

# Comparison of conventional C-MAC video laryngoscope guided intubation by anesthesia trainees with and without Frova endotracheal introducer: A randomized clinical trial

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## Abstract

**Background and Aims:** Successful intubation with video laryngoscopes necessitates good hand-eye coordination and the use of intubation adjuncts like bougie and stylet. We proposed this study to find whether using Frova introducer with C-MAC video laryngoscope will reduce the intubation time in trainee anesthesiologists.

**Material and Methods:** We enrolled 140 adults without any difficult airway predictors. They were randomly assigned to undergo C-MAC video laryngoscope guided intubation by anesthesia residents using tracheal tube preloaded over Frova introducer ( $n = 70$ ) or without Frova introducer ( $n = 70$ ). Primary outcome was the intubation time. Secondary outcomes were the number of redirections of tracheal tube or Frova introducer toward glottis, need for external laryngeal maneuvers (ELMs), first attempt intubation success rate, and ease of intubation.

**Results:** The median actual intubation time (IQR) in Frova and non-Frova group, respectively, were 25.46 (28.11–19.80) and 19.96 (26.59–15.52) s ( $P = 0.001$ ). The number of redirections of TT or Frova introducer toward glottis, first attempt success rate, and ease of intubation were comparable. The need for ELMs [ $n$  (%)] was 15 (21.4) and 26 (37.1) in Frova and non-Frova group, respectively ( $P = 0.04$ ).

**Conclusion:** Frova introducer guided endotracheal intubation with C-MAC videolaryngoscope in patients with normal airways had a marginally prolonged intubation time with a significant reduction in the need of external laryngeal manoeuvres but with a comparable number of redirections and attempts. Further research is needed to generalize these findings to patients with difficult airways.

**Keywords:** Bougie, C-MAC videolaryngoscope, frova tracheal tube introducer, novice learners, video-assisted intubation success, trainee anesthesia

## Introduction

Over the years, the C-MAC videolaryngoscope (VLS) C-blade has shown to enhance the laryngeal view during intubation.<sup>[1-3]</sup> Video-based intubation necessitates skilled hand–eye coordination and intubating aids like bougie/stylet for successful intubation.<sup>[3-5]</sup> It is a well-known fact that the

indirect view of glottis obtained with a videolaryngoscope does not always guarantee easier passage of tube in spite of a good Cormacke Lehane (CL) grade.<sup>[3]</sup> The manufacturer does not recommend the use of a stylet with standard C-MAC blade as it has a Macintosh like curvature, but it depends on individual preferences.<sup>[6,7]</sup> In such situations, the Frova introducer with its bent tip and narrow diameter enables better maneuverability and passage through glottis. The optimal

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learning technique is unclear for the standard C-MAC VLS as intubation can be done with or without bougie/stylet.<sup>[2,6,7]</sup> We evaluated whether using Frova introducer with C-MAC VLS would reduce the intubation time especially in learners. The primary objective was to compare the intubation time. Secondary objectives were the number of redirections of tracheal tube or Frova introducer toward glottis, need for external laryngeal maneuvers, first attempt success rate, and ease of intubation.

## Material and Methods

After approval from the institute ethics committee (JIP/IEC/2017/0260) and registration in the clinical trials registry of India (CTRI/2017/09/009793), this randomized, parallel-arm, prospective, single-center clinical trial was undertaken from April 2018 to June 2019. After informed written consent, a total of 140 patients in the age group of 18–60 years of age, belonging to the American society of anesthesiologists physical status (ASA PS) I and II scheduled to undergo elective surgery with orotracheal intubation were included in this study. Patients who fulfilled the inclusion criteria of mouth opening more than 3 cm, full range of neck movements, thyromental distance more than 6 cm, Modified Mallampati (MMP) class less than or equal to two were included in the study. Any patient requiring rapid sequence induction or with anticipated difficult airway predictors was excluded from the study.

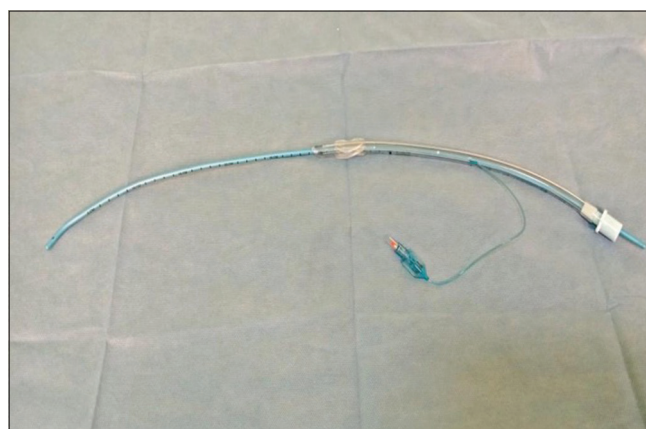
Randomization was done during the pre-anesthetic visit using a computer-generated random number table of varying block sizes by an investigator not involved in the study. Concealment to the group allocation was done using sequentially numbered opaque sealed envelope (SNOSE). The patients were randomly assigned in a 1:1 ratio to undergo intubation by anesthesia trainees with a tracheal tube (TT) preloaded over the Frova introducer (Group F) or TT alone, without Frova introducer (Group WF). The anesthesia trainees had at least 1 year of training in anesthesia and had practiced C-MAC VLS guided intubation for ten times in a manikin.

All patients underwent pre-anesthetic checkup a day before surgery and informed written consent was obtained. On the day of surgery in the operating room, standard ASA monitors like electrocardiogram, noninvasive blood pressure, pulse oximetry were attached and baseline vital parameters were recorded. The patients were positioned in sniffing position and preoxygenated with 100% oxygen followed by intravenous induction with propofol, fentanyl, and vecuronium. Mask ventilation was done for 3 min with isoflurane in 100% O<sub>2</sub> to achieve a minimum alveolar concentration (MAC) of one. In

both groups, the C-MAC C-blade (Karl Storz, Tuttlingen, Germany) of size three and appropriate size polyvinyl chloride TT were used for intubation.

The C-MAC Videolaryngoscope blade was inserted into the patient's oral cavity and the tongue was displaced to the left side in a manner similar to conventional direct laryngoscopy. Then the C-MAC VLS screen was observed for the CL grade obtained. On reaching the base of the tongue, the tip of the blade was kept in the vallecula and the epiglottis was lifted. After glottic visualization, in group F, intubation was attempted with the lubricated TT preloaded over a Frova intubating introducer without the stiffening stylet (14 Fr, 70 cm long, Cook Medical, Bloomington, USA). The lubricated TT was preloaded on the Frova introducer such that 30 cm length was free from the distal (patient) end as shown in Figure 1. After the distal tip of Frova introducer entered the glottis, the TT was railroaded over it till the intubation marker was at the level of vocal cords, while an assistant stabilized the introducer. Once the intubation marker just reached the glottis, the Frova introducer was withdrawn. In group WF, after glottic visualization, the trachea was intubated using TT separately without the aid of Frova introducer.

After the successful passage of TT beyond the glottis, the laryngoscope was removed and TT was connected to the anesthesia circuit. Anesthesia was maintained using isoflurane in air and oxygen mixture. The primary outcome was to compare the intubation time using a TT with Frova introducer vs TT alone. The total intubation time was regarded as the time interval between the introduction of the C-MAC C-blade into the patient's mouth to the appearance of the ETCO<sub>2</sub> trace. The total laryngoscopy time was regarded as the interval between the introduction of the C-MAC C-blade into the patient's mouth to the best visualization of the glottis on the video screen. The total laryngoscopy time was subtracted from



**Figure 1:** Tracheal tube preloaded on the Frova tracheal introducer (till the 30 cm mark from its distal tip)

the total intubation time to derive the actual intubation time. This eliminated the confounding effect of a faulty laryngoscopy technique on the actual intubation time.

The secondary outcome parameters were the number of redirections of the TT or Frova introducer toward glottis, first attempt intubation success rate, CL grade observed, need for external laryngeal maneuvers (ELMs), and ease of intubation measured on a Likert scale (1- very easy passage of tube/bougie through glottis, 2- easy passage of tube/bougie through glottis, 3- moderately difficult to pass tube or bougie through glottis, 4- very difficult to pass tube/bougie through glottis). Any attempt that is taken to push the TT or the Frova introducer in the direction of the glottis was regarded as one redirection attempt. Passage of the TT (in group WF) or the Frova introducer (in group F) in the first attempt without redirection was considered as intubation success at the first attempt. External laryngeal maneuvers (ELMs) such as the thyroid manipulation were performed if required to facilitate glottic visualization for intubation and were noted. If the total duration of intubation took more than 120 s or if any adverse event like airway injury or desaturation (oxygen saturation <95%) occurred, the intubation attempt was considered as a failure and appropriate actions were initiated. All patients were blinded to the group allocation. Blinding of anesthetist performing intubation could not be done as they were informed about the technique to be used. All the study parameters were noted by a separate anesthesiologist not involved in the study except for the ease of intubation, which was reported by the intubator using an ordinal scale. The biased interpretation was eliminated by objectively defining the intubation time, laryngoscopy time, and the number of redirections toward glottis.

The sample size was calculated using the statistical formula for comparing two independent means based on the study done by Hodgetts *V et al.*<sup>[8]</sup> The sample size was estimated as  $n = 140$  ( $n = 70$  in each group) with a minimum expected mean difference in the time taken for intubation of 10 s, a standard deviation of 20 s, power of 80%, 5% level of significance and an attrition rate of 10%. The statistical analysis was done using SPSS software version 19 (IBM Corp Armonk NY). The distribution of categorical variables such as gender, need for ELMs, need for redirection of TT or Frova introducer toward glottis, first attempt success rate of intubation was expressed in terms of frequency or percentage and was compared using Chi-square test/ Fishers test as relevant.

The distribution of continuous and discrete variables such as age, weight, height, body mass index, total intubation time, laryngoscopy time, actual intubation time, and the number of attempts at redirection of the endotracheal tube was expressed

in terms of the median with interquartile range or mean with standard deviation and analyzed with Mann–Whitney test or independent Student's *t*-test, respectively, based on the normality distribution of the data as estimated by Shapiro–Wilk test. The comparison of ordinal data such as MMP Class, Cormack-Lehane (CL) grade, ASA PS class, and the ease of intubation (ordinal scale) was done using Chi-square test or Fisher's exact test. All statistical tests were performed at a 5% level of significance.

## Results

A total of 162 patients were enrolled and assessed for eligibility. Out of these, 22 patients were excluded as they did not give consent to participate in the study. After obtaining written informed consent the remaining 140 patients were equally allocated to two groups as depicted. The demographic and airway characteristics were comparable as represented in Tables 1 and 2.

The median (IQR) actual intubation time was significantly higher in Group F 25.46 (28.1-19.8) s as compared to Group WF 19.96 (26.59–15.52) s,  $P = 0.001$ . The median laryngoscopy time was comparable between the groups. The median (IQR) number of redirections toward glottis [1 (2-0) vs. 1 (3-0)] was comparable in both the groups. The passage of the Frova introducer through glottis in the first attempt without any redirection was 44.3% in group F and in group WF the passage of the TT through glottis in the first attempt without any redirection was 40%, which was not statistically different ( $P = 0.61$ ). In group WF, there was a significantly increased need for ELMs than in group F (37.1% vs. 21.4%),  $P = 0.04$ . There was a significantly higher proportion of patients with CL II grade of laryngoscopy view in group WF (20% vs. 2.9%),  $P = 0.001$  [Table 3].

The perceived ease of intubation was comparable between the two groups,  $P = 0.67$  [Table 4]. There was no airway injury, failed intubation, or incidence of desaturation in either of the groups.

## Discussion

The advent of video laryngoscope in 20<sup>th</sup> century has ushered a remarkable change in the approach toward difficult airways. The Difficult airway society (DAS) 2015 guidelines mention early use of VLS in plan A of unanticipated difficult intubation.<sup>[4]</sup> The C-MAC VLS has been found to enhance the glottic view by at least one CL grade, thus enabling easier intubation.<sup>[3,9,11]</sup> As VLS might be the standard of care in future there is need for all trainees to familiarize with the equipment and to find an optimal technique of its use.

In our study, we found that the median total and actual intubation times were marginally prolonged by about 5 s when TT preloaded over Frova introducer was used for C-MAC VLS guided intubation by anesthesia residents, as compared to TT alone, in patients without any difficult airway predictors. The number of redirections toward glottis and the first attempt intubation success rate was similar in both the groups. The need for ELMs was significantly more in the non-Frova group. The ease of intubation on an ordinal scale was comparable in the two groups.

The Frova introducer because of its narrow diameter (4.7 mm) and a bent coude tip can be maneuvered toward glottis easily with less encroachment of glottic view compared to the TT with a greater diameter.<sup>[12,13]</sup> Its stiffer nature enables it to be a good alternative to gum elastic bougie in various studies.<sup>[14-16]</sup> Though we hypothesized that the Frova introducer will reduce the intubation time by reducing the intubation attempts because of its easy maneuverability, there was no reduction in the intubation time with the use of Frova introducer in our study. The higher

intubation time needed in the group F could be because of the time taken for railroading the TT over the introducer or because of the need for rotation of the TT if there was arytenoid impingement.

Though statistically significant, the difference of 5.11 and 5.5 s in the median total and actual intubation time respectively is of questionable clinical significance in healthy adult patients since the median intubation times were still found to be in near range with other studies involving experienced anesthetists.<sup>[12,13,17]</sup>

The comparable number of redirections and first attempt intubation success rate among the groups may be because of the involvement of patients without any difficult airway parameters. The advantage of Frova introducer guided tracheal intubation may be appreciated better in patients with difficult airway parameters where one may encounter difficulty in passing the tracheal tube despite a good laryngeal view noted on the video screen. In such scenarios, an endotracheal introducer can be easily passed through the glottis with

**Table 1: Patient demographic characteristics**

Parameter	Group F (n=70)	Group WF (n=70)	P
Age (years) [median (IQR)]	43 (52.5-29.75)	45 (54.25-29.5)	0.64
Gender (Male/Female) [n (%)]	27/43 (39/61)	35/35 (50/50)	0.17
Height (m)[mean (SD)]	1.57 (0.04)	1.60 (0.06)	0.001*
Weight (kg) [mean (SD)]	59.9 (11.01)	58.83 (9.25)	0.70
BMI (kg/m <sup>2</sup> ) [median (IQR)]	24.52 (27.01-20.14)	22.12 (25-20)	0.11
ASA PS class (I/II) [n (%)]	25/45 (36/64)	23/47 (33/67)	0.72

<sup>†</sup>Group F - C-MAC VLS with Frova introducer, Group WF- C-MAC VLS without Frova introducer. ASA PS - American Society of anesthesiologists physical status, BMI - Body mass index. Age and BMI are represented as median (interquartile range). Gender and ASA PS class are represented as a number (percentage). \*P<0.05

**Table 2: Airway characteristics**

Parameter	Group F (n=70)	Group WF (n=70)	P
Mouth opening >3 cm [n (%)]	70 (100)	70 (100)	1
MMP class (I/II) [n (%)]	22/48 (31.4/68.6)	15/55 (21.4/78.6)	0.18
Full range of neck movements [n (%)]	70 (100)	70 (100)	1
Thyromental distance >6 cm [n (%)]	70 (100)	70 (100)	1

<sup>†</sup>Group F - C-MAC VLS with Frova introducer, Group WF- C-MAC VLS without Frova introducer. MMP - Modified Mallampati Classification. All airway parameters are represented as a number (percentage)

**Table 3: Intubation conditions and characteristics**

Parameter	Group F (n=70)	Group WF (n=70)	P
Total intubation time (s) [median (IQR)]	35.48 (38.7-30.21)	30.37 (37.8-25.34)	0.005*
Laryngoscopy time (s) [median (IQR)]	10.24 (11.47-9.33)	10.57 (12.46-8.98)	0.94
Actual intubation time (s) [median (IQR)]	25.46 (28.11-19.80)	19.96 (26.59-15.52)	0.001*
Median number of attempts of redirection of TT/ bougie towards glottis [median (IQR)]	1 (2-0)	1 (3-0)	0.25
First attempt success rate [n (%)]	31 (44.3)	28 (40)	0.61
Need for ELMs [n (%)]	15 (21.4)	26 (37.1)	0.04*
CL grade (I/II/III/IV) [n (%)]	68/2/0/0 (97.1/2.9/0/0)	56/14/0/0 (80/20/0/0)	0.001*

<sup>†</sup>Group F - C-MAC VLS with Frova introducer, Group WF- C-MAC VLS without Frova introducer. TT- Tracheal tube, ELMs - External Laryngeal manoeuvres, CL grade - Cormack-Lehane grading of laryngoscopic view. First attempt success rate, need for ELMs, redirections and CL grade are represented as number (percentage). The total intubation time, actual intubation time, laryngoscopy time in seconds and number of redirections towards glottis are represented as median (interquartile range). \*P<0.05.

**Table 4: Comparison of ease of intubation (ordinal scale)**

Parameter	Group F (n=70)	Group WF (n=70)	P
Perceived ease of intubation [n (%)]			0.67
Very easy	7 (10)	10 (14.3)	
Easy	56 (80)	52 (74.3)	
Moderately difficult	7 (10)	8 (11.4)	
Very difficult	0	0	

\*Group F- C-MAC VLS with Frova introducer, Group WF- C-MAC VLS without Frova introducer. The perceived ease of intubation is represented as number (percentage). \*P<0.05

lesser attempts by virtue of its narrower diameter and maneuverability.<sup>[12,13,18-22]</sup>

This feature of the Frova introducer could have also led to a decreased need for ELMs for the passage of Frova introducer toward glottis in group F. A significantly higher number of patients with CL grade II in the non-Frova group, could have also resulted in more need for ELMs to optimize the glottis visualization for TT passage in that group.

The preference for the intubation technique among the trainees between both the groups was similar, though we expected that the Frova introducer would be preferred because of its easy maneuverability as shown in other studies.<sup>[19]</sup> This could be explained because of the lack of familiarity with a pre-railroaded TT over the Frova introducer technique [Figure 1], as it is not routinely used by our residents.

The Frova tracheal tube introducer has an established role as a rescue intubation aid, especially in difficult airways.<sup>[18-21]</sup> Sakles *et al.*, Hasegawa *et al.*, and Mort *et al.* have used bougie as a primary intubating aid routinely for all cases instead of using it as a rescue device for difficult airways.<sup>[22-24]</sup> This has shown to reduce the number of intubation attempts and hence decreased the airway morbidity in these studies.

The routine use of bougie for intubation has also shown an increased first attempt intubation success rate even in novices with less training.<sup>[12,17,18]</sup> Angerman *et al.* demonstrated a significantly increased success rate of intubation with the routine use of Frova introducer guided TT with C-MAC VLS for all cases in the emergency department irrespective of the airway examination of patients.<sup>[17]</sup> Driver *et al.* also noted a higher first attempt success rate of intubation using C-MAC VLS with bougie versus stylet in patients with or without difficult airway characteristics.<sup>[12]</sup> The higher first attempt success rate with bougie noted in these studies could be because of the enrolment of patients with at least one difficult airway predictor in which the use of bougie would have been more beneficial, whereas in our study, the potential benefit of bougie in reducing the intubation attempts was not seen which could be because of the enrolment of patients without any difficult airway parameters.

The study limitation entails the inclusion of patients without any difficult airway parameters hence the findings cannot be generalized to those with anticipated difficult airway parameters wherein Frova introducer guided intubation with video laryngoscopy could be of greater benefit potentially. This study was restricted to the single-use Frova TT introducer with a distal anterior curvature which may not be generalizable to other types of bougies that lack a stiff nature. Another limitation was the lack of familiarity with the technique of preloading the TT on the Frova introducer which could have influenced the ease of intubation score by the residents. Recording of the primary objective (total intubation time) from the introduction of CMAC C-blade into the patient's mouth till ET<sub>CO<sub>2</sub></sub> appearance could have led to a prolongation in group F due to the time taken to remove the introducer before connecting the breathing circuit. Instead, the usage of time until observation of TT/Frova introducer passage through glottis would have been a better parameter.

## Conclusion

Frova introducer guided endotracheal intubation with C-MAC C-blade VLS by trainee anesthesiologists in patients with normal airway parameters had a marginally prolonged intubation time but with a comparable number of redirections and first attempt success rate to that of intubation without Frova introducer. Hence Frova introducer may not serve as a superior intubating aid for anesthesia trainees using C-MAC videolaryngoscope in patients with normal airway parameters. Further studies are needed to generalize these findings to all patients undergoing routine anesthesia care including obese patients and difficult airways.

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## Conflicts of interest

There are no conflicts of interest.

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