Awake Fiberoptic or Awake Video Laryngoscopic Tracheal Intubation in Patients with Anticipated Difficult Airway Management

A Randomized Clinical Trial

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ABSTRACT

Background: Awake flexible fiberoptic intubation (FFI) is the gold standard for management of anticipated difficult tracheal intubation. The purpose of this study was to compare awake FFI to awake McGrath® video laryngoscope, (MVL), (Aircraft Medical, Edinburgh, Scotland, United Kingdom) intubation in patients with an anticipated difficult intubation. The authors examined the hypothesis that MVL intubation would be faster than FFI.

Methods: Ninety-three adult patients with anticipated difficult intubation were randomly allocated to awake FFI or awake MVL, patients were given glycopyrrolate, nasal oxygen, topical lidocaine orally, and a transtracheal injection of 100 mg lidocaine. Remifentanil infusion was administered intravenously to a Ramsay sedation score of 2–4. Time to tracheal intubation was recorded by independent assessors. The authors also recorded intubation success on the first attempt, investigators' evaluation of ease of the technique, and patients reported intubation-discomfort evaluated on a visual analog scale.

Results: Eighty-four patients were eligible for analysis. Time to tracheal intubation was median [interquartile range, IQR] 80 s [IQR 58–117] with FFI and 62 s [IQR 55–109] with MVL ($P = 0.17$). Intubation success on the first attempt was 79% *versus* 71% for FFI and MVL, respectively. The median visual analog scale score for ease of intubation was 2 (IQR 1–4) *versus* 1 (IQR 1–6) for FFI and MVL, respectively. The median visual analog scale score for patients' assessment of discomfort for both techniques was 2, FFI (IQR 0–3), MVL (IQR 0–4).

Conclusions: The authors found no difference in time to tracheal intubation between awake FFI and awake MVL intubation performed by experienced anesthesiologists in patients with anticipated difficult airway.

What We Already Know about This Topic

- Awake fiberoptic intubation is a gold standard technique for patients with anticipated difficult tracheal intubation. Video laryngoscopy provides better laryngeal view than conventional Macintosh direct laryngoscopy.

What This Article Tells Us That Is New

- This multicenter randomized controlled trial evidenced no difference of performance of awake tracheal intubation between flexible fiberscope and video laryngoscope.

DIFFICULT tracheal intubation is a cause of severe patient damage and death documented in several studies of closed claims, national audits, and patients' complaints.[1–5] Confirmed difficulties with previous airway management or a preoperative airway examination can assist anesthesiologists in a risk assessment of potential difficulties. Mallampati classification, head and neck mobility, mouth opening, the ability/inability of prognathism, body weight,

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and the thyromental distance are included in the simplified airway risk index (SARI).[6] Difficult airway algorithms recommend awake tracheal intubation as the gold standard for patients with at least one variable associated with a difficult airway.[7,8] The flexible fiberoptic endoscope has for many years been the preferred instrument in such situations, but the maintenance of the necessary psychomotor skills for fiberoptic intubation can be a significant problem. In this context, closed claims analysis has documented severe complications such as brain damage and death associated with anticipated difficult airway management and awake intubation.[2] Therefore, it is imperative to search for simple, reliable, safe, and effective intubation equipment.

The McGrath® Series 5 video laryngoscope (MVL), (Aircraft Medical, Edinburgh, Scotland, United Kingdom) is a new portable laryngoscope that is found useful in patients with a difficult laryngoscopy or intubation.[9]

The MVL can improve visualization of the glottic structures one to two grades using the Cormack-Lehane classification system compared with conventional laryngoscopy using a Macintosh® laryngoscope (Teleflex Medical Europe Ltd, Athlone, Ireland). Recently, awake tracheal intubation using video laryngoscopes has been described in case reports.[10] However, video laryngoscopes for awake intubation have not systematically been evaluated in a randomized clinical trial. The psychomotor skills needed for MVL intubation resembles those used with the traditional Macintosh laryngoscope. Consequently, the MVL may prove to be easier, faster, and safer to use in patients with anticipated difficult airway management. It is not yet known if the MVL can serve as a replacement for the flexible fiberoptic endoscope. Thus, we examined the hypothesis that awake MVL intubation would be faster than awake flexible fiberoptic intubation (FFI) in sedated spontaneously breathing patients with an anticipated difficult intubation scheduled for oral intubation. We also compared awake MVL with awake FFI with respect to intubation success on the first attempt, anesthesiologists' assessment of ease of the technique, and patients' reported discomfort with the procedure.

Materials and Methods

This multicenter trial was conducted in the period from January 2009 until June 2011 in three departments of anesthesiology at Copenhagen University Hospitals, Hillerød, Herlev and Rigshospitalet's Juliane Marie Centre and approved by the Danish local Committee on Biomedical Research Ethics, Region Hovedstaden, Hillerød, Denmark (File number H-C 2008–032). All patients provided written informed consent. The study was performed according to the Declaration of Helsinki.

Adult, elective, American Society of Anesthesiologists class I-III patients with an anticipated difficult laryngoscopy or intubation and a SARI score ≥4, requiring general anesthesia including oral intubation, were included. Patients were scheduled for gynecologic, abdominal, urologic, and ear, nose, and throat surgical procedures.

Patients scheduled for awake fiberoptic intubation were seen by one of six investigators for inclusion in the study. All investigators are consultants and have employments including on-duty services and are consequently not present during the daytime on all weekdays. Eligible patients were therefore elective patients who were having awake intubations performed when investigators were present during the daytime. Investigators were thoroughly trained in difficult airway management and also specifically experienced in using FFI and MVL. Laryngoscopy and intubation were performed on sedated patients with preserved spontaneous breathing to avoid situations with difficult mask ventilation.

Exclusion criteria were age younger than 18 yr, American Society of Anesthesiologists class IV or V, mouth opening less than 15 mm, poor dental status, surgeon request of nasal intubation as well as contraindication for transtracheal injection (tumor immediately below the cricothyroid membrane, inability to identify the cricothyroid membrane, or infection).

Patients were informed and consent obtained by one of six investigators at the preoperative evaluation the day or a few days before surgery after an extensive airway examination with anticipated difficult laryngoscopy or intubation and a SARI score ≥4. The SARI score as described by el-Ganzouri[6] consists of information regarding a previous difficult airway, the Mallampati classification, mobility of the neck, mouth opening, prognathism ability, the thyromental distance, and body weight. In this study, a modified SARI score was applied as body mass index (kg/m^2) was substituted for weight as a risk factor for difficult intubation.[11]

Randomization into two groups, FFI and MVL intubation was conducted in the operating theater immediately before anesthesia induction. If the first technique failed after three attempts, then a change to the other technique took place. Endotracheal tube and size were chosen before randomization.

For randomization we used variable block-size randomization, a computer generated random numbers, the first block included 20 patients, and the second block 15 patients for each of the three centers. Information regarding group and number assignment was kept in sealed envelopes. An envelope was drawn in the presence of other staff immediately before the patient arrived in the operating theater. It was not possible for patients, investigators, or care providers to be blinded for treatment allocation.

The sniffing position was used for patients randomized for MVL, whereas patient positioning used for FFI was left to the discretion of the investigator.

In case the first technique failed after three attempts, then optimal patient positioning was secured before an attempt at tracheal intubation with the alternative device.

Glycopyrrolate 4–5 μg/kg (maximum dose 0.4 mg) was administered after placement of an intravenous catheter.

Through a nasal catheter 2–4 l of oxygen was administered and sedation was provided with a continuous remifentanil infusion of 0.1–0.15 $\mu g \cdot kg^{-1} \cdot min^{-1}$ using ideal body weight; (height in cm—100 and 105 for men and women, respectively).

If needed, a remifentanil bolus dose of 0.75 μg/kg or a propofol bolus dose of 10–20 mg could be administered intravenously. We aimed for a patient sedation equivalent to a Ramsay score of 2–4.[12]

For topical analgesia we used a lidocaine 10% metered spray, delivering 10 mg per dose with the lidocaine applied directly on the mucosa of the oropharynx spraying from the tip to the back of the tongue. Patients were asked to keep the lidocaine in the mouth as long as possible and gargle before swallowing. This procedure was repeated. In addition, a transtracheal injection of 50–100 mg lidocaine in a maximum volume of 2 ml was administered. A maximum dose of 3 mg/kg lidocaine was allowed to avoid toxic reactions. Analgesia was provided to avoid coughing and to achieve acceptance of the endotracheal tube. The sufficiency of the pharyngeal and laryngeal analgesia was evaluated by the patients' acceptance of an oral airway lubricated with lidocaine jelly 2% placed 1–2 min before an attempt of intubation. All intubations were performed by one of six investigators experienced in difficult airway management and in using both devices. Patients were monitored with pulse oximetry, electrocardiogram, noninvasive blood pressure, and capnometry. Patients were hereafter orally intubated with either the flexible fiberscope or the MVL. In case of FFI, a Berman II intubation airway, (Vital Signs, Sussex, Village Barnham, United Kingdom), size 8 or 9 was used for women and size 9 or 10 for men. An assistant performed jaw thrust to expand the oropharyngeal space. At intubation with the MVL, a stylet was used to bend the tip of the tube 80–110° into the shape of a hockey stick. Endotracheal tube placement was confirmed with capnography and bilateral auscultation. The primary endpoint was time to tracheal intubation (TTI) confirmed by capnography measured from the advancement of the flexible fiberscope or the MVL behind the teeth until the appearance of a capnograhy curve. An independent observer assessed TTI with a stopwatch.

We also recorded intubation success on the first attempt, number of intubation attempts, number of esophageal intubations and failure of technique, glottic visualization using the Cormack-Lehane classification with an extra class included for the achievement of blind intubation with no view over glottic structures, the anesthesiologists' evaluation of the ease of the technique using a visual analog scale (VAS) 0–10, as well as potential complications, *e.g.*, desaturation less than 90%, tooth damage, and any signs of soft-tissue damage. Patients' potential discomfort during the procedure was registered at discharge from the recovery department on a VAS score, with 0 expressing no discomfort at all and 10 for worst possible discomfort. All authors collected data.

Statistical Analysis

With a SD of 50 s and clinical relevant difference of 30 s between the two techniques, awake FFI and awake MVL intubation, a significance level of 5%, and a power of 80%, we calculated the necessary sample size to 88 patients. Data are expressed as median and range or interquartile range (IQR) unless specified. We used nonparametric statistic Mann–Whitney U test for comparison of the median values. Fisher exact test was used at comparisons of percentages, all comparisons were two-sided and a P value less than 0.05 was considered statistically significant. Statistical analyses were performed with the computer software, SAS statistical software, Version 9.1 (SAS Institute, Cary, NC).

Results

A total of 93 patients were enrolled in the study (fig. 1). Nine patients were excluded after randomization, two patients in the MVL group due to lack of cooperation during the procedure. In seven patients from both groups transtracheal li-

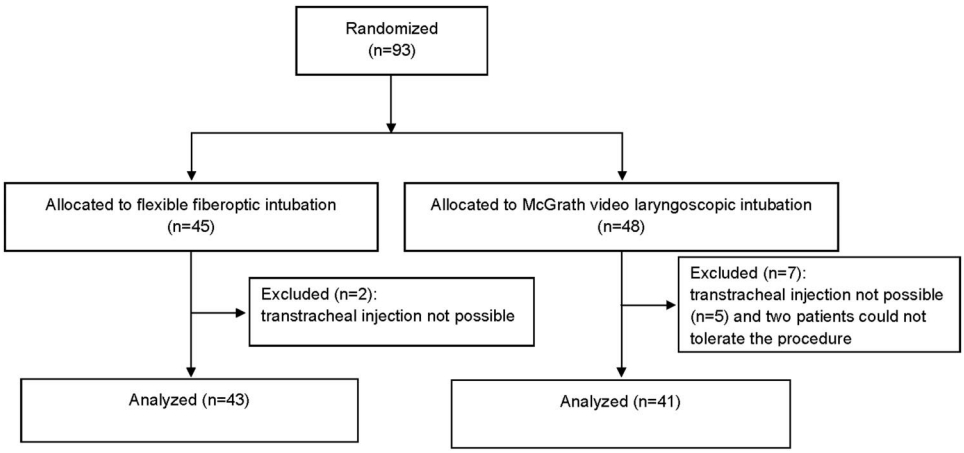

Fig. 1. Flow diagram of patient distribution. McGrath® video laryngoscope, Aircraft Medical, Edinburgh, Scotland, United Kingdom.

Table 1. Demographic Data of the Patients

	Flexible Fiberoptic Intubation n = 45	McGrath® Video Laryngoscope Intubation n = 48
Sex (male/female)	51/49	52/48
Age, (yr)	64 [45–83]	65.5 [42–85]
ASA (%)		
1	4 (8.9)	6 (12.5)
2	28 (62.2)	24 (50)
3	13 (28.9)	18 (37.5)
Body mass index (kg/m^2) median [range]	31 [14–57]	29 [18–47]

Values are numbers (percent), or median [range]. (McGrath® video laryngoscope, Aircraft Medical, Edinburgh, Scotland, United Kingdom.)

ASA = American Society of Anesthesiologists class.

docaine injection was impossible as the cricothyroid membrane could not be identified, due to previous neck radiation therapy (2 patients), neck obesity (2 patients), enlargement of the thyroid gland (1 patient) and lateral tracheal displacement (2 patients). Consequently, 84 patients were eligible for analysis; 43 in the FFI group and 41 in the MVL group (fig. 1).

There were no demographic differences between the two groups (table 1). The median modified SARI score was 6 [range 4–10] in both groups (table 2). A total of 42 patients had a previous general anesthesia with a documented difficult laryngoscopy or intubation. In five patients, there was no anesthesia record, but the preoperative interview indicated a suspicion of a difficult laryngoscopy/intubation. In six patients there was documentation of previous difficult mask ventilation.

The median TTI with the flexible fiberscope was 80 s (IQR 58–117), and with MVL 62 s (IQR 55–109), (P = 0.17) (table 3), the difference between the mean values of TTI was 2.2 s [95% CI, −40.0; 44.5 s] (table 3). Intubation success on the first attempt was 79% *versus* 71% for FFI and MVL intubation, respectively. More than one attempt was required in nine patients with the FFI and in 12 patients with MVL intubation. In one patient, three failed attempts with the FFI were followed by a successful MVL intubation. In nine FFI and five MVL patients, oxygen saturation fell below 90%. There was one esophageal intubation in the FFI group and two in the MVL group. Using FFI a total of 34 patients had a Cormack-Lehane score of 1 or 2 and with MVL, the same applied to 37 patients (table 3).

Investigators found both techniques easy to perform (P = 1.0), median VAS for FFI was 2 (IQR 1–4) and median VAS for MVL was 1 (IQR 1–6), and patient discomfort during the procedure was low and equal in both groups, median VAS for FFI 0 (IQR 0–3) and median VAS for MVL 2 (IQR 0–4) (P = 0.55) (table 3). Five patients, three in the FFI and two in the MVL group, had minor bleeding during the procedure requiring no further treatment (table 4). The Ramsay

Table 2. Airway Assessment and Body Mass Index

	Flexible Fiberoptic Intubation n = 45		McGrath® Video Laryngoscope Intubation n = 48	
	n	%	n	%
Mouth opening				
≥4 cm	24	53.3	32	66.7
<4 cm	21	46.7	16	33.3
Thyromental distance				
≥6.5 cm	31	68.9	33	68.8
6–6.5 cm	8	17.9	11	22.9
<6.0 cm	6	13.3	4	8.3
Mallampati class				
1	1	2.2	3	6.2
2	4	8.9	15	31.3
3	40	88.9	30	62.5
Neck movement				
≥90°	17	37.8	18	37.5
80–90°	11	24.4	9	18.8
<80°	17	37.8	21	43.7
Prognathism ability				
Yes	32	71.1	31	64.6
No	13	28.9	17	35.4
BMI				
<25	9	20.0	9	18.8
25–30	10	22.2	19	39.6
>30	26	57.8	20	41.6
History of difficult intubation, No	26	57.8	20	41.7
Questionable	1	2.2	4	8.3
Yes	18	40.0	24	50.0
History of difficult mask ventilation	5	11.1	1	2
Modified SARI [range]	6	[4–10]	6	[4–10]

McGrath® video laryngoscope, Aircraft Medical, Edinburgh, Scotland, United Kingdom.

BMI = body mass index in kg/m^2; SARI = simplified airway risk index. Modified SARI; BMI substitute weight.

sedation score and amount of remifentanil used were similar in the two groups (table 4).

Discussion

We found no difference in TTI between awake FFI and awake MVL when experienced investigators performed the intubations. Most patients were intubated using only one attempt. Only one patient in the FFI group could not be intubated using this technique and was shifted to a successful MVL intubation. Investigators evaluated both techniques as easy to perform, and patient discomfort during both procedures was low.

The strength of our study is that we only used trained difficult airway management investigators, who also were

Table 3. Comparison of Time to Successful Tracheal Intubation, Number of Attempts, Change of Technique, Laryngoscopic View, Patient Desaturation, Visual Analog Scale for Anesthesiologists Perceived Ease with Intubation and Patient Assessment of Discomfort

	Flexible Fiberoptic Intubation (n = 43)	McGrath® VL Intubation (n = 41)	*P* Value
Time to tracheal intubation, s			
Median [range]	80 [33–424]	62 [20–678]	0.17*
[IQR range]	[58–117]	[55–109]	—
Number of attempts, (%)			
1	34 (79.1)	29 (70.7)	0.64
2	8 (18.6)	10 (24.4)	—
3	1 (2.3)	2 (4.9)	—
Esophageal intubation	1 (2.3)	2 (4.9)	—
Change of technique, (%)	1 (2.3)	0 (0)	—
Cormach-Lehane score, (%)	n = 42	—	—
1	22 (52.4)	20 (48.8)	—
2	12 (28.6)	17 (41.5)	—
3	5 (11.9)	3 (7.3)	—
4	2 (4.8)	1 (2.4)	—
5	1 (2.4)	0 (0)	—
Number of patients with desaturation <90%, (%)	9 (20.9)	5 (12.2)	—
Duration of desaturation, s			
Median [range]	0 [0–120]	0 [0–240]	0.19
[IQR range]	[0–0]	[0–0]	
Anesthesiologists assessment of ease of procedure, VAS			
Median [range]	2 [0–10]	1 [0–9]	1.0
[IQR range]	[1–4]	[1–6]	
Patientś assessment of discomfort, VAS	n = 42	n = 41	0.55
Median [range]	2 [0–6]	2 [0–10]	—
[IQR range]	[0–3]	[0–4]	—

McGrath® video laryngoscope, Aircraft Medical, Edinburgh, Scotland, United Kingdom.

* The difference between the mean time to tracheal intubation values 2.2 s (95% CI, −40; 44, 5 s).

IQR = interquartile range; VAS = visual analog scale.

trained in FFI and MVL intubation. Thereby, we examined the difference between the two intubation techniques and not the differences between different intubators with varying levels of intubation skills. However, this also has the implication that the results of this study may not be applicable for less skilled anesthesiologists. Awake intubation is a high-risk procedure associated with severe complications such as brain damage and death. In accordance with these findings, it is necessary to analyze which specific devices are the most appropriate for difficult airway management.[13]

Two previously published studies have compared awake FFI with the Bullard laryngoscope[14] and the lighted intubating stylet[15] in patients with cervical spine disease. Both studies using trained investigators found significant faster intubation times with the alternative instrument. The studies included 17 patients and 32 patients, respectively. The results of these studies may not be directly transferrable to the current study because the studied patient populations only had one variable associated with an anticipated difficult airway in contrast to our patient population.

We substituted weight with body mass index in the SARI score coherent to the results of a previous study, where body mass index was found to be a better measure than weight as a risk factor for difficult intubation.[11]

There are limitations in our study. It was not possible to blind investigators and patients to the technique. Consequently, we cannot rule out the possibility of biases in both patients and investigators in the comparisons between the two intubation techniques. All of our patients were scheduled for elective procedures, thus excluding patients with upper airway emergencies as well as the stress and complex crisis resource management factors inherent in emergency situations. The wide variability in time to tracheal intubation in both groups reflects the fact that the SARI score only describes some of the difficulties encountered during difficult airway management. In daily clinical practice, the pharyngeal and laryngeal anatomy of difficult airway patients can vary substantially and sometimes it is very difficult to obtain a clear view of the glottic structures. Therefore, our study may have had insufficient statistical power to demonstrate a difference between the techniques. However, the 95% CI for the differences between the mean intubation time values indicate that the true difference between awake FFI and awake MVL is no more than 40 s.

Table 4. Ramsay Sedation Score, Remifentanil and Propofol Requirements, and Complications during the Intubation

	Flexible Fiberoptic Intubation n = 43	McGrath® Video Laryngoscope Intubation n = 43
Ramsay sedation score*, no. (%)		
2	18 (41.8)	15 (36.6)
3	14 (32.6)	24 (58.6)
4	11 (25.6)	1 (2.4)
5	0 (0)	1 (2.4)
Amount of remifentanil, μg/kg/min of IBW, median [range]	0.12 [0.35–0.20]	0.13 [0.07–0.30]
Propofol bolus, mg, median [range]	0 [0–60]	0 [0–80]
Complications, bleeding	3 (7.0)	2 (4.7)
Dental trauma	0 (0)	0 (0)

McGrath® video laryngoscope, Aircraft Medical, Edinburgh, Scotland, United Kingdom.

* Sedation score by Ramsay.[11]

IBW = ideal body weight.

We aimed for detecting a difference in TTI of 30 s. Whether this difference is truly relevant can certainly be debated. In our assumptions we have considered an anxious patient in respiratory distress perhaps also at risk of aspiration with the possibility of losing a patent airway. In such a patient a reduction in airway instrumentation time may be beneficial. Whether the difference in TTI is no more than 30 or 40 s is most likely without clinical importance.

Intubation success rate on the first attempt would be an interesting outcome parameter, but a study with a significance level of 5% and a power of 80% would require a sample size of 1,000 patients to detect a difference between 79% and 71% success rate in intubation on the first attempt using awake FFI or awake MVL.

Because difficult intubation occurs in a maximum of 5% in our adult population, we consider such a trial impossible.

We used the Cormack-Lehane classification for quantifying the view of the glottic structures during both awake FFI and awake MVL, although this classification is used in conjunction with direct laryngoscopy using the Macintosh laryngoscope. This classification was applied because no other validated system is available for estimation of investigators visualization of the laryngeal structures.

We required a uniform topical and transtracheal analgesia in both study groups.

Awake MVL intubation may not prove as easy in using the "spray as you go" technique, because insertion of the MVL blade causes pressure on the tongue and on the laryngeal structures, thereby probably creating a greater degree of patient discomfort compared with introducing the flexible fiberscope and secondly applying the "spray as you go" analgesia.

A depiction of the hemodynamic response to the intubation may have added to the description of patient comfort. We recorded noninvasive blood pressure and pulse every 5 min. Most of our patients received tracheal intubation within 5 min. In addition, our studied patient population ranging from American Society of Anesthesiologists class I-III is heterogeneous with some of the patients being treated with antihypertensive medication. Therefore, we do not consider the design of our study to be sufficient to answer the question regarding the hemodynamic response to intubation.

Patient discomfort during both procedures was low. Despite avoiding benzodiazepines for sedation, we cannot reject that patients may have had problems with recalling the intubation procedure correctly.

Although awake MVL intubation was not found to be faster than awake FFI in patients with anticipated difficult airway, this technique proved a valid alternative to FFI. This could be valuable in the management of the difficult airway. FFI is a difficult technique to learn and master, and if rarely used, competence is difficult to maintain. Proficiency in difficult airway management is determined not only by mastering one technique as patients with difficult airway are a heterogeneous patient population where mastering several techniques may prove useful in solving potential difficulties. On the other hand, competence with difficult airway equipment is essential for intubation success with the implication that only a limited number of different devices can be introduced into a local difficult airway guideline.

Authors have found a steep learning curve with the MVL in novice users, with a success rate of more than 90% in fewer than six attempts in a simulated normal airway.[16] Therefore, inexperienced users may find awake MVL intubation easier than awake FFI in patients with a difficult airway. The MVL intubation has been described as a rescue intubation technique in unanticipated difficult airway management and has also been used in presented case series for anticipated difficult airway management.[17] Video laryngoscopes, in general, are currently introduced into difficult airway algorithms.[18] However, to our knowledge no previous study has compared FFI with MVL for awake intubation.

Measuring time as an endpoint for intubation success is a surrogate parameter, but inherent in this "endpoint" is information regarding the difficulty of the technique. Naturally, it is much more important that the intubation is achieved without causing patient harm, but analyzing patient complications to FFI or MVL would imply studying a much larger patient population.

International guidelines recommend awake intubation with preserved spontaneous breathing in patients with anticipated difficult airways and do not distinguish between anticipated difficult mask ventilation and anticipated difficult laryngoscopy/intubation. One could advocate for merely securing the difficult airway after the induction of general an-

esthesia, because mask ventilation will be difficult in only a minority of patients. However, the problem is to identify patients with difficult mask ventilation correctly. Predictors for a difficult laryngoscopy and a difficult mask ventilation are somewhat overlapping, *e.g.*, in the SARI score with Mallampati and weight being predictors for both situations. In addition, predictors for difficult airway management unfortunately have low negative predictive values.

A contraindication for FFI is inexperience in using the technique. MVL intubation and the skills needed for this procedure resembles those needed for Macintosh intubation. However, there are also certain distinct differences important for intubation success. Future studies are necessary to investigate if inexperienced users will find MVL intubation in difficult airway patients easier than FFI.

In conclusion, we found no significant difference in time to awake tracheal intubation using experienced investigators with the McGrath® Series 5 video laryngoscope compared with the flexible fiberoptic endoscope in sedated spontaneously breathing difficult airway patients. Awake MVL intubation seems as a potential alternative to awake FFI.

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