Trends in Anaesthesia and Critical Care 50 (2023) 101258

Contents lists available at ScienceDirect

Trends in Anaesthesia and Critical Care

journal homepage: www.elsevier.com/locate/tacc

Bougie-assisted C-MAC video laryngoscope versus C-MAC video stylet for awake endoscopic intubation in anticipated difficult airways: A randomized controlled trial

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ARTICLE INFO

Article history:
Received 15 March 2023
Received in revised form
5 April 2023
Accepted 19 April 2023

Handling Editor: Robert Greif

Keywords:
Difficult airway
Awake tracheal intubation
Semirigid video stylet
Video laryngoscope

1. Introduction

In cases of anticipated difficult airway management, especially when difficulty with ventilation is suspected, the maintenance of spontaneous patient breathing is of paramount importance to reducing the possibility of dramatic complications and the need for 'rescue' procedures [1,2]. Recent international guidelines [2,3] recommend so-called 'awake tracheal intubation' (ATI), which consists of tracheal intubation, while keeping the patient in spontaneous breathing with supplemental oxygen delivery, after performing optimal topical anesthesia, together with appropriate sedation [4].

The first endoscopic device available for this procedure was the flexible bronchoscope, but over the last decade our team has contributed to the increasingly widespread use of video laryngoscopes and rigid fiberoptic/video endoscopes as alternative techniques for this procedure, as has been well reported in the literature [2,3,5–15].

More recently, new types of device have been proposed for ATI in cases of expected difficult airway management, such as the C-MAC video stylet (C-MAC VS®; Karl Storz AG, Tuttlingen, Germany), which combines the advantages of rigid stylets with those of flexible optical scopes [16].

To our knowledge, no clinical trial has been yet carried out to compare this new device with the most established video laryngoscope for ATI.

The aim of this non-inferiority randomized clinical trial was to compare the efficacy for ATI of the C-MAC video laryngoscope (VLS) and the C-MAC video-stylet (VS) in patients with predicted severe difficult airway scheduled for elective surgery.

Intubation success rate was the primary endpoint. Evaluations of intubation times, hemodynamic parameters, and any complications or adverse events resulting from intubation were the secondary aims. The hypothesis to be verified was that there is no difference in terms of success rate between the two devices for awake tracheal intubation.

2. Methods

This non-inferiority randomized clinical trial was conducted from September 2020 to December 2022 in a tertiary teaching hospital (Azienda Ospedaliero-Universitaria delle Marche Ancona, Italy). The study was approved by the Regional Ethics Committee on April 1, 2020 (CERM-Protocol N. 2020–14; Chair: Prof. Paolo Pelaia). The study conformed to the Declaration of Helsinki and Good Clinical Practice guidelines, and informed consent was collected from all patients enrolled prior to data acquisition.

The trial was registered at ClinicalTrials.gov with registration number NCT04532138. Four anesthesiologists (SF, LP, MB, AM) — consultants for over 7 years and each one with experience of more than 50 tracheal intubations with rigid scopes and VLS —

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https://doi.org/10.1016/j.tacc.2023.101258

performed oral awake intubations with both C-MAC VS and C-MAC VLS.

The inclusion criteria were as follows: patients >18 years undergoing elective non-cardiac surgery under general anesthesia with one or more of the following anthropometric criteria predictive of difficult airway management at the preoperative assessment: limited cervical spine movements (traumatic or surgical arthrodesis), Mallampati score (MS) = 4, thyromental distance (TMD) < 6 cm, interincisor distance (IID) < 3 cm, suspected difficult ventilation via face mask, and history of difficult or failed intubation.

The following were considered exclusion criteria: patient refusal, patients scheduled for surgery not requiring tracheal intubation, patients with tracheostomy, urgent/emergency surgery, and patients with respiratory failure.

On arrival in the operating room, nasal oxygen (10 L/min) and routine monitoring (NIBP, HR, SpO_2, ECG) were established.

Heart rate and blood pressure were recorded upon patient arrival and every 3 min until the end of the procedure, while arterial oxygen saturation was continuously recorded.

For all enrolled patients, spontaneous breathing was preserved and the same protocol of analgosedation and topical anesthesia of the upper airways applied, consisting of the intravenous administration of midazolam 0.03 mg/kg and fentanyl 2 mcg/kg, alongside puffs of lidocaine 10% spray in the oral cavity and nebulization of lidocaine 2% in the larynx through an atomizer (MADgic® Laryngo-Tracheal Mucosal Atomization Device; Teleflex Medical, Athlone, Ireland). Patients were maintained at a Ramsay sedation scale score of 2 (cooperative, oriented, and calm) at all times.

Anthropometric data were collected for each subject recruited, including height, weight, body-mass index (BMI), thyromental distance, interincisor distance, and Mallampati score. General anesthesia induction was carried out just after the completion of ATI, and muscle relaxants were not administered until proper tracheal tube placement was verified by waveform capnography.

VLS intubation technique (Fig. 1).

After administration of lidocaine 10% spray on the tongue surface and onto the oropharynx, a C-MAC hyperangulated blade was inserted into the midline of the oral cavity, sliding gently over the tongue until visualization of the epiglottis and laryngeal inlet (Fig. 1a). A 5 ml dose of 2% lidocaine was nebulized through an atomizer onto the glottis, under endoscopic visualization, then a bougie (Frova Introducer®; Cook, Bothell, USA) was inserted through the vocal cords and the tracheal tube railroaded over the bougie.

VS intubation technique (Fig. 2).

The same endoscopist who performed the ATI provided topical anesthesia via the administration of lidocaine spray 10%, puffed into the oral cavity, in particular the right vestibule. After slightly opening the mouth, the device was introduced into the right side of the oral cavity vestibule and, sliding behind the molars, advanced along the pharyngeal wall (retromolar approach). At the posterior pharyngeal wall (tonsil pillar), the device tip was rotated, using a lever at the handpiece, in an anterior direction to visualize the epiglottis. Then it was advanced toward the vocal cords. After applying an instillation of lidocaine 2% on the glottis inlet, via an atomizer under endoscopic visualization, the VS was introduced through the laryngeal inlet and the mounted tube railroaded over it using a gentle rotation.

The maximum time allowed for each intubation attempt was 10 min. A decrease in SpO_2 to under 90% was considered an additional criterion for abandoning the procedure.

In cases of difficulties with oxygenation, alternative rescue procedures, supraglottic devices (SGAs), and a cricothyroidotomy set were ready, as established by the international guidelines [2,3].

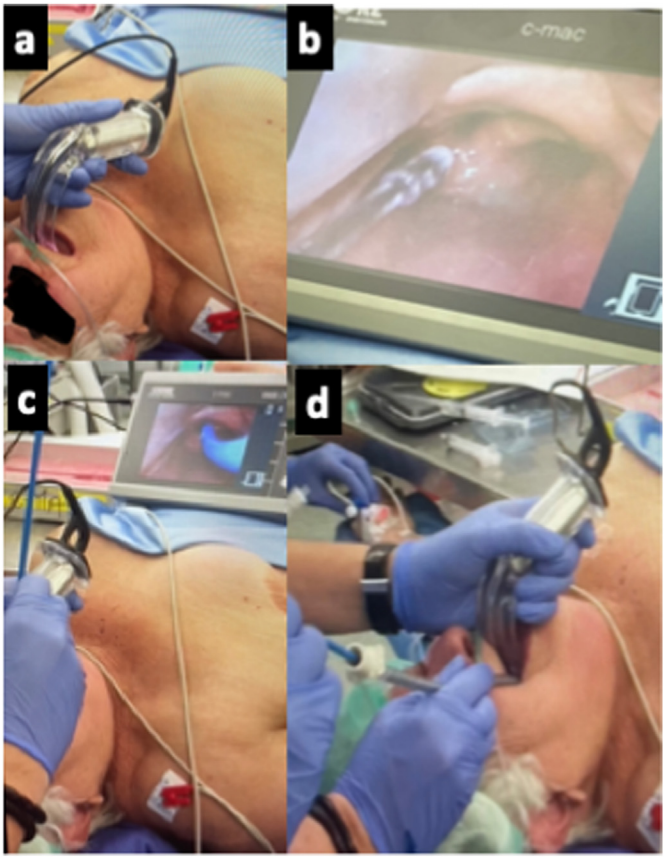

Fig. 1. C-MAC video laryngoscope awake tracheal intubation. (a) D-blade introduction in the oral cavity, sliding over the tongue. (b) Nebulization of local anesthetic in the glottis via an atomizer. (c) Bougie insertion through the vocal cords. (d) Tracheal tube insertion into the trachea, railroading over the bougie.

2.1. Outcome measures

The primary endpoint was the success rate (%) of the procedure, defined as correct positioning of the tracheal tube, verified endoscopically and via a capnographic curve of end-tidal carbon dioxide ($EtCO_2$).

The secondary endpoints were as follows: first-pass success rate (FPSR); total number of attempts needed; intubation time (counted from the device insertion in the oral cavity to the definitive positioning of the tracheal tube as verified by $EtCO_2$ detection); and the incidence of any complications (i.e. pharyngeal/laryngeal bleeding, arterial desaturation/hypoxia, cough, vomiting).

A numerical rating scale (NRS) was used for grading patient tolerance of the procedure, as obtained on the first postoperative day (ranked from 1 = *no unpleasant memories* to 5 = *extreme intolerance and need for sedation*), and the operator's difficulty experienced with device manipulation (ranging from 1 = *extremely difficult* to 5 = *very easy*).

2.1.1. Patient allocation and randomization

The selection and randomization, follow-up, and analysis processes are presented in Fig. 3, in accordance with the CONSORT 2010 flowchart [17].

Randomization was performed by a statistician, using a computer-generated random numbers table to assign participants in a 1:1 ratio for having intubation with VS or VLS.

Group allocation was concealed in sealed, opaque envelopes. The anesthetic team only revealed the randomization allocation on

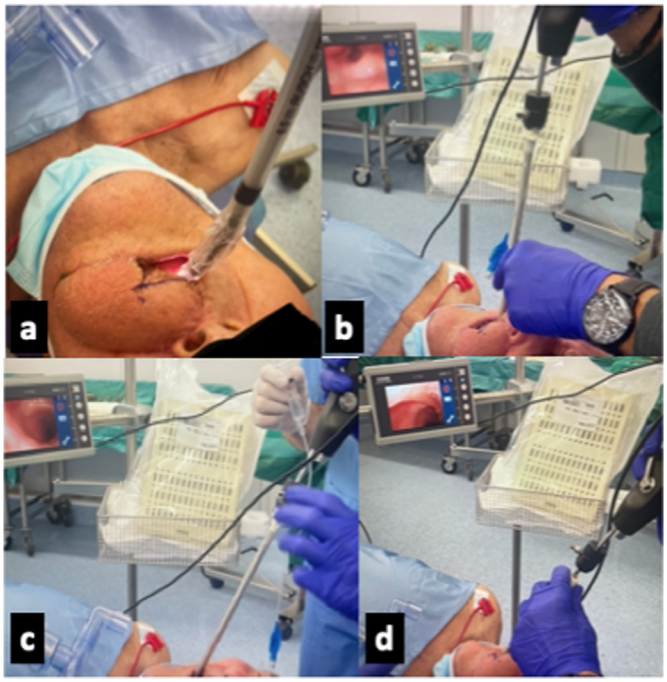

Fig. 2. C-MAC VS video stylet awake tracheal intubation. (a) Video stylet introduction in the oral cavity. (b) Video stylet advanced in the right vestibule, with visualization of the glottis inlet. (c) Nebulization of local anesthetic in the glottis via an atomizer. (d) Tracheal tube insertion into the trachea, railroading over the video stylet.

the day of surgery. Patients were not informed of the group allocation.

2.1.2. Statistical analysis

The Medcalc 7.3.0.1 statistics program was used for statistical analysis.

Normally distributed data are expressed as mean ± standard deviation and 95% confidence interval, while non-normally distributed data are given as median and interquartile range. The frequency (%) for each category is also presented.

The Kolmogorov-Smirnov test was used to evaluate the normality of the continuous variables.

The *t*-test for normally distributed data was used to compare the two groups. Alternatively, the nonparametric Mann–Whitney test was used. A *p*-value of less than 0.05 was considered statistically significant. The difference in total ATI success rate between the two groups of patients was evaluated using Fisher's exact test. Differences in operator difficulty NRS and in patient tolerance NRS between the two groups were evaluated using the chi-squared test.

The non-inferior efficacy of the video stylet (VS) compared with the standard method (video laryngoscope with D-blade) should have been confirmed if the difference, with 95% confidence interval, was less than the non-inferiority margin established a priori as equal to 10%, in accordance with the literature [5] and clinical judgment.

Assuming an intubation success rate with the two devices of 99%, an alpha error of 5%, and a study power of 90%, a total sample of 30 patients (15 per group) was needed to rule out the null

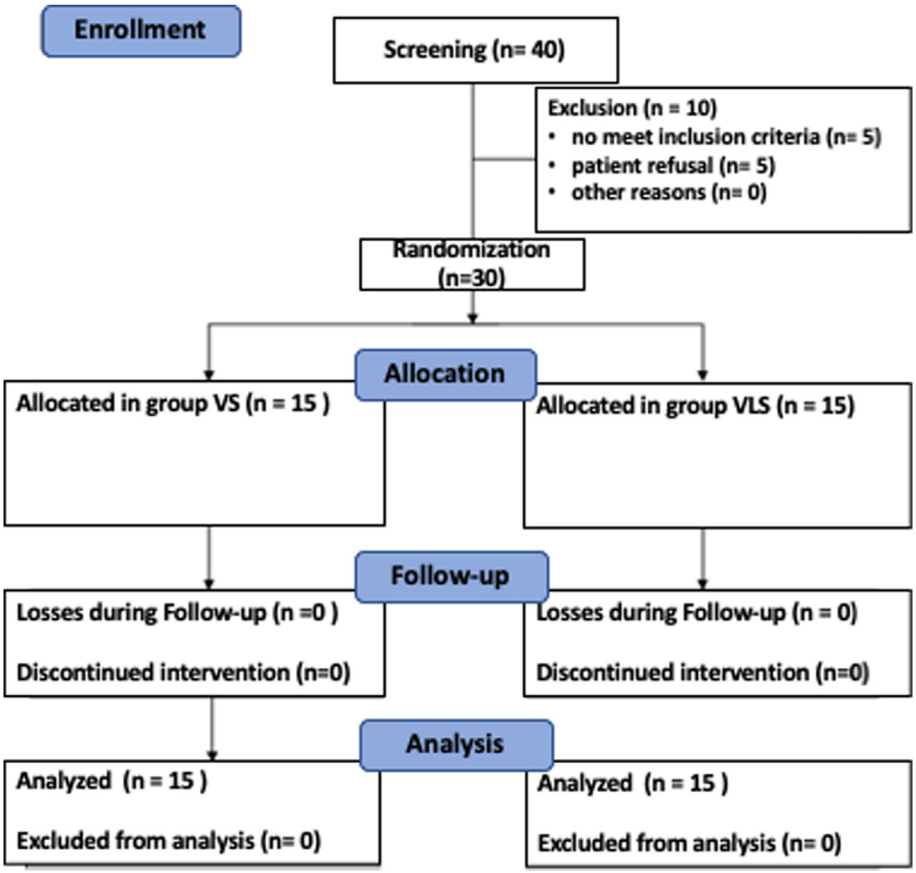

Fig. 3. CONSORT flowchart of the study.

hypothesis of a difference >10% in the rate of successful intubations in favour of the video laryngoscope technique.

3. Results

In total, 40 patients were reviewed for inclusion; five were eliminated because they did not meet the inclusion criteria and another five for refusal to participate, as shown in the study flowchart (Fig. 3). Thirty patients were randomly assigned to be intubated with either VS or VLS (15 patients in the VS group and 15 patients in the VLS group), thus completing the study protocol. The patients' demographic data are presented in Table 1.

The predictive criteria for difficult airway management, suggesting the ATI procedure for the patients enrolled in the study, are shown in Table 2. The anthropometric parameters shown in Table 2 occurred singly or in combination.

The video stylet was used for ATI in 14 patients (93%) with a Mallampati score (MS) = 4, in eight patients (53%) with interincisor distance (IID) < 3 cm, in nine patients (60%) with thyromental distance (TMD) < 6 cm, in four patients (26%) with predicted difficultly with bag-mask ventilation (PDBMV), and in two patients (13%) with low neck mobility.

The video laryngoscope was used for ATI in nine patients (60%) with MS = 4, in five patients (33%) with IID <3 cm, in two patients (13%) with TCD <6 cm, in 10 patients (66%) with PDBMV, and in three patients (20%) with low neck mobility.

The overall success rate of ATI was 100% in both groups, with a successful first attempt rate of 80% in the VS group and 86% in the VLS group ($p = 1.0$) (Table 3). The maximum rate of attempts made for a successful intubation was two in both groups, and the reason for withdrawing the device and retrying the procedure in all these cases was the presence of secretions due to the lack of an aspiration channel.

The median intubation time was 25 s (range 17–85) in the VS group and 60 s (range 45–120) in the VLS group ($p = 0.0213$) (Fig. 4).

No statistically significant differences emerged between the two groups regarding the other secondary endpoints, such as operator difficulty NRS (Table 4) and patient tolerance of the procedure NRS (Table 5).

No serious complications (pharyngeal/laryngeal bleeding, arterial desaturation/hypoxia, vomiting), occurred during or after ATI in both groups. A little coughing occurred in three patients in the VS group and two patients in the VLS group during tracheal tube insertion through the vocal cords, but without compromising the successful outcome of the procedure.

4. Discussion

This randomized controlled trial demonstrated the non-inferior efficacy of video stylet compared with the more standardized technique based on video laryngoscope plus hyperangulated blade for awake tracheal intubation in cases of severe predicted difficult airway, as shown by the overall success rate of 100% in both groups of patients.

To our knowledge, no comparison has so far been made between the C-MAC video stylet and the C-MAC hyperangulated blade video laryngoscope, which currently has more widespread use among anesthesiologists for ATI [3–5].

In our opinion, rigid endoscopes and video stylets are less

Table 1
Patients' demographic data.

	VLS ($n = 15$)	VS ($n = 15$)
Age	58.6 (±14.3)	63.5 (±13.4)
Male gender, *n* (%)	8 (53.33)	4 (26.67%)
Weight (kg)	77.20 (±16.98)	78.73 (±24.59)
Height (cm)	162.4 (±6.9)	167.47 (±7.4)

Table 2
Predictive criteria for difficult airway management.

Predictive criteria	VLS ($n = 15$)	VS ($n = 15$)
Mallampati score 4	9 (60%)	14 (93%)
Interincisor distance (IID) < 3 cm	5 (33%)	8 (53%%)
Thyromental distance (TMD)	2 (13%)	9 (60%)
Difficult bag-mask ventilation (DBMV)	10 (66%)	4 (26%)
Restricted neck mobility	3 (20%)	2 (13%)

Table 3
Number of attempts.

Number of attempts	VLS	VS	Fisher test
1	13 (86.67%)	12 (80%)	$p = 1.000$
2	2 (13.33%)	3 (20%)	

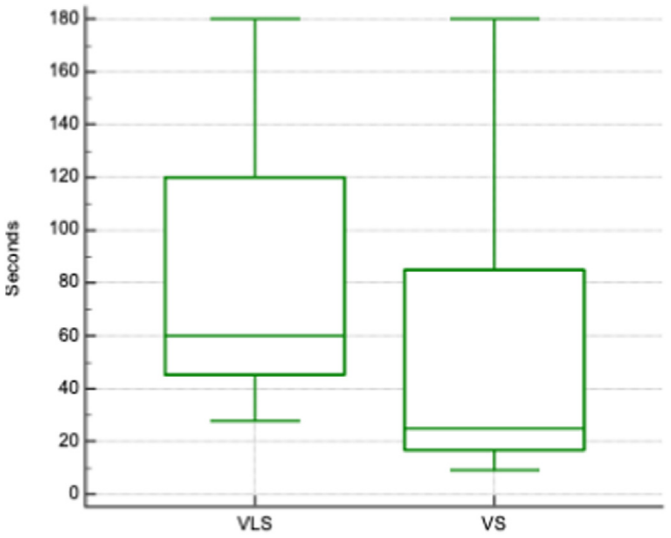

Fig. 4. Intubation times: VLS group = 60 s (45–120 s), VS group = 25 s (17–85 s) (Mann–Whitney test; $p = 0.0213$).

Table 4
Operator difficulty experienced.

Grade of operator difficulty	VLS group	VS group	Chi-squared test
1 (extremely difficult)	0	0	
2 (very difficult)	1 (6.67%)	0 (0%)	
3 (moderately difficult)	6 (40%)	2 (13.33%)	$p = 0.1979$
4 (not difficult)	5 (33.33%)	10 (66.67%)	
5 (very easy)	3 (20%)	3 (20%)	

Table 5
Patient tolerance.

Grade of patient tolerance	VLS group	VS group	Chi-squared test
1 (No memory)	12 (80%)	11 (73.33%)	
2 (Slight annoyance)	2 (13.33%)	4 (26.67%)	
3 (Moderate discomfort)	1 (6.67%)	0	$p = 0.4253$
4 (Serious discomfort)	0	0	
5 (Unbearable discomfort)	0	0	

commonly used than VLS because, despite being older than VLS, it is only recently that more effective and user-friendly VS devices have been launched on the market, probably as a consequence of the more rapid evolution of video technology over optical systems. Before these developments, video stylets were probably considered more challenging for clinicians, more hazardous for patients, and less effective than video laryngoscopes.

In a prospective observational study, Nabecker et al. [16] analyzed the feasibility of successful C-MAC VS awake orotracheal intubation in adult surgical patients with known or predicted difficult airway. This was the first report of the use of the C-MAC VS in predicted difficult airways, and revealed an overall success rate of 97% and a median intubation time of 45 s (IQR 31–88 s).

In a randomized controlled trial, Nassar et al. found that both the Bonfils rigid fiberscope and the GlideScope VLS could be successfully used for ATI in morbidly obese patients with expected difficult airway. The Bonfils endoscope was more tolerated by patients, but the GlideScope-VLS provided shorter intubation time and fewer intubation attempts [18].

With regard to the secondary endpoints of our study, only the median intubation time (IT) showed a statistically significant difference between the two groups of patients, and was shorter in the VS group ($p = 0.0213$) (Fig. 4). This result was probably due to the greater confidence and expertise in the use of VS of the anesthesiologists who performed the ATI. In our hospital this device has been used for several years as an alternative to VLS for tracheal intubation after intubation failure with Macintosh blade, especially in the case of patients with limited mouth opening (a situation in which these devices seem more appealing and exhibit better performance), as suggested in the literature [19–21].

Unfortunately, there are no data on how the device performs in the hands of less-experienced airway operators, or for routine intubations in anesthetized patients. To date, there are no learning curves published that analyze the performance of C-MAC VS when used by beginners, whereas recent studies suggest that routine use of VLS improves performance [22].

In our study, C-MAC VS was as successful, and with similar or even shorter intubation times, as the results found in the meta-analyses of Alhomary et al. [5] and Rosenstock et al. [6], and also in the study by Nabecker et al. [16], showing similar efficacy and reliability to VLS and flexible endoscopes.

Our results showed a first attempt success rate of 80% in the VS group and 86% in the VLS group, which was comparable with various studies on flexible bronchoscopes and video laryngoscopes [5,6,12,23,24]. Moreover, the more favourable NRS score for operator difficulty (Table 4) registered for the VS group confirmed a good feasibility and effective handling when performing a retromolar approach for the ATI. One explanation for this could be the combination of a high level of operator confidence with the device, and lower patient stimulation caused by the retromolar VS stylet insertion in the oral cavity. Conversely, the VLS C-MAC hyperangulated blade, when inserted centrally over the tongue, could generate greater stimulation, causing major patient discomfort, especially if the duration of the procedure is longer or the operator's skill level is not excellent.

An interesting consideration was highlighted after the study regarding the main difference between the two intubation techniques and the devices used. ATI using VLS is characterized by a clear separation of two different intubation phases — glottis visualization and tracheal tube insertion — which could increase time to intubation and patient discomfort. In contrast, with the C-MAC VS technique these two phases coincide. In this regard, VS, in acting as an optical introducer similarly to the flexible endoscope, may allow faster tracheal intubation, in expert hands, with lower patient discomfort (Table 5).

On the first postoperative day, all 30 patients who were enrolled in study were contacted and they recalled only minimal side-effects, consisting of a little coughing during the procedure. No other symptoms or side-effects were reported, and 93% of patients in the VLS group and 100% in the VS group claimed no memory of, or only slight annoyance during, the intubation procedure.

4.1. Limitations of the study

This study had some limitations. First, it was a single-center randomized controlled trial with a low sample size of enrolled patients, and small number of selected anesthesiologists experienced with ATI. Consequently, generalization of our results must be taken with caution, because in other situations and institutions approaches to airway management might be different. Therefore, further multicenter prospective comparative studies should be performed on a larger number of patients and with a large number of operators involved.

Second, within its nature, the study protocol could not include a blind arm.

Third, the study did not compare the learning curves for the two endoscopic devices used. It might be useful for a future study to analyze how many procedures are necessary to obtain the right expertise to successfully perform an ATI with both these instruments, without any risk for the patients.

5. Conclusion

Short intubation time, low failure rate, and no injuries are three important aims in all intubation procedures. Fiberoptic or video flexible optical intubations are still considered the goal standard techniques when an airway is anticipated to be difficult, but the non-inferiority of VLS and rigid video stylets to these devices has not been thoroughly demonstrated [5,6].

Our randomized controlled study demonstrated the non-inferiority, in skilled hands, of a new semi-rigid endoscopic stylet (C-MAC VS) when compared with a bougie-assisted hyperangulated blade-VLS, confirming the VS to be a valid alternative for awake tracheal intubation in anticipated difficult airways.

Assistance with the study

None.

Financial support and sponsorship

None.

Presentation

None.

Funding

No funding was requested for this study.

Institutional review board statement

The study was conducted in accordance with the Declaration of Helsinki, and approved by the Regional Ethics Committee of Marche (CERM) on April 1, 2020 (CERM-Protocol N. 2020–14; Chair: Prof. Paolo Pelaia).

Informed consent statement

Informed consent was obtained from all subjects involved in the study. Written informed consent to publish this paper was obtained from all patients.

Data availability

The datasets used and/or analyzed during this study are available from the corresponding author on reasonable request.

CRediT authorship contribution statement

S. Falcetta: recruited all the patients and performed tracheal intubation with CMAC-VS or CMAC VLS as for randomization protocol, made the patients data collection /curation and manuscript first writing. **L. Pecora:** recruited all the patients and performed tracheal intubation with CMAC-VS or CMAC VLS as for randomization protocol. **M. Borioni:** recruited all the patients and performed tracheal intubation with CMAC-VS or CMAC VLS as for randomization protocol. **A. Montozzi:** recruited all the patients and performed tracheal intubation with CMAC-VS or CMAC VLS as for randomization protocol. **A. Carsetti:** helped to make the statistical analysis; **M. Sorbello** and **R. Cataldo** helped to revise the manuscript for a correct english translation and review the references. **I. Di Giacinto:** made the supervision and the writing of the manuscript. **E. Cerutti:** made the supervision and the writing of the manuscript. **A. Donati:** helped to make the statistical analysis; Massimiliano Sorbello and Rita Cataldo helped to revise the manuscript for a correct english translation and review the references, made the supervision and the writing of the manuscript.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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