ISSN 2515-8260 Volume 09, Issue 09, 2022

# A PROSPECTIVE, RANDOMISED CLINICAL TRIAL FOR EVALUATING EFFICACY OF D-BLADE OF C-MAC VIDEOLARYNGOSCOPE ALONG WITH TWO DIFFERENT ANGULATIONS OF ENDOTRACHEAL TUBE FOR ANTICIPATED DIFFICULT INTUBATION

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**ABSTRACT**

**BACKGROUND:** C-MAC videolaryngoscope works best amongst airway armamentarium for anticipated difficult airways. However, tube manipulation in anterior glottic apertures even under good visualization requires adjuncts. This study aimed at comparing 60° and 90° angled stylets for endotracheal intubation using C-MAC videolaryngoscope in terms of time taken and first-pass success rate (primary outcomes) as well as hemodynamic response and side-effects associated with intubation (secondary outcome).

**METHODS:** This prospective, randomized study was conducted in the department of Anesthesiology, Maharishi Markandashwar University, Amabala, Haryana, India, after ethical committee clearance in 60 ASA status I and II patients within the age group of 18-65yrs, randomly divided into two groups- Group I (n=30): intubated with 60° angled malleable stylet, Group II (n=30):intubated with hockey shaped stylet (90° angle). All data was represented in mean ± standard deviation or proportions. Chi-square test was used for statistical analysis of quantitative data while Student t-test for qualitative data where p value<0.05 was taken significant.

**RESULTS:** First-pass success rate was 90% in group I versus 83% in group II (p value > 0.05). Mean intubation time was less in group I (33s) compared to group II (39.57), p-value 0.000 (highly significant). There was no significant change in haemodynamics in both the groups. Sore throat was seen more in group I (20.0%) and (3.3%), p-value<0.05.

**CONCLUSION:** Use of 60° angulated stylet significantly reduces time for intubation and has relatively more first-pass success rate in comparison to 90° styletted ETT in adults intubated with C-MAC VLS, although the incidence of sore throat is higher.

**KEYWORDS:** Videolaryngoscope, intubation, haemodynamics, sore throat

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## INTRODUCTION

Videolaryngoscopy has reduced the time for intubation and airway complications in patients presenting with difficult airways. However, at the same time, utilisation of external laryngeal manipulation and axilliary airway armamentarium in the form of stylet, light wand, bougie etc. has not reduced despite excellent perilaryngeal views as the negotiation of endotracheal tube inside the anterior glottis remains a problem. The performance of different angulations of stylet in terms of ease and rapidity of intubation has been extensively researched in literature, not quite with additional usage of C-Mac D-blade laryngoscope.[1,2 ]We conducted this randomised clinical trial to determine whether 60˚ or 90˚ angulation of stylet is superior in practicing endotracheal intubation with C-Mac D-blade laryngoscope in patient with anticipated difficult airway. The aims of this study are :

1) Comparison of time taken and number of attempts required for intubation using C-MAC videolaryngoscope using 60 to 90 degrees stylet angle.

2) Comparison of hemodynamic response associated with intubation using different shape of stylet using C-MAC videolaryngoscope.

## MATERIAL AND METHODS

This prospective, randomized study was conducted in the department of Anesthesiology, Maharishi Markandashwar University, Amabala, Haryana, India after ethical committee clearance in 60 patients at a tertiary care hospital in Haryana, India over a period of 2 years (2018-2020). The patients in the age group 18-65 years posted for elective surgical procedure under general anesthesia and fulfilling one or more criterion for difficult intubation-MP grade 3 and 4, Body Mass Index>35, thyromental distance <6cm, mouth opening <3 finger breadth was included in the study. The exclusion criteria included patients refusing to give consent, having distorted upper airway anatomy or mouth opening <1.5 finger breadth.

The study population was grouped in two groups with 30 persons in each group.

Group 1(n=30): Malleable stylet (60-degree angle)
Group 2(n=30): Hockey shaped stylet (90-degree angle)

A written informed consent was taken from all the patients. A thorough pre-anaesthetic evaluation was done a day prior to the surgery and all the necessary routine investigations including complete blood count, renal function test, liver function test, serum electrolytes including Na+ and K+, electrocardiograph, chest X-ray etc. The airway assessment was done in detail to include- mouth opening, evaluation of dentition for any bucked teeth or artificial denture, Modified Mallampatti Grading, thyromental and sternomental distance, neck extension and flexion, jaw sliding and gliding motion, etc. Only the patients fulfilling one or more criterion of difficult intubation were included in the study and randomly allocated by means of sealed opaque envelopes opened by the anaesthesiologist not involved in the observations.

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Every patient was kept NPO after midnight. Tab Alprazolam 0.25 mg and tab Ranitidine 150 mg was given the night before surgery and again on the day of surgery at 6am with a few sips of water as pre medication. In the pre operating room, baseline parameters- peripheral oxygen saturation, heart rate, systolic, diastolic and mean blood pressure was noted. Inside the operation theatre (OT), availability, charging and proper functioning of C-MAC videolaryngoscope D-blade was checked. The difficult intubation cart was kept ready with appropriately sized endotracheal tubes, laryngeal mask airway, oral and nasopharyngeal airway, suction apparatus and tubing, C-Mac videolaryngoscope of appropriately sized D-shaped blade, Magill's forceps, lightwand, stylet (Romson's soft tip), bougie, jet-ventilation apparatus etc. After securing intravenous access in the OT, patients were denitrogenated by black rubber mask with O2 10 $Lmin^{-1}$ for 3 minutes.

After preoxygenating patients for 3 minutes, induction was achieved with nalbuphine (0.2 $mgkg^{-1}$), propofol (2.5$mgkg^{-1}$) iv, and thereafter, neuromuscular blockade was achieved with succinylcholine (1.5$mgkg^{-1}$). After 1.5 minutes of mask ventilation till disappearance of fasciculations from foot, patients were intubated by senior anaesthesiologist who was blinded regarding the study protocol. C-Mac D blade was used to intubate the patients with Group 1 patients intubated with stylet inserted inside endotracheal tube of appropriate size and angulated to 60˚ while Group 2 patients intubated with stylet angulated to 90˚. D-blade was inserted through midline upto valleculum and tongue was displaced. After visualization of epiglottis on the monitor, it was lifted and endotracheal intubation done. The CL grading of each patient was noted and time to intubation was recorded from insertion of laryngoscope till appearance of first capnographic wave. If saturation falls below 90% during the procedure, patient was taken on manual ventilation with 100% oxygen and after improvement of saturation to >94%, next attempt was taken. Two attempts were taken with the same angulation of stylet, if failed the patient was manually ventilated with 100% O2 and the patient's intubation plan changed. These patients were excluded from study analysis. After intubation, vecuronium (0.1$mgkg^{-1}$ iv) was used as a muscle relaxant. Maintainance of anaesthesia was done with isoflurane (1.2-1.4 v/v%), oxygen:nitrous oxide (1:1) and vecuronium 0.02 $mgkg^{-1}$. Total time required from the moment of insertion of blade between teeth until the endotracheal tube was seen passing through the vocal cords,Number of attempts taken for successful intubation, Blood pressure, pulse, EtCO2 and oxygen saturation before and after the procedure was noted. Post operatively patients were asked about sore throat, dysphagia and hoarseness of voice.

Statistical analysis was done for all quantitative variables of each group. All data presented as range, mean ± standard deviation, frequencies and percentages and number of patients were compared. Student t- test and Mann - Whitney U test was used for independent samples for parametric and non- parametric data. Repeated ANOVA test calculating difference between time period and Chi Square test ($\chi^2$) was performed for comparing categorical data. For expected frequency less than 5 exact test was used. P-value of less than 0.05 was considered statistically significant. All statistical calculation were done using SPSS (statistical package for the social science) 21 version statistical program for Microsoft Windows. Observation tables were made and conclusions were drawn.

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## RESULTS

All the patients were similar for baseline demographic data including age, gender, ASA grading and parameters positive for anticipated difficult intubation. (Table 1)

The table 2 demonstrates that number of patients who had successful intubation in first attempt were 27 (90%) and 25 (83%) in group I and group II respectively. Both groups are comparable with non-significant p-value (>0.05).

The table 3 demonstrates mean intubation time of group I as 33 $\pm$ 4.60 and of group II was 39.57 $\pm$ 4.76. The difference of two means is statistically significant (p value-0.000).

The table 4 shows that haemodynamic variables like mean heart rate, blood pressures, EtCO2 and SpO2 levels were similar in both the groups before and after intubation for first 15 minutes. (p value>0.05)

The table 5 reflects the distribution of occurrence of various complications in both groups. It was observed that no subject had dysphagia while hoarseness was seen in 6 (20%) patients from group I and 2(7%) in group II. Both these groups were comparable to each other with non-significant changes. Sore throat was observed more in group I as compared to group II. Group I, 6 patients (20%) and group II, 1 patient (3.3%) had sore throat with a significant difference (p-value <0.05).

### Distribution of difficult intubation characteristics in both group

**Table 1a: Distribution of MP GRADE in group I & group II subjects**

| | | GROUP | | | | Total | Chi-square value | p-value |
|---|---|---|---|---|---|---|---|---|
| | | I | | II | | | | |
| MP GRADE | 3 | 12 | 40% | 17 | 57% | 29 | 1.669 | 0.196 |
| | 4 | 18 | 60% | 13 | 43% | 31 | | |
| Total | | 30 | 100% | 30 | 100% | 60 | | |

**Table 1b: Distribution of Thyromental distance (TMD) in group I & group II subjects**

| | | GROUP | | | | Total | Chi-square value | p-value |
|---|---|---|---|---|---|---|---|---|
| | | I | | II | | | | |
| TMD | 5 | 14 | 47% | 13 | 43% | 27 | 0.067 | 0.795 |
| | 5.5 | 16 | 53% | 17 | 57% | 33 | | |
| Total | | 30 | 100% | 30 | 100% | 60 | | |

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**Table 1c: Distribution of mouth opening measurement in group I & group II subjects**

| | GROUP I | | GROUP II | | t | p-value | 95% Confidence Interval of the Difference | |
|---|---|---|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | | | Lower | Upper |
| MO | 4.49 | 0.50 | 4.34 | 0.50 | 1.133 | 0.262 | -0.11 | 0.41 |

**Table 2: Comparison of number of attempts in group I & group II subjects**

| | | GROUP | | | | Total | Chi-square value | p-value |
|---|---|---|---|---|---|---|---|---|
| | | I | | II | | | | |
| ATTEMPT | 1 | 27 | 90% | 25 | 83% | 52 | 0.577 | **0.448** |
| | 2 | 3 | 10% | 5 | 17% | 8 | | |
| Total | | 30 | 100% | 30 | 100% | 60 | | |

**Table 3: Distribution of BMI in group I & group II subjects**

| | GROUP I | | GROUP II | | t | p-value | 95% Confidence Interval of the Difference | |
|---|---|---|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | | | Lower | Upper |
| BMI | 28.90 | 1.31 | 27.61 | 1.55 | -0.558 | 0.579 | -0.95 | 0.53 |

The table No.3 demonstrates that mean BMI of group I is 28.90 $\pm$ 1.31 and mean BMI of group II is 27.61 $\pm$ 1.55. Therefore, two groups are comparable with statistically insignificant values.

**Table 4: Comparison of intubation time (in seconds) taken in group I & group II subjects**

| | GROUP I | | GROUP II | | t | p-value | 95% Confidence Interval of the Difference | |
|---|---|---|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | | | Lower | Upper |
| INTUBATION TIME (seconds) | 33.00 | 4.60 | 39.57 | 4.76 | -5.432 | **0.000** | -8.99 | -4.15 |

**Table 5: Comparison of haemodynamic parameters- mean heart rate, blood pressure, EtCO2 and SpO2 in both the groups**

| HR | GROUP I | | GROUP II | | T | p-value | 95% Confidence Interval of the Difference | |
|---|---|---|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | | | Lower | Upper |
| PRE | 74.90 | 7.21 | 74.57 | 7.84 | 0.171 | 0.864 | -3.56 | 4.23 |
| T1 | 90.60 | 7.88 | 88.90 | 7.10 | 0.878 | 0.384 | -2.18 | 5.58 |
| T5 | 82.20 | 5.75 | 80.93 | 7.10 | 0.759 | 0.451 | -2.07 | 4.61 |
| T10 | 78.53 | 5.91 | 77.27 | 7.08 | 0.752 | 0.455 | -2.10 | 4.64 |
| T15 | 75.23 | 6.57 | 75.47 | 6.95 | -0.134 | 0.894 | -3.73 | 3.26 |
| SPO2 | GROUP I | | GROUP II | | Z | p-value | 95% Confidence Interval of the Difference | |
| | Mean | SD | Mean | SD | | | Lower | Upper |
| PRE | 97.47 | 1.41 | 98.17 | 0.95 | -1.861 | 0.663 | 0.01 | 0.11 |
| T1 | 97.47 | 1.41 | 98.17 | 0.95 | -1.861 | 0.663 | 0.01 | 0.11 |
| T5 | 98.03 | 1.27 | 98.27 | 1.11 | -0.680 | 0.597 | 0.40 | 0.60 |
| T10 | 97.47 | 1.41 | 98.17 | 0.95 | -1.861 | 0.663 | 0.01 | 0.11 |
| T15 | 98.03 | 1.27 | 98.27 | 1.11 | -0.680 | 0.597 | 0.40 | 0.60 |

| SBP | GROUP I | | GROUP II | | T | p-value | 95% Confidence Interval of the Difference | |
|---|---|---|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | | | Lower | Upper |
| PRE | 121.47 | 5.68 | 122.67 | 5.93 | -0.801 | 0.427 | -4.20 | 1.80 |
| T1 | 138.87 | 5.66 | 137.87 | 6.25 | 0.650 | 0.518 | -2.08 | 4.08 |
| T5 | 133.53 | 5.34 | 131.30 | 5.04 | 1.667 | 0.101 | -0.45 | 4.92 |
| T10 | 127.87 | 5.30 | 127.63 | 4.82 | 0.178 | 0.859 | -2.38 | 2.85 |
| T15 | 121.13 | 5.34 | 122.60 | 4.19 | -1.184 | 0.241 | -3.95 | 1.01 |

| ETCO2 | GROUP I | | GROUP II | | Z | p-value | 95% Confidence Interval of the Difference | |
|---|---|---|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | | | Lower | Upper |
| PRE | 35.00 | 1.46 | 35.03 | 1.38 | -0.030 | 0.976 | 0.97 | 1.00 |
| T1 | 38.00 | 1.80 | 38.10 | 1.47 | -0.270 | 0.787 | 0.74 | 0.90 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| T5 | 36.40 | 2.49 | 36.30 | 1.34 | -0.553 | 0.581 | 0.56 | 0.74 |
| T10 | 34.63 | 1.27 | 34.87 | 1.25 | -0.761 | 0.547 | 0.30 | 0.50 |
| T15 | 34.87 | 1.28 | 35.03 | 1.19 | -0.554 | 0.580 | 0.41 | 0.61 |

**Table 6: Distribution of various complications in group I & group II subjects**

| | | GROUP | | | | Total | Chi-square value | p-value |
|---|---|---|---|---|---|---|---|---|
| | | I | | II | | | | |
| SORE THROAT | NO | 24 | 80.0% | 29 | 96.7% | 55 | 1.564 | 0.034 |
| | YES | 6 | 20.0% | 1 | 3.3% | 5 | | |
| DYSPHAGIA | NO | 30 | 100% | 30 | 100% | 60 | 0.601 | 0.438 |
| HOARSENESS | NO | 24 | 80% | 28 | 93% | 52 | 2.308 | 0.129 |
| | YES | 6 | 20% | 2 | 7% | 8 | | |
| Total | | 30 | 100% | 30 | 100% | 60 | | |

## DISCUSSION

To the best of our knowledge, intubation is a crucial step during any operative procedure with general anesthesia. C-MAC video laryngoscope is one of the latest airway gadget that facilitates endotracheal intubation with real-time visualization of glottis and passage of endotracheal tube. The D-blade provided with the C-Mac videolaryngoscope has an upward-inclined distal portion which allows for better perilaryngeal view in conditions where pharyngeal, oral and laryngeal axis cannot be optimally targeted to a straight line. Although it improves CL grading in cases where direct laryngoscopic views might be extremely difficult for negotiating the tube, the upward angulation of blade requires the endotracheal tube curvature to be similarly moulded for synchronising the distal angulation of endotracheal tube to approach the glottis opening.[3,4] This modification can reduce intubation time, number of attempts and consequently blunt hemodynamic changes to stress response.

In this study, we compared two different angulations of malleable stylet (60˚ and 90˚) for endotracheal intubation in patients with anticipated difficult intubation posted for elective surgeries under general anaesthesia. It was found that first pass intubation and mean number of attempts taken for intubation were lesser in 60˚ styletted tubes as compared to 90˚ styletted tubes, although the result was statistically insignificant. The time taken for intubation was found to be significantly higher in 90˚ angulation than 60˚ angulation of endotracheal tube.

A simulation study performed by Omur D et al in a manikin with simulated difficult airway found similar results with both angles of endotracheal tube used in conjunction with Storz C-Mac D-blade in terms of intubation success and time required for intubation as compared to those performed without using stylet/ bougie. [5] Although this study provided an important insight to improve utilisation of C-Mac videolaryngoscope, the intubation was done arbitrarily be anaesthesiology experts as well as residents, which could have created a huge procedure bias in the study.

Lim H et al compared two different styles; one angulated corresponding to the angulation of C-Mac blade, while the other angulated to 60˚ for intubation performance in difficult intubation. [6] It was found that both the modifications of stylet performed similarly for

intubation, but in patients with BMI>30mgkg$^{-2}$, J-shaped angulation had longer TTI (Time To Intubation) than the other group. Thus, 60˚ styletted endotracheal tube was found to be better for use while doing intubation with C-Mac videolaryngoscope, which is similar to our study results.

Kelly F.E. et al and Xue F.S. et al in their articles have also inferred that the rate of failed intubations increased if angulated stylets were not used while intubating with C-Mac videolaryngoscope and also opined that disposable bougies which cannot be angulated offered no benefit in this regard; hence cannot replace stylet in such a scenario. [7,8]

Lee J et al in their comparative trial also found that the degree of intubation difficulty was unaffected by different angulations, although time taken for intubation was shortest in 60˚ angulated endotracheal tube. [9] The haemodynamic response to intubation was found to be comparable in both the groups, thus not significantly affected by prolongation of time for intubation or attempts. The side effects like desaturation, esophageal intubation was also found to be insignificant on inter-group comparison. However, the incidence of sore throat was significantly higher (6 versus 1 patient) in 60˚ styletted tubes as compared to 90˚ styletted tubes. Bacon E.R. et al in their article also acknowledged that the incidence of sore throat with styletted endotracheal tubes was higher while intubating with glidescope videolaryngoscope. He suggested that the removal of stylet outward towards the chest and feet of the patient following its original angulation helped in reducing trauma and thus, sore throat post procedure.[10]

There are several valid good points highlighted in our study with C-mac videolaryngoscope. Firstly, all intubations were performed by residents which is more commonly practiced trend in tertiary care hospitals of India but only after minimum 40 successful intubations, hence the results could be easier translated into modern clinical practice. Also, the anesthesiologists performing the procedure were divided into those performing with 60º angulation and 90º angulation so that they were unaware of the different group allocations, hence could not possibly allow observer bias. Furthermore, only patients with anticipated difficult intubation were enrolled as our hypothesis based on previous studies was to look into the difference made by angulation in the difficult intubation scenario itself.

The major disadvantage of the clinical trial was that we could have used bougies with anterior angulation as well to demonstrate its value over the other two when used with D-blade C-Mac videolaryngoscope.

## CONCLUSION

The use of angulated stylets improves intubation performance with D-blade of C-Mac videolaryngoscope. 60˚angulation offers faster intubation times than 90˚ angulation, although the number of attempts are similar. The incidence of sore throat has been found to be higher in the former, possibly due to trauma while removing the stylet. In conclusion, C-Mac videolaryngoscopy has become the ideal airway equipment for anticipated difficult intubations where angulated stylets improve the efficacy of procedure. Experience must be gained with the instrument on simulation and sequentially on patients to avoid any potential complication.

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MAIN POINTS:

1. C-Mac videolaryngoscope has been the research project for long in anticipated difficult intubation where pharyngeal-laryngeal-tracheal axis need no alignment for optimising view, thus steering the tube even with good CL grading remains a drawback
2. Angulated hyperangulated stylets have been proposed as better ancilliary equipment than bougies for this purpose, where 60º angulation with D-blade reduced time to intubation better than 90º angulation; although incidence of sore throat was more with the former.
3. Hence, D-blade videolaryngoscopy in patients with anticipated difficult intubation and thyromental distances 5-5.5cm as in our study (moderately anterior larynx) need angulation corresponding to deviation in the pharyngeal and tracheal axis, 60º offering better outcome than 90º
4. More research on the inter-axial angle and corresponding selection of angulation of stylet is desired to translate the preceeding study including our study into clinical practice
5. The incidence of sore throat can be catered to by removing the stylet

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