



Awake intubation with C-MAC video-stylet versus fiberoptic bronchoscope in predicted difficult airway patients: Comparative randomised study

Rehab Abd El-Raof Abd El-Aziz and Yasser Mohamed Osman

Department of Anaesthesia and Surgical Intensive Care, Faculty of Medicine, Alexandria University, Alexandria, Egypt

ABSTRACT

Background: This work was conducted to examine the efficiency of using C-MAC video stylet (VS) in awake intubation by comparing it to the standard method using fiberoptic bronchoscope (FOB).

Patients and methodology: Eighty patients were included in this study and divided into two groups according to the device used for awake intubation: VS group and FOB group.

Results: The intubation time ranged between 25 and 245 s with median of 45.5 s in VS group, while in the FOB group, it ranged between 36 and 279 s with median of 80 s with P value < 0.001. Successful intubation was done in 36 patients (90%) on the first attempt in VS group versus 29 patients in the FOB group (72.5%) with P value 0.04. As regard SpO_2 , insignificant difference was found all through measurement times. Heart rate and mean arterial blood pressure showed significant increase in FBO group more than in C-MAC-VS group at 1 and 5 min after intubation with P value < 0.001.

Conclusion: Using the C-MAC VS in awake intubation proved to be easier and more successful than using the FOB.

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1. Introduction

Awake intubation is mainly used in clinical circumstances of expected difficult airway to avoid the hazards of this situation [1]. According to 2003 ASA guidelines, many versions of video laryngoscopes (VLs) were adopted to replace the traditional methods for awake intubation [2,3]. The fiberoptic bronchoscope (FOB) is traditionally and till now used in predicted difficult airway and was successfully in about 88–100% of the cases [4]. But with the use of FOB, there are a lot of associated risks, including haemorrhage from the nose, hyperactive airway, over-sedation, and sometimes complete airway occlusion leading to severe hypoxia. [5] In addition, the procedure also needs adequate preparation for the tools used and for the patient and all these preparations usually take a considerable amount of time.

The C-MAC video stylet (VS) is a recently introduced new device of intubation video endoscope. The device has many merits and benefits of the intubating endoscopes either the rigid or the flexible one. It is not heavy so it can be carried easily from one place to another, and can be used for several times without the need to recharge. [6]

It possesses a faster learning curve when compared to other fiberoptic intubating devices as FOB due to its advanced design and unique features. [6,7]

This work was designed to examine the possibility of using C-MAC-VS in awake intubation and to compare its efficiency to the standard method of using the FOB. Assessment of intubation time was the primary endpoint. Evaluation of the first intubation attempts success rate, haemodynamic parameters changes, and any complications or adverse events resulting from intubation were the secondary aims. Our hypothesis was that the C-MAC VS might be an alternative to FOB for awake intubation.

2. Patients and methods

After approval of Ethical Committee, written informed consents were taken from all participants in the study. This research work was done according to the World Medical Association Declaration of Helsinki Ethical Principles for medical research, and it was registered at ClinicalTrials.gov with registration number NCT04759287. The study included 80 patients aged between 18 and 60 years, of both gender of ASA Physical Status I and II. All the participants were undergoing elective surgeries and were scheduled for awake intubation due to the presence of any predictors of difficult intubation as score of Mallampati ≥ 3 ; thyromental distance ≤ 6 cm; inter-incisor distance ≤ 3 cm; obese patients with BMI ≥ 35 kg/m²; neck extension $\leq 80^\circ$ from neck flexion; and also patients with past

history of difficult endotracheal intubation or difficult mask ventilation. Patients with any hazard of pulmonary aspiration, and any medical condition that may affect the morbidity or the studied parameters such as cardiac, respiratory, hepatic, and renal diseases were excluded from the study.

Computerized randomization method was used to divide patients randomly into two equal groups. All participants were blinded to the allocated group. For patients in Group VS, awake intubation was done using the KARL STORZ, C-MAC-VS (Figure 1). On the other hand, in Group FOB, awake intubation was done using flexible FOB (model, Olympus Porta-View LFGP; outer diameter, 4.1 mm). Intubation was performed only by expert anaesthesiologist familiar with the use of these devices (experience with more than 100 times of intubations with each device).

All patients fasted for 6–8 h and underwent a detailed preoperative preparation. Anaesthesia plan was standardized for both groups. Upon arrival to the operating room, a peripheral intravenous line and basic monitoring channel were placed. The operator stood behind the patient who was semi-recumbent on the operating table. All patients received continuous oxygen via a nasal catheter with a flow rate of 3 l/min.

Conscious sedation with 30 µg fentanyl and 1 mg midazolam was administered for all patients before the start of the procedure.

In both groups, awake intubation was done under topical anaesthesia of the oral cavity with lignocaine spray 10% (each puff has 10 mg of lignocaine). Two puffs were applied on the oral mucosa, back of the throat, and hard palate. Lignocaine was kept in the mouth for about 5 min after puffing till tingling of the upper airway occurred. [8] Standby standard airway and emergency equipment were ready and within reach.

In VS group, the anaesthesiologist asked the patient to open his mouth and used his left hand to support the tongue and jaw to display the entrance of the larynx. Using the other hand, the VS preloaded with ETT (Mallinckrodt Hi-Lo Oral, Cuffed Murphy Eye – internal diameter 7.0) was entered orally in the midline

parallel to the sagittal plane. As the distal end of the VS passes the incisors, close observation of VS advancement was done using the monitor display. Then, VS was introduced further till its distal end became immediately visible above the vocal cords, and hence a complete image of the true vocal cords was obtained. After passing the vocal cords, ETT was pushed to enter the trachea and stopped when the cuff was seen on the monitor crossing the vocal cords on the screen. Subsequently, while gripping the ETT firmly in its site, VS was taken away by the other hand. [6,7]

In FOB group, flexible bronchoscope was used to facilitate intubation. The FOB loaded with the ETT (Mallinckrodt Hi-Lo Oral, Cuffed Murphy Eye) was manoeuvred through the airway visually guided till it passes through the vocal cords. Then, it was advanced into the trachea till its tip reaches 2–3 cm above the carina. The scope was removed once the tube was fixed firmly in place. [8]

If severe choking or gagging occurred, extra more puff of lignocaine 10% was sprayed under direct vision, and intubation was started again after 1 min.

An intubation attempt is considered unsuccessful if the used device is withdrawn without insetting the ETT in its correct position. After three failed intubation trials, another airway management alternative was considered.

Intubation time in seconds was calculated from insertion of C-MAC VS or FOB in the mouth till confirmation of ETT was done by capnography. Time needed to intubate, number of trials of intubation, and its successful rate were measured. Changes in patients' hemodynamic parameters, which include heart rate (HR), mean arterial blood pressure (MABP), and O₂% saturation, were recorded immediately pre-intubation as baseline reading and then at 1 and 5 min post-intubation. Complications or side effects during intubation such as blood clots on the device due to dental or lip trauma and postoperative sore throat were noted.

Sample size was calculated based on a previous study and by using MedCalc statistical software. The



Figure 1. VS with its metal rigid stylet and a mobile flexible tip, which deflects till 60° so the navigation of the airway occurs smoothly.

study assumed area under ROC to be 0.80, an alpha of 0.05, and power of study 80.0%. A typical advice is to reject the null hypothesis H_0 if the corresponding P -value is smaller than 0.05. A minimum sample size required for this study was 76 patients. [9, 10]

Statistical analysis

Statistical calculation of sample size was done using Statistical Package for Social Sciences software (SPSS/ version 21). A minimal total hypothesized sample size of 76 eligible patients was needed to complete the study; taking into consideration the power of study to be 80% and assuming area under ROC to be 0.80, an alpha of 0.05 with $P < 0.05$ was considered statistically significant. [9,10] A chi-square and Fisher's exact test were used for analysis of non-parametric qualitative data and Mann-Whitney (U-test) and unpaired

t-test were used for analysis of quantitative data. Results were presented in the form of range, median, percentage (%), arithmetic mean, and standard deviation.

3. Results

Ninety-three patients on the surgical list were recruited. Of these, 12 patients were excluded as they refused to participate in this research work or did not have the inclusion features. Only 81 patients fulfilled all criteria, subsequently consented, and were allocated into two groups and statistically analysed with no patient dropouts as shown in the flow chart (Figure 2).

Patients' demographic data, which include gender, age, and body mass index, are shown in Table 1 and revealed that no statistical difference was found between the two groups.

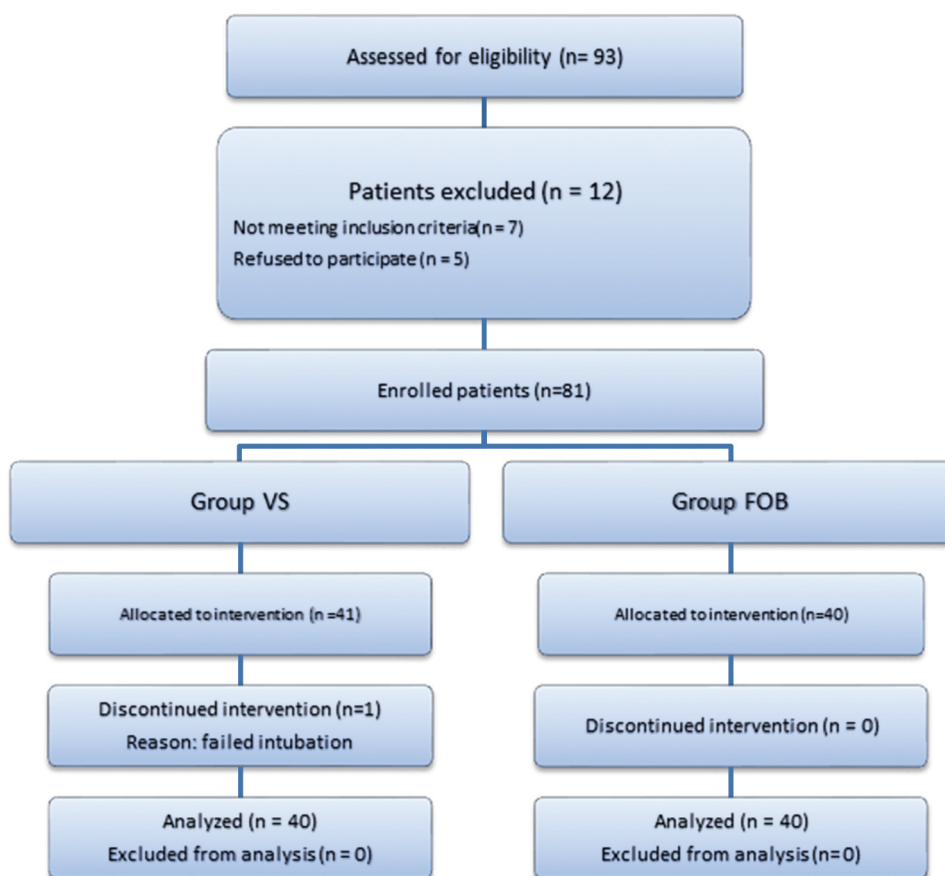


Figure 2. Flow chart of the study.

Table 1. Patients demographic data.

		FOB group n = 40	VS group n = 40	<i>P</i>
Age (yr)	Range	21–60	20–60	0.88
	Median	46.65	49.5	
Sex	Male	21	23	0.65
	Female	19	17	
BMI	Range	23–42	25–42	0.35

BMI, body mass index.

Table 2. Intubation time and success rates in both groups.

		FOB group n = 40	VS group n = 40	P
Intubation time (s)	Range	36–279	25–245	<0.01*
	Median	80	45.5	
First attempt intubation	No. of patients	29	36	0.04*
	Success rate	72.5%	90%	
Second attempt intubation	No. of patients	6	4	
	Success rate	15%	10%	

Data are displayed as median (range), no. of patients, and percentage (%).

* Statistically significant.

The intubation time ranged between 25 and 245 s with median of 45.5 s in VS group, and in the FOB group, it ranged between 36 and 279 s with median of 80 s. The intubation time was statistically significantly shorter in VS group ($P < 0.01$; Table 2). Successful intubation was done in 36 patients (90%) on the first attempt in VS group versus 29 patients in the FOB group (72.5%) with significant statistical difference. Successful rate in the first attempt was higher in the VS group, with statistical difference as P value = 0.04. Intubation was successful in four patients (10%) on the second attempt in VS group versus six patients in FOB group (15%) and five patients after the third attempt.

As regard SpO_2 , no statistical difference was noted all through measurement times in both groups. HR and mean arterial pressure showed significant increase in FBO group more than in CMAC-VS group at 1 and 5 min after intubation with $P < 0.001$ as shown in Figures 3 and 4.

The complications detected in this study were very mild and of no real significance in both groups. With VS, mild soreness of the throat was noted in only three patients (7.5%) and two patients (5%) with traumatized lip. In FOB group, four patients (10%) complained of painful throat and three patients (7.5%) had traumatized lip.

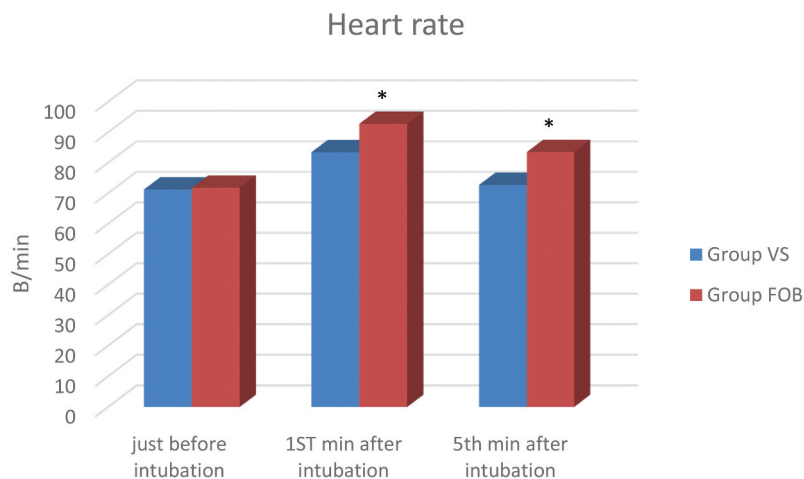


Figure 3. Heart rate beats/minute between both groups. Data are presented as mean \pm SD. *Significant difference.

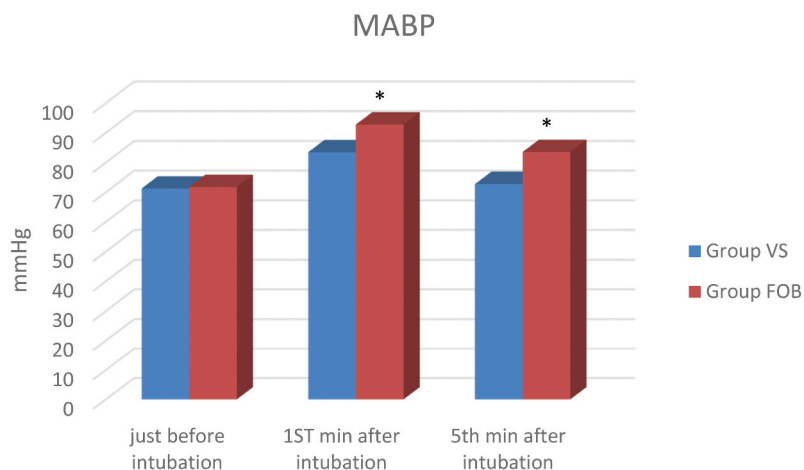


Figure 4. Mean arterial pressure in mm of Hg between both groups. Data are presented as mean \pm SD. *Significant difference.

4. Discussion

This prospective, randomized study showed that C-MAC VS was suitable alternative to FOB in awake intubation. It had significantly shorter intubation time and higher successful intubation compared with the FOB.

Studies performed by Dotson et al., [1] Rosenstock et al., [11] Kramer et al., [12] and Markova et al. [13] have addressed the topic of using the VL for awake intubation. They all concluded the possibility and the superiority of using the VL for awake intubation.

Due to the unique design of VS, only minimal opening of the mouth is enough for ETT entrance. Other advantage is related to its semi-rigid nature, rendering easier navigation. There are some drawbacks with using VS: no port for airway suction is present in the device and it is not suitable for nasal intubation as well. [6]

Unfortunately, there are a limited number of papers investigating VS, C-MAC version in awake intubation, as it is recently introduced and most of these studies were done on manikins.

Harrison et al. [14] reported the first three cases utilizing the ProVuTMVS (which was manufactured by Flexicare Medical Ltd., UK) in awake intubation. These three patients had different causes of difficult intubation (restricted mouth opening, post-radiotherapy, and post-cervical fixation). No problems were detected while performing a successful awake intubation in these three patients.

The current study showed that C-MAC-VS group has significant shorter intubation time compared to FOB group with 30 s difference. This shorter duration may be due to the rigid sheath and movable tip of the VS as it has the advantage of both rigid and flexible intubation endoscopes also C-MAC-VS conveys magnificent images because of its high-resolution camera. This was in agreement with James Pius and his colleagues [7] who tested C-MAC-VS on a manikin study in comparison to VL of C-MAC Macintosh type. Median intubation time was significantly shorter with VS 17 s in comparison to VL 23 s with P value = 0.031.

Ong et al. [15] compared trachway VS for intubation (TVI) versus Macintosh laryngoscope on a manikin in four simulated cases prepared for intubation; these cases were either with normal airway or with conditions that made intubation difficult as fixed cervical spine, tongue swelling, and oedema. They found that, intubation time was shorter when using TVI stylet in scenarios with difficult airway and with tongue oedema.

Syed Hussain Amir et al. [9] in their study compared between rigid VS and FOB in patients with no abnormality in their airway. The study was done on 60 patients. They concluded that intubation took less time using rigid VS than with FOB.

Wahdan et al. [16], in their prospective, randomized study on 50 patients, compared red-light directive rigid VS versus fiberoptic intubating bronchoscopy. They found that intubation took less time when using the rigid VS.

Lee et al. [17] did their work on 80 participants prepared for nasal intubation. The intubation was done either by flexible FOB or with VS. They measured intubation time and the occurrence of any problems with intubation. The study revealed that intubation time using VS was 36.4 s shorter than with FOB. Nevertheless, as regard complications, no statistical difference was found between both groups.

The current research revealed that, the success rate of intubation from the first attempt was significantly higher using the CMAC-VS versus using the FOB. This result might be due to several factors, such as better handling of the CMAC-VS as it has a rigid shaft with a flexible tip. The high flexibility of its tip makes it easier to direct the ETT and guide it through the larynx. On the other hand, the FOB has longer flexible shaft that needs to be carefully handled and kept straight with slower advancement. Another factor that may play a role in this deference is that the CMAC-VS needs only one hand to operate it, direct it, and control the tip position so the other hand may be used to stabilize the mouth opening or assist in the process of intubation as needed in contrast to the FOB that needs both hands of the anaesthesiologist to control it. One hand should be at the handle to control the tip movement and the other hand should be at the distal end to push the FOB into the mouth of the patient.

In this work, post-intubation HR and MABP readings were significantly increased with FOB as compared with VS, and the reason for this significant difference may be the sympathetic response as a result of excessive manipulation of vocal cord and beyond in FOB in comparison to CMAC-VS; also, the longer intubation time in the FOB group leads to higher levels of sympathetic stimulation for a longer time.

The complications detected in the study were mild and of no clinical significance. Sore throat was absent in most of the cases and very difficult to assess due to the generous use of local anaesthetic needed to perform the awake intubation.

The major limitation of this work is the inability to perform it as a double-blinded form.

5. Conclusions

We concluded that CMAC-VS could be used successfully for awake intubation. It can be considered as a better and easier alternative to the traditional FOB in awake intubation as it has shorter intubation time and minimal complications.

Disclosure statement

No potential conflict of interest was reported by the author(s).

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