Utilization of C-MAC videolaryngoscopy for direct and indirect assisted endotracheal intubation

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Abstract
Background: The experiences of seasoned practitioners with the new C-MAC indirect videolaryngoscope system have shown promising results in the management of difficult airways. However, a comparison of direct and indirect laryngoscopy utilizing the C-MAC system as its own control has not been performed in a cohort of anesthesiologists-in-training. The primary aim was to compare direct and indirect laryngoscopy in terms of intubation time with secondary outcomes including laryngoscopy time and airway view with the same size 3 blade.

Methods: The study was registered with www.clinicaltrials.gov (NCT01104090). Oral and written informed consent was obtained from 50 adult patients with BMI < 40 kg/m² who required general anesthesia for elective surgery with tracheal tube placement. The patients were randomized to two groups, each receiving two laryngoscopies, n=25 direct-first and n=25 indirect-first.

Results: All patients except for one were successfully intubated on the first attempt. The intubation time was 12.3±11.1 sec immediately following videolaryngoscopy (direct laryngoscopy first group) and 9.8±7.1 sec immediately following direct laryngoscopy (videolaryngoscopy first group), p=0.35. The first laryngoscopy time was 8.7±4.7 sec in the direct group and 13.3±10.7 sec in the indirect group, p=0.06. Twenty-percent of direct first cases compared to 0% of indirect first cases showed an improvement in airway view score by at least two classes on the second laryngoscopy, p=0.02. Backward-upward-rightward pressure was used in 36% of direct first and 12% of indirect first patients, p=0.047.

Conclusions: This study corroborates previous results on the use of the C-MAC videolaryngoscopy system during endotracheal-assisted intubation. Although there was no difference in intubation time between direct laryngoscopy and videolaryngoscopy, the C-MAC system was found to improve laryngeal views and reduce the number of necessary laryngeal manipulations. A larger randomized study utilizing a similar model is necessary to definitively determine significant clinical results.

Trial registration: ClinicalTrials.gov NCT01104090.

Keywords: Indirect laryngoscopy, airway management, difficult airway, videolaryngoscopy, intubation

Introduction
Videolaryngoscopes (VL) are a relatively new class of airway devices that allow indirect view of the laryngeal structures without the necessity of alignment of the oral, pharyngeal, and tracheal axes. Hence, laryngoscopy performed using a VL has proven to provide superior views compared to direct laryngoscopy in both normal and difficult intubation situations [1-4].

The C-MAC (Karl Storz Endoscopy, Inc., Tuttlingen, Germany) is one of the most recent Macintosh-blade based VLs and it became commercially available in the United States in March 2009. A micro video module is contained in the C-MAC handle and the blade is fitted with an image-light bundle that projects to a video console. The C-MAC platform is to our knowledge the only VL that allows the clinician to perform both direct and indirect laryngoscopy with the same blade. Therefore, it serves as both an innovation for difficult airway management and as a powerful teaching tool [5-7].

Recently, several studies investigating the use of the C-MAC in the hands of seasoned practitioners have reported promising results in regards to the management of difficult airways [8-11], whether expected (morbidly obese patients), unexpected (suboptimal glottic views), or simulated (with manikins). However, a comparison of direct and indirect laryngoscopy utilizing the C-MAC system as its own control has not been performed. Because successful airway management is also operator dependent, studying anesthesiologists-in-training may be potentially more suitable to compare the efficacy of the instrument, especially in less experienced trainees.

Therefore, we conducted a randomized controlled crossover trial in an academic anesthesiology residency training program. We hypothesized that performing a randomized assignment to direct versus indirect assisted laryngoscopy by the C-MAC would show better laryngeal grade views in a faster time. Using the C-MAC for direct and indirect assisted laryngoscopy would maintain the novelty of using the same device as its own control, instead of comparing it with a Macintosh blade as most previous investigations have done [8-10]. The primary aim was to compare direct and indirect laryngoscopy in terms of intubation time. Secondary outcomes included number of
successful intubations, airway view score, time to successful view, and ease of endotracheal intubation with the same blade.

Materials and Methods
The study was registered with www.clinicaltrials.gov (NCT01104090). After approval from the Institutional Review Board (IRB), oral and written informed consent was obtained from 50 adult patients who required general anesthesia for elective surgery with tracheal tube placement. Inclusion criteria were: age between 18-80 years, American Society of Anesthesiologist (ASA) score I-III and Mallampati class I-III. The patients were excluded from the study if they had a history of a difficult airway or potential risks factors for difficult intubation (morbidly obese patients with BMI ≥ 40 kg/m², Mallampati class > III, mouth opening < 3 cm, and neck movement >2 on a scale of 1 [no reduction] to 3 [severe reduction]).

Power analysis was based on the primary outcome and performed using Stata (Stata Corp., College Station, TX). It was hypothesized that, between the two groups, there would be a 4-second difference in intubation time and a standard deviation of 5 seconds in each group. The sample size necessary to achieve a significant result (alpha = 0.05) with a power of 0.80 was determined to be 49 patients, or 24.5 per group (two-tailed test of means).

Immediately before induction of anesthesia, each patient randomization was revealed by computer generated assignment. No blocked randomization was used. The patients were randomized to two groups, each receiving two laryngoscopies, n=25 direct first and n=25 indirect first. Both laryngoscopies were performed with the C-MAC blade size 3; however, a size 4 was available. The size 3 blade was used initially to standardize the intubation process because the longer size 4 blade itself may be a sufficient solution in cases with difficult airway views [9]. A second laryngoscopy was performed using the opposite technique from the first. Residents were instructed to not stylet the endotracheal tube and to first check if they could intubate without it; they were allowed a maximum of one unsuccessful intubation with an endotracheal tube that was not styletted. Laryngeal manipulation with backward-upward-rightward pressure (BURP) was recorded if necessary, and in these cases the change to the view after the manipulation was applied was also recorded. BURP was applied when the laryngoscopy view had a Cormack and Lehane (C&L) score [12] greater than 2b, in an attempt to improve the view, prior to picking up the endotracheal tube.

Patients were intubated after the second laryngoscopy. Laryngoscopy and intubation were performed by an anesthesiology resident physician under direct supervision of an attending anesthesiologist. Each resident was allowed up to two total attempts of direct and indirect laryngoscopy. Residents in the CA-2 and CA-3 year of training only performed the laryngoscopies and intubations. All the residents and the attending anesthesiologists were trained based on manufacturer’s recommendations and performed a minimum of three intubations with the C-MAC VL prior to working on any patients in clinical conditions, as well as three laryngoscopy and intubations on a manikin (Trucorp Airsim Advance, Trucorp Ltd, Ireland) to simulate the study conditions (attempts, direct indirect first, positioning, timing, and record collection). Resident physicians who participated in this study did so voluntarily.

Per ASA, standard monitoring was placed on the patient in the operating room. Baseline measurements of blood pressure, pulse rate, and oxygen saturation were recorded before induction of anesthesia. After 3 minutes of preoxygenation, anesthesia was induced (time zero) and vital signs were monitored continuously and recorded every minute for up to five minutes after the successful intubation. The hemodynamic variables were collected to monitor for possible differences in direct vs. indirect laryngoscopy in the setting of the crossover design of the study. It was anticipated that there would not be any significant differences in these variables between the two groups. Thus, these variables were not primary outcomes and not included in the power analysis.

General anesthesia was induced by bolus administration of propofol (2-3 mg/kg) and fentanyl (1-2 mcg/kg). Rocuronium (0.6 mg/kg) was administered following successful facemask ventilation. Once muscle relaxation conditions were achieved (3 minutes of administration of the muscle relaxant with a train of four of 0 at neurostimulation), the first laryngoscopy was attempted and the C&L score was used to evaluate the laryngoscopic view. Thereafter, the first blade was retracted on the level of the incisors and the second laryngoscopy was performed. After obtaining the second visualization, the resident was allowed to intubate the trachea. The time frame from holding the endotracheal tube to the first CO2 trace after successful intubation was defined as the intubation time. During direct laryngoscopy, the monitor of the C-MAC was oriented away from the resident and the supervising attending anesthesiologist was able to score the indirect view obtained by the resident, who remained blinded to the result. Direct laryngoscopy was graded with a video to assess differences in view between the two methods, a result of using a single device with both capabilities. This is the only way to have immediate validation of the view without attempting another direct laryngoscopy when real patients are involved. Indeed, the video view may not be exactly the same as the direct view due to positioning of the optic. Patients were continuously monitored for desaturation or unexpected changes in vitals signs. Anesthesia was maintained with sevoflurane.

The primary outcome (intubation time) and secondary outcomes (laryngoscopy time [defined as the time between advancing the laryngoscope and obtaining optimal view]), airway view [C&L score] number of successful intubations, and subjective ease of laryngoscopy and intubation {both rated on a scale from 1 = very easy to 5 = very difficult}) were recorded. Hemodynamic parameters (heart rate and blood pressure) were recorded at the following time points: 1) pre-
Table 1. Demographics.

| Variable                  | Direct First(n=25) | Indirect First(n=25) | p-value |
|---------------------------|--------------------|----------------------|---------|
| Female (%)                | 18 (72%)           | 17 (68%)             | 0.76    |
| Age (years)               | 46±1±±14.2         | 49±1±±15.2           | 0.49    |
| BMI (kg/m²)               | 30.4±6.6           | 29.4±5.9             | 0.62    |
| Neck Circumference (cm)   | 39.0±5.3           | 39.1±4.4             | 0.98    |
| Thyromental distance (cm) | 9.2±1.7            | 8.8±1.5              | 0.41    |
| Inter-incisor distance (cm)| 5.1±0.7          | 4.7±0.8              | 0.08    |
| Sternomental distance (cm)| 16.8±2.5          | 16.3±2.5             | 0.46    |
| ASA class (I/II/III)      | 2/13/10            | 1/16/8               | 0.65    |
| Mallampati class (I/II/III)| 11/11/3          | 8/12/5               | 0.60    |

BMI = body mass index.

Table 2. Procedure parameters and primary and secondary outcomes.

| Variable                       | Direct First (n=25) | Indirect First (n=25) | p-value |
|--------------------------------|---------------------|-----------------------|---------|
| Heart rate (bpm)               |                     |                       |         |
| Pre-induction                  | 73±1±10.8           | 76.9±11.5             | 0.31    |
| Pre-insertion                  | 72.6±12.8           | 76.1±14.0             | 0.36    |
| First minute                   | 84.6±15.7           | (n=24) 83.0±12.7      | 0.71    |
| BURP used for first laryngoscopy| 9 (36%)             | 3 (12%)               | 0.047   |
| Before BURP                    | 12/7/6/0            | 18/3/1/2              | 0.04(*) |
| After BURP                     | 0/3/6/0             | 0/1/1/2               |         |
| C&L airway view score          |                     |                       |         |
| for first laryngoscopy (1/2a/2b/3)| 1/4/2/0       | 1/1/1/0               | 0.18    |
| BURP used for second laryngoscopy| 3 (12%)             | 7 (28%)               | 0.16    |
| Before BURP                    | 19/4/1/0            | 11/6/5/3              | 0.04(*) |
| After BURP                     | 0/2/1/0             | 0/0/5/2               |         |
| Laryngoscopy time (sec)        |                     |                       |         |
| First                          | 8.7±4.7             | 13±3±10.7             | 0.06    |
| Second                         | 9.1±6.1             | 11.0±7.7              | 0.35    |
| Improvement in C&L airway view|                     |                       |         |
| score by 2 classes between    | Before BURP         | 5 (20%)               | 0.02(*) |
| first and second laryngoscopy  | After BURP          | 0%                    |         |
| Laryngoscopy difficulty (1/2/3/4/5)| 15/5/4/1/0  | 13/4/5/3/0            | 0.71    |
| Intubation time (sec)          | 12.3±11.1           | 9.8±7.1               | 0.35    |
| >1 intubation attempts (%)     | 0%                  | 1 (4%)                | 0.31    |
| Stylet used                    | 5 (20%)             | 9 (36%)               | 0.21    |
| Intubation difficulty (1/2/3/4/5)| 14/6/4/1/0  | 16/4/4/1/0            | 0.91    |
| Laryngeal view completeness    | 20/3/2              | 15/9/1               | 0.13    |
| Fog or secretions              | 2 (8%)              | 3 (12%)               | 0.64    |

bpm = beats per minute, BURP = backward-upward-rightward pressure, C&L = Cormack and Lehane.

induction (prior to anesthesia induction), 2) preinsertion (after induction, prior to inserting the blade), and 3) one minute after tracheal tube placement. Any complications with either procedure were noted, including mucosal injury, recovery of blood on the blade, and fogging of the lens.

Attention was given to the total apnea time between each laryngoscopy attempt, and ventilation was provided as necessary to maintain adequate oxygen saturation. The expected time to complete intubation was less than 2 minutes.

Data are presented as mean±standard deviation and percentage. Data were compared by two-tailed Student’s t-test (continuous variables) and chi-square test (categorical variables). Data were analyzed with Stata (Stata Corp., College Station, TX). Comparisons were considered statistically significant if p<0.05.

Results

The patient demographics are summarized in Table 1. Patient characteristics, including gender, age, BMI, neck circumference, thyromental distance, inter-incisor distance, sternomental distance, ASA class, and Mallampati class, did not significantly differ between the direct first and indirect first groups.

Procedure parameters are summarized in Table 2. Heart rate during pre-induction, pre-insertion, and post-intubation did not significantly differ between the groups. Although not a significant difference, stylets were used more often in the indirect first group compared to the direct first group. In 14 cases, a stylet was used in single-intubation attempts; this was because the research team was not able to check the standard practice of stylet insertion in the endotracheal tube prior to each intubation attempt. Intubation time did not significantly differ between the direct first (i.e., indirect visualization just prior to intubation, 12.3±11.1 sec) and indirect first (i.e., direct visualization just prior to intubation, 9.8±7.1 sec) groups, p=0.35. With the exception of one patient in the direct first group, all patients were successfully intubated on the first attempt. There was no significant difference between CA-2 and CA-3 residents in regards to use of BURP, stylet use, laryngoscopy time, or, intubation time.

The distribution of C&L scores before backward-upward-rightward pressure (BURP) application differed significantly between the groups (p=0.04); however, there was no significant difference in the prevalence of clinically difficult airway views (class 2b or 3) between the direct laryngoscopy first group (24%) and the indirect laryngoscopy first group (12%), p=0.27. BURP was used significantly more often in the direct first group (36%) compared to the indirect first group (12%), p=0.047, and in all cases led to an improvement in C&L score by at least one grade. Comparing the C&L score between the first and second laryngoscopies (prior to application of BURP), there was a significant difference in the rate of improvement in C&L score by two classes (3 to 2a or 2a to 1) between the direct first (20%) and indirect first (0%) groups, p=0.02. The first laryngoscopy time did not significantly differ whether it was performed under direct (8.7±4.7 sec) or indirect (13.3±10.7) visualization, p=0.06. The second laryngoscopy times remained different between the two approaches, but the gap between the mean times of both groups decreased from 4.6 sec to 1.9 sec.

Discussion

This is to our knowledge the first study to compare direct laryngoscopy and indirect VL with a single device as its own control in the hands of resident anesthesiologists. Cavus
et al., [5,9] described the benefit of visualizing the glottis and intubation process on the monitor as optimizing the physician education and ease of intubation, including necessary external laryngeal manipulation. In the present study, it is difficult to directly determine the benefit of improved views on improving resident education, but we similarly showed a significantly reduced use of unnecessary external laryngeal manipulation in the indirect first group. Whereas the same individual evaluated both the direct-indirect airway views in the study by Cavus et al., [9], in the present study the airway views were independently assessed using the C-MAC view module. This difference in assessment of the indirect view vs. direct view laryngoscopy and intubation process, albeit not significantly different, could potentially be used to benefit training of anesthesiology residents. The lack of a significant difference may also be attributable to the tandem nature of the direct-indirect (or vice-versa) procedure by each resident, which may have led to familiarity with the process on the second attempt. Although the distribution of airway views in this study was observed to be the same between laryngoscopic approaches, some authors have claimed that the classification does not apply to indirect video views [13]. The C&L classification system for grading airway view was used from a practical clinical stand point.

The ease of indirect intubation was confirmed with the C-MAC video laryngoscope. Videolaryngoscopy, especially with blades that simulate the common design of a Macintosh blade, is replacing direct laryngoscopy because of the ability for others to see and teach, and potentially reduce complications while maintaining common skills using a typical airway device used by trainees [14]. It is a valuable companion device, and where available, useful for difficult laryngoscopy [15]. The efficacy of the C-MAC to improve the grade of a laryngoscope view, even in limited 2b or 3 views, could improve the success of alternative devices such as a bougie or rigid light/optic stylets.

As part of the investigation, we utilized a traditional Macintosh technique that elevates the epiglottis during laryngoscopy. In four cases (n=2 direct first and n=2 indirect first), the initial attempt at indirect laryngoscopy provided a view of the glottis as one would expect from a Miller approach (epiglottis suspended within the blade). We incidentally noticed that the view was actually improved in all patients (from class 2b to class 2a), even with the C-MAC blade size 3 used in the present study. These findings were similar to those described by Cavus et al., [9], in that this manipulation caused the C&L score to improve by two classes in 20% of unexpected difficult intubations in the direct first group, without laryngeal manipulation. In general, the use of the blade directly towards the vocal cords did improve the view without the need of manipulation; however, we suggest caution because of the potential harm to the larynx and vocal cords.

An interesting result, even if not statistically significant, was the relationship between direct view and indirect view, as noted by the different ratings given by the attending and the resident. This confirms previous findings of the differences obtained by direct vs. indirect vision and respective manipulations. In this regard, one may expect the laryngeal views to worsen with indirect visualization compared to direct visualization, a phenomenon not limited only to the C-MAC device [16]. The adoption of videolaryngoscopy for routine or difficult intubation by anesthesiologists trained only in direct laryngoscopy may follow a pattern similar to the experience reported in this study of resident anesthesiologists, as in both situations a learning curve exists.

The potential for variation in ventilation could have been problematic. However, the mean time to intubate the patients’ trachea was 10-12 sec and not significantly different between the two groups. According to Massen and McElwain [10-11], there are a few implications in the use of the stylet and the benefit of VL. Although we did not find a significant difference in stylet usage between the indirect first and direct first groups, the stylet usage was greater in the indirect first group.

Most previously published studies on C-MAC have been conducted using experienced personnel [8-10], whereas at least one has used medical students [17]. We decided to involve our residents in this study to simulate actual in-training conditions, reduce variability in laryngoscopy performance, and reduce training time. We did not correlate outcomes with the residents’ year of training or objectively measure the achieved skills in a simulated setting. However, the standardization of airway management and airway rotations in our program makes the variability less likely.

The findings of this study should be considered in the context of its limitations. First, there was no comparison with other VL devices, specifically in regards to the relative ease of use among anesthesiologists-in-training. Second, the more difficult airway view in the direct first group compared to the indirect first group was not possible to control a priori; however, it did not result in significantly different laryngoscopy or intubation times between the groups. Third, the definition of the primary outcome (intubation time) may not have reflected difficult laryngoscopy with either technique, but rather difficult tube passage that may have been related only to inconsistent stylet use. Finally, this study may have been underpowered in regards to the secondary outcomes, as a significant difference was not detected (p=0.06) between the groups despite a 4.6 sec difference in laryngoscopy time, which is clinically significant. This is most likely due to the large variation in times in the indirect first group (standard deviation of 10.7 sec), because a post-hoc power analysis using our results indicates a sample size of 102 patients (n=51 in each group) required to detect a significant difference with a power of 0.8 for this secondary outcome.

Conclusions

This study corroborates previous results on the use of the C-MAC VL system during endotracheal assisted intubation.
First, the system improved laryngeal views as measured by the Cormack and Lehane score, and reduced the number of necessary laryngeal manipulations (i.e., backward-upward-rightward pressure) in the hands of anesthesiologists-in-training. Second, this cohort of overweight and obese patients did not pose severe difficulties for direct or indirect laryngoscopy, with the latter approach resulting in a slightly longer time for intubation (not statistically significant). Third, the ability for trainees to serve as their own control when using the C-MAC device makes it a beneficial educational tool. Larger prospective randomized studies comparing complications and intubation success rates are necessary to definitively determine significant clinical results.

Competing interests
The authors declare that they have no competing interests.

Authors’ contributions

| Contribution            | DC | LF | CBP | VM | VM | SDG | AVA | CAH |
|-------------------------|----|----|-----|----|----|-----|-----|-----|
| Study design            | √  |    |     |    |    |     |     |     |
| Data acquisition        | √  | √  |     |    |    |     |     |     |
| Data analysis           |    | √  |     |    |    |     |     |     |
| Data interpretation     | √  | √  |     |    |    |     |     |     |
| Drafting manuscript     | √  |    |     |    |    |     |     |     |
| Revising manuscript     | √  | √  | √   |    |    |     |     |     |
| Approving final manuscript| √  | √  | √   |    |    |     |     |     |

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