

Intubation Times with the Bougie versus Stylet in the Immobilized Cervical Spine: A Randomized Trial

Amarjyoti Hazarika*, Namratha D, Divya Jain, Nidhi Bhatia, Sarvdeep Singh Dhatt, Madhivanan Karthigeyan, Chirag Kamal Ahuja and Ananya Ray

Department of Anaesthesia and Intensive Care, Institute of Medical Education and Research, Chandigarh, India

*Corresponding author: Amarjyoti Hazarika, Department of Anaesthesia and Intensive Care, Institute of Medical Education and Research, Chandigarh, India, Tel: 919990238972; E-mail: greenamar28@rediffmail.com

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Abstract

Purpose: Endotracheal Intubation (ETI) in patients with an immobilized cervical spine is often challenging, urging the use of airway adjuncts like bougie and stylet and a Video Laryngoscope (VL). Owing to the scarcity of comparative literature, we aimed to compare the intubation characteristics when using either a bougie or a stylet with a VL in these patients.

Methods: This randomized controlled study involved eighty six adult ASA I/II patients with cervical spine immobilized with a collar or traction, scheduled for cervical spine surgery, between July 2020 and December 2021. ETI was performed with the C-MAC VL, assisted with bougie (group ETB) or stylet (group ETS). The primary outcome was time to successful ETI. First Attempt Success (FAS) rate, overall successful ETI, cervical spine motion detected using fluoroscopy and complications were secondary outcomes.

Results: The time for ETI in group ETB was 52.38 ± 6.23 sec ($n=43$), and in group ETS was 52.39 ± 32.85 sec ($n=43$), $P=0.958$. There was no significant difference in FAS rate, overall success of intubation or cervical spine movement between the groups. No complications were encountered.

Conclusions: In patients with an immobilized cervical spine, there was no significant difference in the intubation times when comparing the bougie and the stylet. The FAS rate was also similar in both groups with minimal motion at C1, C2. Both bougie and stylet are equally useful adjuncts when used with a VL, while intubating patients in whom neck movements are restricted.

Keywords: Cervical spine injury; Bougie; Stylet; Difficult airway; Endotracheal Intubation (ETI)

extension while securing the airway. This leads to failure in aligning the laryngeal, pharyngeal and oral axes, making the visualization of the larynx difficult [1]. Hence, airway management of cervical spine injury is challenging and requires expertise and training. It becomes difficult to visualize the glottic aperture without adequate head and neck positioning and the sniffing position is universally recommended during intubation [2]. To overcome this difficulty, a Video Laryngoscope (VL) can be used for Endotracheal Intubation (ETI) to minimize cervical spine movement and achieve a better view of the larynx [3]. If, ETI is still difficult due to poor laryngoscope view, one can facilitate it by using adjuncts like bougie and stylet.

The gum elastic bougie, or simply a bougie, is a device that allows a rail roading technique of intubation. The bougie is used when the conventional method of ETI fails or provides a poor Cormack Lehane (CL) grading [4,5]. However, the effect of routine use of bougie on first attempt intubation success is unclear.

Stylets are malleable metal rods with an atraumatic tip, used to give an endotracheal tube a specific shape that aids navigation of the tube into the laryngeal inlet. Many practitioners use stylet with ET with an increased rate of successful intubation.

Studies have compared the intubation success between bougie and stylet in a varied group of patients, including difficult airways, both actual and simulated. However, there is a lack of literature comparing the time required for ETI using bougie and stylet in patients with immobilized cervical spine. We hypothesized that the time to successful intubation would be less with bougie than with the stylet.

Materials and Methods

Study design

This prospective randomized controlled trial was conducted between January, 2020 and January, 2021, in postgraduate institute of medical education and research, Chandigarh, India. Institutional ethics committee approval with I

Introduction

In cervical spine injury patients, the neck is stabilized by neck collar and traction, limiting neck movements like flexion or

RB no.INT/IEC/2019/002173, dated 15 October 2019, was granted. Written informed consent was obtained from all participants. The study was registered in the clinical trial registry of India before enrolment of the first patient.

Patient selection

Patients with American Society of Anesthesiologists (ASA) physical status I and II, aged 18 years and above, with cervical spine injury immobilized with a collar or traction, scheduled to undergo elective cervical spine surgery requiring endotracheal intubation were included in the study.

Patients having mouth opening of less than three finger breadths, pre existing known upper airway malformation, ASA physical status >II, emergency surgery, and pregnant women were excluded.

Randomization and allocation

Patients were randomized using computer generated random number tables and allocated by sequentially labeled opaque sealed envelope method to one of two groups: Group ETB, in which endotracheal intubation with a VL was facilitated using a bougie; and group ETS wherein endotracheal intubation with a VL was facilitated using a stylet.

Intervention

All eligible patients were evaluated before the surgery and underwent a standard Pre Anesthetic Checkup (PAC). As per the institutional protocol, following confirmation of nil per oral status, the patients were shifted to the Operating Room (OR). Standard ASA monitors (pulse oximetry, Electrocardiography (ECG), Non Invasive Blood Pressure (NIBP) were attached on arrival and an Intravenous (IV) access was secured. Gas monitoring, end tidal carbon-dioxide monitoring and invasive blood pressure monitoring by a peripheral arterial cannula (i.e., radial/dorsalis pedis/post tibial) was performed in all patients after induction of anesthesia. Cervical collar application or traction was continued along with Manual in Line Stabilization (MILS) throughout the procedure. After pre oxygenating for 3 minutes, the patient was administered 1-2 mcg/kg IV fentanyl and induced with IV propofol at a dose of 1-2 mg/kg in a titrated manner. Once adequate Bag and Mask Ventilation (BMV) was confirmed, injection atracurium 0.5 mg/kg IV or vecuronium 0.1 mg/kg IV was administered for muscle relaxation, as per decision of the primary anesthesiologist. BMV was continued till there was adequate muscle relaxation, assessed by a target Train of Four (TOF) count of zero. ETI was performed by the "first anesthetist" as per randomization. Correct placement of the ETT into the trachea was confirmed by auscultation and capnography on the monitor. Time to Intubation (TTI) was recorded by the "second anesthetist". TTI was measured from the time of introduction of the C-MAC video laryngoscope (KARL STORZ SE and Co. KG, Tuttlingen) in the oral cavity, to the appearance of the first capnography waveform.

The first pass success rate, CL grade, complications like desaturation, bleeding, trachea bronchial perforation, pneumothorax, and vocal cord injury were recorded. Failure to

negotiate the ET in the first attempt was taken as a failed intubation. In those cases, intubation was accomplished by other alternate technique. The anesthetist performing intubation had an experience of more than 30 intubations using a VL. In our study, we used a C-MAC video laryngoscope. Any movement of the atlanto occipital joint during ETI was noted by fluoroscopy image at:

T1: At the neutral position (during bag and mask ventilation after induction).

T2: Point of insertion of the ETI through the glottis aperture.

The movement at the atlanto occipital joint was calculated measuring the vertical distance between the most inferior point of the occipital bone and the C1 reference line (line passing through the anterior and posterior arches of the atlas), measured in millimeters. The images were obtained using the C-arm mobile intensifier (Philips, Veenpleius, Netherlands). Data of the images was taken through a data cable, and the radiologist who was blinded to the group allocation evaluated the fluoroscopic images. Desaturation was defined as drop in saturation (SpO₂) less than <92% during ETI.

Outcome measures

Time to successful intubation was studied as the primary outcome. Overall, the First Attempt Success (FAS) rate of ETI, cervical spine motion by fluoroscopy, complications like desaturation, bleeding, trachea-bronchial perforation, pneumothorax, and vocal cord injury were recorded as secondary outcomes.

Statistical analysis

Nolan, et al. studied ease and time to intubation in simulated cervical injury patients with and without using a gum elastic bogie as an adjunct. The absolute difference in median time to ETI was 25% between the groups in the study. Assuming a difference of 20% between our intervention groups, a sample size of 43 was calculated for each group, assuming a power of 90% with an alpha error of 0.05.

Sample population data collected is described as mean \pm SD, median (inter quartile range), frequencies (number of cases), and percentages. Data were tested for normal distribution by Kolmogorov–Smirnov test. Quantitative variables between the study groups were compared using student's t-test followed by post hoc tests for independent samples if normally distributed. Non-normally distributed quantitative and ordinal data was calculated using Mann–Whitney U test. A *chi-square* test was used for calculating categorical data. All statistical tests were two-sided and performed at a significance level of $\alpha=0.05$. All analysis was performed using IBM™ SPSS™ version 25 software.

Results

Eighty six patients were randomized into group ETB and ETS. The demographic data was comparable between the two groups (Table 1).

Table 1: Demographics, ASA physical status and CL grade between the two groups.

Parameters	ETB, n=43	ETS, n=43	P value
Age, years	41.404 ± 3.83	39.94 ± 3.93	0.084*
Weight, kgs	64.31 ± 1.7	65.05 ± 1.8	0.053*
Gender (male/female)	28/15	35/8	0.142†
Percentage	65.11/34.88	81.39/18.60	
ASA grade (I/II)	31/12	32/11	1.00†
Percentage (%)	72.09%/27.90%	74.41%/25.58%	
CL grade			
1	28	26	0.803‡
2	12	13	
3	3	3	
4	0	1	
* α -Student's t-test; †-Fisher's exact test, ‡-chi square test. P value >0.05 is significant. Abbreviations: ASA: American Society of Anaesthesiologists physical status; CL grade: Cormack-Lehane grade; ETB: Bougie assisted Endotracheal intubation; ETS: Stylet assisted Endotracheal Intubation			

Primary outcome: Time to intubation

The mean TTI in group ETB was 52.38 (20.85) sec (n=43), and that in group ETS was 52.39 (32.85) sec (n=43) (P=0.96), which proved the null hypothesis. There was also no significant

difference in TTI when Cormack Lehane grades were compared between the groups (Table 2).

Table 2: The overall time to successful intubation, time to successful 1st attempt intubation and overall success rate.

Parameters	Group ETB, n=43	Group ETS, n=43	P value
Time to successful intubation, mean ± SD, in seconds	52.389 ± 20.85	52.395 ± 32.85	0.958*
Time to intubation with respect to each CL grade mean ± SD, in seconds			
1	50.66 ± 18.8	46.14 ± 27.70	0.664*
2	51.3 ± 21.80	52.11 ± 28.32	0.937
3	72.1 ± 32.41	69.33 ± 23.79	0.91
4		71.23 ± 21.08	
1 st attempt successful intubation	34	37	0.323†
Percentage of successful 1 st attempt intubation	79.06%	86.04%	

1 st attempt success rate between different CL-grades			
1	25	26	1.00 [†]
2	7	9	1
3	2	1	1
4		1	
Overall success (includes 2 nd and consequent attempts to intubate)	40/43 (93.02%)	41/43 (95.34%)	0.212 [‡]

*Unpaired t-test, [†]-Fischer exact test, [‡]- *chi square* test.

P value>0.05 is significant.

Abbreviations: CL grade: Cormack Lehane grade; ETB: Bougie assisted Endotracheal Intubation; ETS: Stylet assisted Endotracheal Intubation

Secondary outcomes

First attempt successful intubation: First attempt success rate was 79.06% (n=34/43) in Group ETB and 86.04% (n=37/43) in Group ETS respectively (P=0.32). Overall, the success rate for ETI was 93.02% in Group ETB and 95.34% in Group ETS (P=0.21).

Fluoroscopy: Overall, 71 patients were analyzed with fluoroscopy, of which 34 were in group ETB and 37 in

group ETS. The mean angulation at time points T1 and T2 had no significant difference between the groups (Table 3). The change in angulation was also not significantly different.

Table 3: Shows change in angulation between cervical vertebra C1 and C2 as measured during intubation by fluoroscopy.

Table 3: Shows change in angulation between cervical vertebra C1 and C2 as measured during intubation by fluoroscopy.

Fluoroscopy	Group ETB, n=34	Group ETS, n=37	P value*
At baseline (T1)	9.36 ± 0.665	9.57 ± 0.583	0.16
At time of ETI (T2)	8.10 ± 0.552	8.23 ± 0.749	0.411
Change in angulation (ΔT)	1.31 ± 0.464	1.33 ± 0.471	0.857

*Unpaired t-test

P value>0.05 is significant.

Abbreviation: ETB: Bougie assisted Endotracheal Intubation; ETI: Endotracheal Intubation; ETS: Stylet assisted Endotracheal Intubation

Complications: No complication like desaturation, bleeding, trachea bronchial perforation, pneumothorax, or vocal cord injury was noticed during the study in either group.

Discussion

The evolution of anesthetic practices and management modalities has led to a paradigm shift in inpatient care, including better perioperative airway management and its outcomes. Endotracheal intubation with a laryngoscope has been shown to produce excessive movement at the atlantooccipital junction and the upper cervical spine [6]. In patients with cervical spine injury, the cervical spine is usually immobilized with either traction or collar for stabilization, to minimize further damage. Consequently, airway management often poses a difficulty due to limited neck movements. VL is useful airway management

equipment during difficult intubation, like in the immobilized cervical spine. Although, Fiberoptic (FOB) intubation is ideal for cervical spine injury patients, the learning curve is long, and availability, expense and maintenance of such advanced instruments limit their use. VL improves the CL grade, the rate of successful intubation and is less traumatic. It may be used as a primary intubating device in an anticipated difficult airway [7]. Moreover, its learning curve is less compared to FOB and is less cumbersome in maintenance. In our study, we used a C-MAC video laryngoscope with a curved blade in all the patients.

Bougie and stylet are necessary armaments in the armory of difficult airway management. Using a bougie with VL reduces the time for successful intubation [8]. Similarly, the use of a stylet with VL significantly reduces the Intubation Difficulty Score (IDS) [9].

In our study, our primary aim was to calculate the time taken for the First Attempt of Successful (FAS) endotracheal intubation using bougie versus stylet. The mean time to FAS intubation was similar in both the groups. Gataure, et al. in their study too found no significant difference between the two groups [10]. Driver, et al. in their study, found that in group ETB, time to FAS intubation (38 sec) was significantly different than in group ETS (34 sec) [11]. Similarly, another study by Kingma, et al. found that the time to first pass success in difficult airway using stylet was significantly lesser than with a bougie (25 sec vs. 43.2 sec) [12]. Jurgens, et al. too observed that time to FAS was less using stylet than using bougie (18 ± 6 sec vs. 35 ± 7 sec; $P < 0.001$;) [13]. In the above quoted studies, the time to FAS intubation in both groups was less than in our study. Most of these studies were simulated studies or mannequin studies and one with a difficult airway with no mention of whether the difficulty was due to cervical injury. In our study, the increase in time may be because the cervical collar or traction was left *in-situ*. Using a cervical collar or traction minimizes cervical movement, decreases glottic view, and causes mal alignment of the oropharyngeal-laryngeal axis. Moreover, in this study, all intubation was done by applying MILS which is known to prolong the time to intubation [14].

We also observed that the rate of FAS intubation between the groups was 79.06% in ETB and 86.04% in ETS. Studies have found the rate of FAS intubation using bougie to be 100% and that with stylet to be less [15]. This contrast may be due to ETI being performed in either the normal airway or difficult airways without cervical injury. Our study also differed in that all intubations were performed with the C-MAC and not the direct laryngoscope. In support of this is a study by Omur, et al. who found that the rate of FAS intubation improves remarkably from 75% to up to 98% after using CMAC with stylet [16]. Using VL reduces the need to align the anatomic axis for a better glottic view [17]. Our study found no significant difference in overall success rate of ETI between the groups. However, in other studies, ETI rates are reported overwhelmingly in favor of the bougie (96-100% in bougie vs. 66-72% in the stylet group) [18]. Although VL improves ETI, literature also warns that the presence of cervical immobility is one of the causes of unsuccessful intubation even when using VL. This is more so with collar or traction *in-situ* and with the application of MILS in the actual airway.

The degree of movement of the atlanto occipital joint during intubation was also observed between the two groups by taking a fluoroscopy image because the greatest degree of motion happens at the atlanto occipital joint [19]. There was no change in angulation between the bougie and the stylet group ($P = 0.893$). There are no studies directly comparing cervical spine motion during intubation using bougie or stylet. Turkstra, et al., in their study on cervical spine movement with and without using bougie found that the change in the degree of movement is reduced in bougie group [20]. The same author in another study found 52% less C spine motion at occiput C1 junction using stylet then to not using it during ETI [21]. Moreover, the mean change in the degree of angulation was less than 1.5° in our study in both groups which is lesser than 4° , the average cut off for a stable spine to become unstable. The number of patients

for whom fluoroscopic examination was performed was less as we obtained images only for first successful intubation to minimize radiation exposure to the patients.

Our study also found that with the increase in CL grade, there is an increase in time to FAS intubation within groups, but there was no difference between the groups for the same grade of CL. We also observed that the percentage of FAS didn't change with an increase in CL grade between the groups. In our study, all intubations were performed using C-MAC which might have improved the glottic view and ease of intubation. Noguchi, et al. in their study found that the time to intubation was more in the stylet group than in bougie with increasing CL grade [22].

Complications related to the airway can occur while intubating patients, especially while managing difficult airways like cervical spine injury. The airway complications can be avoided during ETI, even in cervical immobilization [23]. Studies have observed complications like esophageal intubations, pneumothorax, lip lacerations, iatrogenic bleeding from the oropharynx or dental trauma. Still, most of them were emergency ETI where there is a time constrain to proper airway preparation during ETI.

A bougie and stylet are simple adjuncts for tracheal intubation. However, they are not the same. A bougie is a device composed of Dacron polyester with a resin outer layer to provide stiffness; flexibility; and a slippery, water impermeable surface. On the other hand, the stylet is made of various types of metal, rigid, and has little flexibility. Besides, a stylet protruding out of the tube is a serious hazard to the larynx and tracheal wall. When intubation needs to be carried out without glottic visualization, using a stylet sometimes makes it difficult to differentiate whether it is in the trachea or esophagus [24]. On the contrary, a bougie can be advanced blindly towards the vocal cords, and successful tracheal placement often can be confirmed by both 'click' and 'distal hold up sensations' [25].

Conclusion

In patients with immobilized cervical spine injury, there was no significant difference in the time to intubation when comparing the bougie and the stylet. The first pass intubation success was also similar in both groups. Both bougie and stylet are equally useful adjuncts, while intubating patients in whom neck movements are restricted.

Strengths of our study

This study was performed on real patients compared to simulation studies performed earlier. Secondly, we did not remove the cervical collar while ETI and used VL for ETI, minimizing cervical spine movements. The mode of intubation was kept uniform for all patients *i.e.* use of a VL, in order to reduce the movement at the C-spine.

Limitations

The result of the study cannot be generalised to all scenarios as it was performed in a controlled environment by an

experienced anesthetist. We used a single type of VL (C-MAC) in the study. Hence results may not be generalized to other types of VL available.

Acknowledgements

None

Conflicts of Interest

None

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