

Original Article

Impact of direct laryngoscopy vs. videolaryngoscopy on signal quality of recurrent laryngeal nerve monitoring in thyroid surgery: a randomised parallel group trial

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Summary

In thyroid surgery, intra-operative neuromonitoring signals of the recurrent laryngeal nerve can be detected by surface electrodes on a tracheal tube positioned at the vocal fold level. The incidence of difficult tracheal intubation in patients undergoing thyroidectomy for nodular goitre ranges from 5.3% to 20.5%. The aim of this study was to compare videolaryngoscopy with conventional direct laryngoscopy as methods for proper placement of the surface electrode to prevent insufficient intra-operative nerve signal quality. In this prospective randomised trial, adult patients requiring tracheal intubation during thyroid surgery were randomly allocated to two groups of C-MAC[®] (Macintosh style blade) videolaryngoscope or direct laryngoscopy using the Macintosh laryngoscope. Primary outcome was the incidence of insufficient signal electromyogram amplitude level ($< 500 \mu\text{V}$) after successful tracheal intubation. A total of 260 (130 per group) participants were analysed. An insufficient signal was more frequent with direct laryngoscopy (35/130, 27%), compared with C-MAC (12/130, 9%, $p < 0.001$). First-pass tracheal intubation success rate was lower with direct laryngoscopy (86/130 (66%)) compared with the C-MAC (125/130 (96%)) ($p < 0.0001$). Cormack and Lehane grade ≥ 3 was observed more frequently with direct laryngoscopy (16/130 (12%)), compared with the C-MAC (0/130, (0%)) ($p < 0.0001$). The results suggest that videolaryngoscopy has an impact on the quality of the initial intra-operative neuromonitoring signal in patients undergoing thyroid surgery, and this technique can provide optimised surface electrode positioning.

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Introduction

Globally, elective thyroid surgery is one of the most frequently performed interventions in the field of endocrine surgery [1–4]. The incidence of difficult laryngoscopy has been estimated at between 5.8% and 20.5% during thyroid surgery [3–7]. In addition, a recent multicentre observational study illustrated that 35.3% (95%CI 14.2–61.7%) of airway problems were associated with acute or chronic diseases localised in the head, neck or trachea [8].

The gold standard for intra-operative neuromonitoring of the recurrent laryngeal nerve requires recording of electromyography signals at the vocal fold level by tracheal tube-based surface electrodes [9–12]. However, to achieve an adequate electromyography signal (>500 μ V), it is important to place the tracheal tube-based surface electrodes under visual control by laryngoscopy to ensure that the electrodes are correctly positioned at the vocal fold level [11–13].

In some patients, the relative position between the exposed surface electrodes and vocal cords may not be clearly identified because of the poor view under direct laryngoscopy [3–5]. Videolaryngoscopy is associated with a better glottic view [12–18]. Currently, there is a lack of evidence as to whether videolaryngoscopy facilitates improved intra-operative neuromonitoring through an optimised glottic view in patients undergoing elective thyroid surgery with normal airways.

Because of the known advantages of videolaryngoscopy, we hypothesised that using the C-MAC[®] videolaryngoscope (Karl Storz[®], Tuttlingen, Germany) would decrease the frequency of insufficient initial electromyography signal compared with direct laryngoscopy to prevent vocal cord palsy. The aim of the study was to evaluate whether the use of the C-MAC improved intra-operative neuromonitoring by optimised placement of the tracheal tube electrode compared with direct laryngoscopy in elective thyroid surgical patients with an expected normal airway undergoing general anaesthesia.

Methods

This study was an open-label, patient-blinded, randomised controlled trial performed at a tertiary hospital between January 2017 and February 2019. It was conducted in adherence to the current version of the Declaration of Helsinki and good clinical practice guidelines. Before participant recruitment, local ethics committee approval was obtained from the Medical Association of the State of Rhineland Palatine, Germany. Written informed consent was obtained from all participants.

Eligible patients were those aged > 18 y, scheduled for elective thyroid surgery under general anaesthesia, requiring tracheal intubation (and mechanical ventilation of their lungs) via a tracheal tube. Patients were not studied if they had an anticipated difficult airway (airway difficulty score > 8 [18]); ASA physical status 4; BMI \geq 40 kg.m⁻²; an increased risk for pulmonary aspiration; or were pregnant or breastfeeding.

The C-MAC videolaryngoscope (Macintosh style blade) and a standard laryngoscope (HEINE Macintosh classic, Herrsching, Germany) with a size 3 or 4 Macintosh blade (according to the anaesthetist's preference) were used in this trial.

The expertise of the participating anaesthetists ranged from novice (residents with 1–5 years of anaesthesia experience) to consultant anaesthetists. All anaesthetists received hands-on training and theoretical introduction to the use of the C-MAC and correct placement of the tracheal tube electrode. In both groups, participants were monitored using ECG, oxygen saturation (S_pO₂) and arterial blood pressure (non-invasive or invasive as appropriate). Participants were randomly allocated to the C-MAC or direct laryngoscopy group for tracheal intubation. A randomisation sequence (single sequence of random assignments) was computer generated (QuickCalcs, GraphPad[®] Software, La Jolla, CA, USA) and distributed by a research assistant who was not involved in participant recruitment. Randomisations were re-used to allow a complete sample size in case of participants excluded from analysis after initial allocation.

After sufficient pre-oxygenation (end-tidal O₂ > 90%), general anaesthesia was induced with sufentanil (0.2–0.5 μ g.kg⁻¹) and propofol (2–3 mg.kg⁻¹), and anaesthesia was maintained with either propofol infusion or volatile anaesthetics. Laryngoscopy was attempted after administration of a sufficient dose of a neuromuscular blocking drug (mivacurium 0.2 mg.kg⁻¹; or succinylcholine 1–2 mg.kg⁻¹) and sufficient paralysis when the train-of-four count was 0/4. External laryngeal manipulation could be used to improve the view of the glottis. The size of the tracheal tube (7.0–8.5 internal diameter) was chosen according to the anaesthetist's preference based on patient assessment. In the C-MAC group, a malleable stylet with a 90° 8 cm from the distal tip was used [19]. In the direct laryngoscopy group, we employed no stylet for the first intubation attempt. For intra-operative neuromonitoring, we used a standard surface tracheal tube electrode (Inomed[®] Medizintechnik, Emmendingen, Germany).

A successful laryngoscopy attempt was defined if the tracheal tube was placed with a single blade insertion within

120 s [20]. Any manipulation/retraction or repositioning of the laryngoscope at the laryngeal level was defined as an additional attempt. Appropriate tracheal tube placement was confirmed with waveform capnography. A tracheal intubation attempt was defined as an introduction of the laryngoscope blade into the mouth and its removal regardless of whether a tracheal tube was successfully inserted. A total of two laryngoscopy attempts with the same device was allowed in accordance with clinical standards [21, 22]. An additional individual, not involved in patient care, was present during induction of anaesthesia to record the study parameters, although they were not blinded to group assignment. All participants received a pre-operative and postoperative video-recording of vocal cord movement with flexible fibre videolaryngoscopy assessed for detecting vocal cord palsy and intubation injuries. This is a part of routine care in thyroid surgery at our institution.

The primary outcome was the incidence of insufficient electromyography signal, defined as an initial electromyography amplitude level of $< 500 \mu\text{V}$ (which in the course of the surgical operation was optimised to $> 500 \mu\text{V}$), using the C-MAC or direct laryngoscopy [9]. The $500 \mu\text{V}$ threshold was chosen in accordance with current studies and guidelines as necessary for effective intra-operative monitoring. Secondary outcome measures were: overall success rate; elapsed time to view; elapsed time to tracheal tube placement; failures/crossovers to other rescue techniques; use of external laryngeal manipulation; glottic view using Cormack and Lehane grading [23]; percentage of glottic opening score; intubation difficulty score [24]; and complications (e.g. dental injury, lip lesions, intubation granuloma). In a subgroup analysis, the influence of anaesthetic experience on insufficient signal and first-pass tracheal intubation success rate was evaluated.

Since there were no previous data on the primary outcome measure, we assumed (based on the optimised glottic visualisation and associated placement of the tracheal tube electrode) a higher quality of intra-operative neuromonitoring using the C-MAC. The study was conducted based on the assumption that a difference in probability of correct placement of the tracheal tube electrode by at least 10% between the two groups was clinically relevant. The sample size was determined by assuming that the baseline probability for correct placement was at least 50% with direct laryngoscopy. An overall significance level of 5% was chosen. As two subgroup analyses (e.g. comparison of first-pass tracheal intubation success rate and anaesthetic experience) were planned, individual tests of the primary hypotheses were performed at the 1.67% significance level. In 260 patients,

an increase in the proportion of participants with an adequate electromyography signal from 50% to 60% was demonstrated with a power of 90% at the 1.67% significance level; an increase of only 4% was still demonstrated with a power of 80%. We performed intention-to-treat analysis according to randomisation. Binary data were analysed using chi-square or Fisher's exact test. The Kruskal–Wallis test was used for ordinal data. For continuous data, we tested for normal distribution using Q–Q plots and Shapiro–Wilk test. An independent sample Kruskal–Wallis test was used for comparison of more than two groups of non-continuous data. An unpaired Student's t-test was used for the comparison of two groups of continuous data. Logistic regression with pairwise comparisons and Bonferroni–Holm corrections were used for post-hoc comparisons of statistically significant results.

Statistical analysis was carried out using SPSS® 9.4 (SAS Institute Inc., Cary, NC, USA). To test whether anaesthetists' experience influenced the incidence of insufficient initial electromyography signal, a logistic regression model was calculated in which the interaction of the type of laryngoscope with the anaesthetists' experience was included in addition to the main effects.

Results

In total, 320 patients were assessed for eligibility and 267 were included in the full analysis set (Fig. 1). Seven patients were excluded after allocation because they failed to meet the inclusion criteria (four were classified as ASA physical status 4 and three had a predicted difficult airway with an airway difficulty score ≥ 9). Thus, a total of 260 patients (130 in each group) were randomly allocated to direct laryngoscopy and C-MAC, respectively. Patient baseline characteristics, thyroid pathology and anaesthetists' characteristics were comparable between groups (Table 1).

Primary and secondary outcomes are reported in Table 2. The primary outcome of an inadequate electromyogram signal was achieved in 35/130 (27%) participants in the direct laryngoscopy group compared with 12/130 (9%) in the C-MAC group ($p < 0.001$). Malpositioning of tracheal tubes was corrected by the surgeon performing recurrent laryngeal nerve stimulation, while the anaesthetist adjusted the tracheal tube in 22/35 (63%) participants in the direct laryngoscopy group and 10/25 (40%) in the C-MAC group. When residents performed the placement of the tracheal tube electrode, insufficient signal was more frequent in the direct laryngoscopy group (24/95 (25%)), compared with 9/88 (10%) in the C-MAC group ($p = 0.012$). When consultants positioned the tracheal tube electrode, insufficient signal was also more

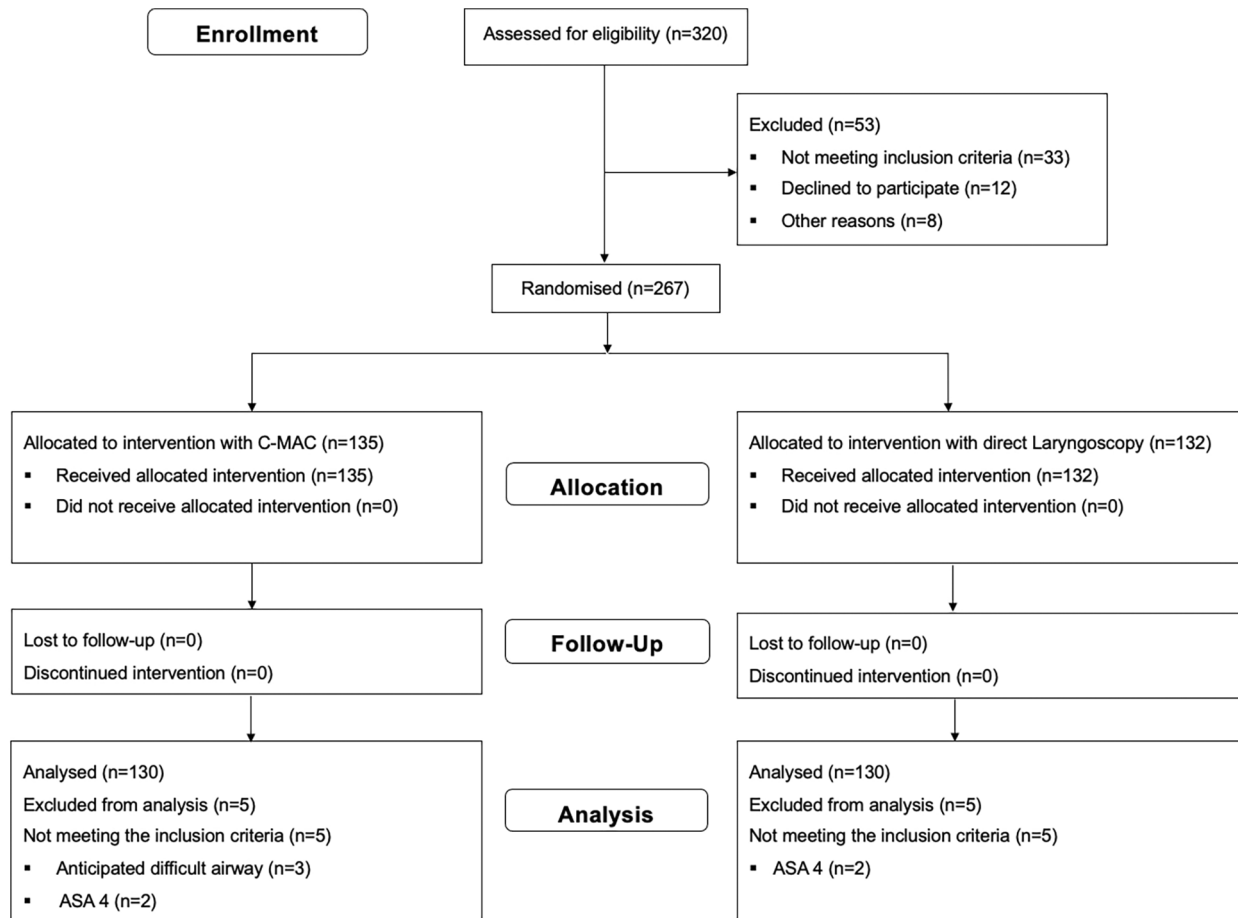


Figure 1 Flow chart of the study population.

frequent in the direct laryngoscopy group 11/35 (31%), compared with 3/42 (7%) in the C-MAC group ($p = 0.008$). The regression model showed no significant influence of anaesthetist experience.

There was a lower first-pass tracheal intubation success rate using direct laryngoscopy (86/130 (66%)) compared with the C-MAC, (125/130 (96%)) ($p < 0.0001$). This resulted in a relative risk (95%CI) of failed tracheal intubation at first attempt of 0.11 (95%CI 0.05–0.28) for the C-MAC compared with direct laryngoscopy ($p < 0.0001$).

Most anaesthetists used indirect glottic visualisation via the screen during the first attempt with the C-MAC (104/130 (80%)). In 13 cases, a second attempt at tracheal intubation with direct laryngoscopy was unsuccessful. In all of these cases, part tracheas were successfully intubated with the C-MAC (11/13 with the C-MAC Macintosh blade and 2/13 with the C-MAC D-Blade). In the direct laryngoscopy group, most failed tracheal intubation attempts (36/44 (82%)) resulted from an insufficient glottic view (Cormack and Lehane grade 2 with a percentage of glottic opening scale

$< 20\%$ or Cormack and Lehane grade ≥ 3). In 8/44 (18%) cases, the time limit of 120 s for laryngoscopy was exceeded. The grade of goitre had no significant influence on first-pass tracheal intubation success rate in both groups. In the C-MAC group, most failed tracheal intubation attempts (5/130 (4%)), resulted from prolonged tracheal intubation time (>120 s) and difficult placement of the tracheal tube despite an optimal glottic view (Table 2). Some technical problems were reported in the C-MAC group (18/130 (14%)), with the most frequently reported relating to fogging of the camera lens. No technical problems with direct laryngoscopy or the use of the tracheal tube electrodes were noted.

The longer tracheal intubation time (median (IQR [range]) 3.5 (2–5 [1–3]) s) in the direct laryngoscopy group was in 8/44 (18%) of the cases associated with a decreased first-pass intubation success rate. Subgroup analyses showed that first-pass tracheal intubation success rate was significantly lower using direct laryngoscopy than with C-MAC (63/95 (66%) vs. 85/88 (97%), respectively;

Table 1 Baseline characteristics. Values are number (proportion) or median (IQR [range]).

	Direct laryngoscopy n = 130	C-MAC n = 130
Sex; female	91 (70%)	99 (76%)
Age; y	55 (44–64 [18–85])	50.5 (41–60 [20–87])
BMI; kg.m ⁻²	25.6 (23.3–30.3 [16.2–39])	26.3 (23.6–30.2 [19.7–39.7])
ASA physical status 1/2/3	11/81/38	19/84/27
Airway difficulty score 5/6/7/8	2/64/52/12	7/54/53/16
Thyroid volume; ml	15 (15–28 [0–150])	20 (15–36.5 [0–160])
WHO classification of goitre*		
Grade 0/1/2/3	73/33/14/8	68/34/15/11
Clinical symptoms before surgery		
Stridor	5 (4%)	5 (4%)
Dysphagia	4 (3%)	6 (5%)
Hoarseness	16 (12%)	16 (12%)
Anaesthetists		
Resident	100 (77%)	95 (73%)
Consultant	30 (23%)	35 (27%)
Experience with direct laryngoscopy		
Anaesthetist used the device:		
<100 times	9 (7%)	7 (5%)
101–500 times	32 (25%)	26 (20%)
501–1000 times	43 (33%)	52 (40%)
>1000 times	45 (35%)	45 (35%)
Experience with videolaryngoscopy		
Anaesthetist used the device:		
<10 times	7 (5%)	5 (4%)
11–50 times	20 (15%)	16 (12%)
51–100 times	49 (38%)	46 (35%)
>100 times	54 (42%)	63 (49%)
Experience with intra-operative neuromonitoring		
Anaesthetist used the device		
<10 times	30 (23%)	23 (18%)
11–50 times	61 (47%)	63 (49%)
51–100 times	13 (10%)	16 (12%)
>100 times	26 (20%)	28 (21%)

*WHO classification of goitre by palpation: grade 0, no palpable or visible goitre; grade 1, palpable but not visible; grade 2, swelling in the neck that is clearly visible with hyperextended neck; grade 3, swelling in the neck that is clearly visible without hyperextend neck.

$p < 0.0001$) among residents; leading to a relative risk of failed intubation at first attempt of 0.10 (95%CI 0.03–0.32) with C-MAC compared with direct laryngoscopy. The first-pass tracheal intubation success rate among consultants was 23/35 (66%) with direct laryngoscopy vs. 40/42 (95%) with the C-MAC ($p < 0.001$); the relative risk of failed intubation at first attempt was 0.14 (95%CI 0.03–0.58) when comparing C-MAC with direct laryngoscopy.

A Cormack and Lehane grade ≥ 3 view occurred 16 times when direct laryngoscopy was used and never when

the C-MAC was used (Table 2). When residents performed laryngoscopy, Cormack and Lehane grade ≥ 3 was more frequent: 10/95 (11%) in the direct laryngoscopy group compared with 0/95 (0%) in the C-MAC group ($p = 0.002$). When consultants performed laryngoscopy a Cormack and Lehane grade ≥ 3 was observed in 6/35 (17%) with direct laryngoscopy compared with 0/42 (0%) with the C-MAC ($p = 0.007$).

The most frequent adverse event was the incidence of intubation granuloma observed with flexible fibre

Table 2 Primary and secondary study outcomes. Values are number (proportion) or median (IQR [range]).

	Direct laryngoscopy n = 130	C-MAC n = 130	p value
EMG signal			
Insufficient (<500 to 100 μ V)	35 (27%)	12 (9%)	<0.001
Loss of signal (<100 μ V)	4 (3%)	1 (1%)	0.37
Vocal cord palsy			
Before surgery	4 (3%)	1 (1%)	0.37
After surgery	6 (5%)	1 (1%)	0.11
No. of tracheal intubation attempts			
First attempt	86 (66%)	125 (96%)	<0.001
Second attempt	31 (24%)	5 (4%)	
Change of device (third attempt)	13 (10%)		
Overall success rate (two attempts)	117 (90%)	130 (100%)	<0.001
Tracheal intubation time; s			
Time to view	12 (7–18.25 [3–48])	9 (7–14 [3–45])	0.008
Time to place	27.5 (20–37 [10–58])	24 (18–32 [11–55])	0.13
Glottic view			
Cormack–Lehane grade 1/2/3/4	48/66/14/2	110/20/0/0	<0.001
POGO (%)	70 (30–95 [0–100])	100 (100–100 [20–100])	<0.001
External laryngeal manipulation			
BURP	71 (55%)	14 (11%)	<0.001
Adjustment of head and neck	32 (25%)	9 (7%)	<0.001
Type of complication			
Dental injury	5 (4%)	2 (1.5%)	0.45
Lip lesions	18 (14%)	2 (1.5%)	<0.001
Intubation granuloma	61 (47%)	32 (25%)	<0.001
Intubation difficulty score			
>5	2 (1–4 [0–13])	0 (0–1 [0–5])	<0.001
	27/130 (21%)	0/130 (0%)	<0.001

EMG, electromyogram; POGO, percentage of glottic opening; BURP, backward-upward-rightward pressure of the larynx.

videolaryngoscopy after 72 h (Table 2) followed by lip lesions. The skill level of the anaesthetist performing tracheal intubation was not associated with the incidence of intubation granuloma. The proportion of intubations with intubation granuloma was 29/95 (31%) for direct laryngoscopy performed by residents and 12/35 (34%) in consultants ($p = 0.68$), compared with 8/88 (9%) for C-MAC in residents and 6/42 (14%) in consultants ($p = 0.38$).

Discussion

This prospective randomised clinical trial compared the efficacy of direct laryngoscopy with videolaryngoscopy with a Macintosh-based blade for an optimised positioning of tracheal tube surface electrodes for intra-operative recurrent laryngeal nerve monitoring during thyroid surgery. Insufficient electromyography signal (<500 μ V to

100 μ V) initially after tracheal intubation was observed to be significantly higher (27%) in the direct laryngoscopy group compared with the C-MAC group (9%).

Most previous studies have described placement of the tracheal tube electrode at the vocal fold level under direct laryngoscopy, and optimal depth was defined by subsequent successful intra-operative nerve monitoring [11, 12, 14]. Lu et al. reported successful intra-operative nerve monitoring after initial tracheal intubation in 94.3% of patients, but in 5.7% patients an initial insufficient signal and poor glottic visualisation were observed [11]. In contrast to our study, the frequency of insufficient signal using direct laryngoscopy was higher and needed more correction of the tracheal tube compared with the C-MAC. There were differences in our study design (e.g. anaesthetic care performed by one anaesthesia nurse and rotation of tracheal tube surface electrodes could be detected by

electromyography impedance) compared with existing research [11].

Studies report difficult tracheal intubation in thyroid surgery in 5.3–12.9% of patients [3, 5, 19, 25–29]. There are different definitions of difficult tracheal intubation between these studies including intubation difficulty score > 5 [25, 27–30], Cormack and Lehane grade ≥ 3 [3–5], or if more than one attempt [2] or three tracheal intubation attempts where necessary [28]. The intubation difficulty score does not include the difficulty of passing a tracheal tube. Tutuncu et al. modified the intubation difficult score by adding the difficulty of passing the tracheal tube (modified intubation difficult score), as large goitres may result in difficult airways due to tracheal compression [29].

First-pass tracheal intubation success rate was observed to be significantly lower in the direct laryngoscopy group compared with the C-MAC group (66% vs. 96% respectively). Other studies have shown lower and higher first-pass tracheal intubation success rates for direct laryngoscopy, ranging from 22% to 93% [5, 29, 31–33]. Smaller, potentially underpowered trials have demonstrated that the use of a Macintosh blade style videolaryngoscope is superior to direct laryngoscopy when used by an experienced senior anaesthetist [31, 34]. Patient characteristics and anaesthesia management were comparable to other studies investigating first-pass tracheal intubation success rate with direct laryngoscopy and videolaryngoscopy in adult thyroid surgery patients [5, 29, 31, 32].

Previous studies have demonstrated improved Cormack and Lehane grades with videolaryngoscopy. In this study, improved glottic visualisation while using the videolaryngoscope did not necessarily translate to a higher rate of first-pass tracheal intubation success due to challenges with tube passage through the glottic opening. Even with optimally shaped stylets, tracheal intubation can be prolonged or impossible.

Tracheal intubation was performed by anaesthetists with different training levels. In contrast to other studies involving only experienced intubators [26, 29, 32], our results demonstrate that less experienced residents obtained greater benefit from using the C-MAC compared with direct laryngoscopy.

We observed adverse events in 49% of patients allocated to the direct laryngoscopy group and 14% in the C-MAC group, comparable to another study examining expected normal airways [32]. Notably, the increased incidence of adverse events was associated with anaesthesia experience and poor glottic visualisation in both groups. This is in agreement with two studies showing oropharyngeal or dental injuries in relation to multiple intubation attempts [32, 35].

Results from this trial may not be generalisable to other settings or situations, including known or anticipated difficult airways, to performance of other available videolaryngoscopes using hyperangulated- or channelled blades, and with non-anaesthetists [36, 37]. We assessed a single type of videolaryngoscope, which has a Macintosh similar blade comparable to the commonly used Macintosh blades used for direct laryngoscopy. Because of the nature of the trial, blinding the anaesthetists using the different devices was not feasible. The presence of a research assistant assessing the performance of the anaesthetists could have led to altered performance due to the Hawthorne effect [38]. Finally, anaesthetists might have subconsciously favoured a specific device, which could cause bias in results such as glottic visualisation or an earlier change of device.

In this randomised, controlled study a significantly lower incidence of insufficient signal for intra-operative nerve monitoring in thyroid surgery and higher first-pass tracheal intubation success rate was demonstrated using a videolaryngoscope with a Macintosh-shaped blade, compared with direct laryngoscopy with a Macintosh blade. Currently, many anaesthetists would not use a videolaryngoscope as a first-choice device for a normal airway for intra-operative nerve monitoring in thyroid surgery and would reserve this technique for patients with difficult tracheal intubation. The results of this trial call this assumption into question. It may be time to consider videolaryngoscopy use as a primary technique in routine thyroid surgery patients, due to its utility for successful intra-operative nerve monitoring. By reducing the occurrence of multiple tracheal intubation attempts and optimised glottic visualisation, patient safety may be improved. Consequently, we suggest that videolaryngoscopy should no longer automatically be relegated to a backup role for tracheal intubation in elective adult patients undergoing thyroid surgery to optimise intra-operative nerve monitoring.

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