGrath® laryngoscope has been most widely studied in the setting of anticipated difficult tracheal intubation.[5 6 20] One of the commonly cited advantages of videolaryngoscopy is an improved laryngeal view. In this study, the McGrath® laryngoscope was associated with both a greater number of Cormack and Lehane Grade 1 views of the larynx (55 *vs* 47) and more frequent visual confirmation of the tracheal tube passing through the vocal cords (57 *vs* 52) than the Macintosh (Table 2), although these differences were not statistically significant. Such differences may be greater, if the incidence of difficult intubations were higher. However, difficulty in tracheal intubation is frequently unanticipated and moreover is most frequently encountered by more inexperienced anaesthetists.

The Macintosh laryngoscope has not previously been compared with the McGrath® laryngoscope when used by those most likely to encounter unexpected difficulty with tracheal intubation. The results of this study suggest that the Macintosh remains the laryngoscope of choice for the first-line use by inexperienced anaesthetists.

Acknowledgements

We would like to thank John Townend for his assistance in initial statistical design of this study. The McGrath® laryngoscopes used in this study were purchased through charitable endowment funds administered by NHS Grampian.

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