Original article

Comparison between gum elastic bougie and malleable stylet as aids to intubation during application of cricoid pressure: A prospective randomised controlled study

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Abstract

Background: Rapid sequence intubation with application of cricoid pressure is widely practiced in all emergency situations to prevent aspiration of gastric contents. Stylet or gum elastic bougie is used as intubation aid for rapidly securing the airway. **Aim:** To compare gum elastic bougie and malleable stylet as aids for endotracheal intubation during application of cricoid pressure. **Results:** Endotracheal intubation was successful in the first attempt in all of the 60 patients enrolled in the study. Time taken for laryngoscopy and intubation was clinically similar in both the groups of patients. However, in the stylet group, successful ET intubation was achieved in about 7 sec less when compared to the bougie group ($p < 0.05$). Ease of intubation as compared using the Visual Analogue Scale (VAS) Score was similar in both groups. Laryngeal view improved in 22 patients of 60 patients (36.66%) after application of cricoid pressure, while it remained the same as before in 22. Overall, the grade remained the same or improved after cricoid pressure in 73.3% of patients. The laryngeal view worsened in 16 patients (27.7%). **Conclusion:** Gum elastic bougie and stylet are equally effective intubation aids during rapid sequence intubation. Intubation aided by bougie takes more time than that of a stylet, even though it is clinically trivial. Cricoid pressure does not affect the laryngoscopic visualisation of glottis in majority of patients.

Keywords: Bougie; cricoid pressure; rapid sequence intubation; stylet.

Introduction

Intensivists and anaesthesiologists frequently come across patients with full stomach who require endotracheal intubation. To protect the airway from aspiration of gastric contents, application of cricoid pressure has been evolved. It was first described by Sellick *et al* in 1961 and has been accepted widely as a standard practice to prevent regurgitation and aspiration during induction of general anaesthesia or emergency airway management in such patients.[1]

Major limitation of Sellick's manoeuvre is that if improperly applied, it causes anatomical distortion of the upper airway that may interfere with laryngoscopy or insertion of other supraglottic devices as a result of distorted anatomical configuration of the laryngeal structures. Premature application may result in activation of upper airway

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reflexes. Overall these factors may result in delay in securing the airway with resultant hypoxaemia, exaggerated cardiovascular responses and airway trauma along with the risk of aspiration.

It is a routine practice to use a stylet or gum elastic bougie to facilitate tracheal intubation during emergencies or during rapid sequence induction of anaesthesia. Stylet is a rigid, malleable metallic instrument designed to fit inside a tracheal tube that aids in providing a predetermined shape to the tracheal tube. Gum elastic bougie was introduced into clinical practice in 1949 by Sir Robert Macintosh.[2] It is used as an aid for intubation when the operator recognises some anatomical landmarks but cannot direct the tip of the tracheal tube into the laryngeal inlet.

Studies simulating difficult intubation have shown a higher success rate of intubation when the gum elastic bougie was used to facilitate intubation when compared to stylet.[3-5]This prompted us to compare the efficacy of these two devices during application of cricoid pressure.

Methods

This prospective, randomised, controlled study was conducted after obtaining approval from Departmental Dissertation Committee and Hospital Ethics Committee. Aim of the study was to compare the gum elastic bougie and malleable stylet as aids for endotracheal intubation during application of cricoid pressure with respect to the time taken, success rate and the ease of intubation as assessed using the visual analogue scale score. A total of 60 adult patients belonging to American Society of Anesthesiologists (ASA) physical status 1 or 2, posted for elective surgeries requiring general anaesthesia were enrolled. After obtaining informed consent, they were randomly allocated using computer generated random sequence of 30 to one of two groups: Group Bougie (B) where intubation was performed using gum elastic bougie as an intubation aid or Group Stylet (S) where intubation was performed using malleable stylet as an intubation aid. Patients were excluded from the study if they had a known or predicted airway difficulty, reactive airway disease or ischaemic heart disease. Preoperatively, patients were kept nil per oral for at least six hours for solids and three hours for clear liquids and were premedicated orally with diazepam 5 - 10 mg based on body weight (less than or more than 50 kg) on the night prior and two hours before the procedure.

In the operating room, after obtaining intravenous (IV) access and establishing monitoring which included electrocardiogram (lead II and V_5), pulse oximetry, capnography and noninvasive blood pressure, patients were induced with IV fentanyl 1.5 μg/kg and propofol 2.5 mg/kg. After confirming ability to mask ventilate, skeletal muscle paralysis was achieved with IV vecuronium 0.1 mg/kg. A peripheral nerve stimulator was set to stimulate the ulnar nerveto deliver a current of 40 mA, train of four (TOF) stimuli at 12 second intervals. Anaesthesia was maintained with 2% isoflurane in oxygen with manual ventilation *via* face mask using circle absorber system. Once TOF count was zero, patients were positioned in sniffing position, laryngoscopy was performed by observer 1 with appropriate size Macintosh blade and the laryngoscopic view noted. After recording the laryngeal view, a brief period of controlled ventilation with 2% isoflurane in oxygen was resumed. The position of cricoid cartilage was confirmed by observer 1. Single handed cricoid pressure was applied by observer 2. Before each attempt, observer 2 practiced the correct force of 3.06 kg (30 N) by simulating it on a weighing scale with the thumb and index finger of right hand. Observer 2 repeated the application of *cricoid pressure* on the scale till the force could be applied consistently and sustained for at least one minute. Laryngoscopy was repeated during application of cricoid pressure, and the view of larynx graded again. Cricoid pressure was maintained until intubation and inflation of the cuff was complete. In both groups, 8.0/8.5 mm internal diameter tracheal tube was used in males and 7.0/7.5 mm internal diameter tube in females. The intubation procedure was performed according to study protocols in each group as described below.

In the bougie group, a well-lubricated gum elastic bougie (Eschmann tracheal tube introducer, Portex, Kent, UK) was gently passed through the vocal

cords. If the glottis was not visible, bougie was passed blindly below the epiglottis towards the vocal cords. Correct endotracheal placement was indicated by sensation of *clicks* as the bougie slid over the tracheal rings. If *clicks* were absent, the bougie was advanced distally to feel the *distal hold up*. Once the bougie was thought to be in the trachea, another assistant steadied the tip of the bougie and, with the laryngoscope still held in the mouth, endotracheal (ET) tube was threaded over the bougie by observer 1. If difficulty was encountered in passing the ET tube through the vocal cords, it was rotated 90° anticlockwise so that the bevel faced posteriorly, easing its passage into the larynx. If the tube hung up on the epiglottis or arytenoid, further rotation (180°) was done. The bougie was withdrawn and the breathing circuit was connected to the tube.

In the stylet group, a well lubricated malleable metal stylet was placed in the tracheal tube. The distal end was bent into a *hockey stick* shape. Once the tube was thought to have entered the trachea, the stylet was withdrawn and the breathing circuit connected.

Successful tracheal intubation was confirmed by appreciation of chest wall movement and appearance of a normal waveform capnography.

In both groups, each attempt at tracheal intubation was allowed for 60 seconds. If the trachea could not be intubated at first attempt, one more attempt using the same device was allowed. If intubation failed after two attempts, another device (cross-over) was planned to be used and one more attempt allowed. Patients were ventilated with 2% isoflurane in oxygen between the attempts. If at any point of the study, arterial haemoglobin oxygen saturation decreased below 95%, the study was abandoned immediately and appropriate treatment instituted. If all attempts at intubation using the stylet or bougie failed, tracheal intubation was performed after releasing cricoid pressure.

Effect of cricoid pressure on grading of laryngeal view, success rate of intubation, intubation time and ease of intubation as assessed by the visual analogue scale (VAS) were recorded during the study. Laryngoscopy time (T_L)was considered as the time from introduction of laryngoscope to visualisation of larynx. Intubation time (T_I) was considered as the time from the visualisation of larynx to confirmation of ET intubation by capnography. In the bougie group, T_I was further divided into, $T_B$which is the time from the visualisation of larynx to correct placement of bougie as confirmed by *clicks* or *distal hold up* and T_R which is the time taken to railroad the ET tube over bougie till confirmation of intubation by capnography.

Ease of intubation was assessed by Visual Analogue Scale (VAS) Score. The scale was constructed using a 50 cm ruler. This ruler was graded on one side from 0 to 100. On the converse side, it had only two inscriptions: *very easy* and *very difficult* corresponding to the 0 and 100 mark respectively. After intubation, observer 1 provided his estimation on the ease of intubation, by locating a point between the *very easy* and *very difficult* markings. Observer 2 then recorded the number corresponding to this point on the alternate side. If more than two attempts were necessary, VAS was scored for the successful attempt.

Data was analysed using SPSS™ version 13.0. All values were expressed as mean ± standard deviation (SD). Demographic data was analysed with unpaired *t*-test and Chi-square test. The change of laryngeal grading after application of cricoid pressure was analysed by Chi-square test. Unpaired *t*-test and Mann-Whitney U test were used to analyse intubation timing. VAS scores were analysed by repeated-measure analysis of variance (ANOVA). A p value of <0.05 was considered statistically significant.

Results

A total of 30 patients were enrolled in each group and none of them were excluded from data analysis. Both the groups were comparable with respect to the demographic variables (*Table 1*). All the patients enrolled belonged to ASA physical status 1 or 2, and 4 patients in each group had a modified Mallampati grading of 3 on preoperative assessment of the airway. There was no significant difference in laryngoscopic grading after application of cricoid pressure (*Table 2*).

Table 1: Demographic data

Parameter	Group B (Bougie) Mean ± SD n = 30	Group S (Stylet) Mean ± SD n = 30	*p* value
Gender : M/ F	15/ 15	17/ 13	0.605 (NS) *
Age (years)	36.50 ± 11.11	35.13 ± 9.59	0.612 (NS)•
Weight (kg)	57.77 ± 11.74	55.90 ± 11.00	0.582 (NS)•
Height (cm)	165.07 ± 10.16	164.53 ± 11.49	0.850 (NS)•
Body Mass Index (kg/m^2)	21.707 ± 3.88	20.56 ± 2.86	0.20 (NS)•

*Chi-square test, •Unpaired *t*- test, NS - Not significant, SD- standard deviation

Table 2: Cook´s grading of the laryngoscopic view before and after application of cricoid pressure

	Grade of laryngoscopy*				
	1	**2a**	**2b**	**3a**	**Total**
Without cricoid pressure	26 (43.3%)	21 (35%)	12 (20%)	1 (1.7%)	60 (100%)
With cricoid pressure	33 (55%)	17 (28.3%)	7 (11.7%)	3 (5%)	60 (100%)

* *Chi- square test* (*p*= 0.389, NS)

The laryngeal view improved in 22 of 60 patients (36.66%) after application of cricoid pressure, while it remained the same as before in 22. Overall, the grade remained the same or improved after cricoid pressure in 73.3% of patients. The laryngeal view worsened in 16 patients (27.7%) (*Table 3*).

Table 3: Number of patients who had a change in laryngoscopy grading with application of cricoid pressure

Laryngoscopy grade after application of cricoid pressure (n - number of patients)	Change in laryngoscopy grading	Number of patients
No change (n= 22)	1 - 1	18
	2a - 2a	4
Improvement (n= 22)	2a - 1	10
	2b - 1	5
	2b - 2a	6
	3a – 2a	1
Worsening (n= 16)	1- 2a	6
	1 - 2b	1
	1 - 3a	1
	2a - 2b	6
	2a - 3a	1
	2b - 3a	1
Total		60

Endotracheal intubation was successful in the first attempt in all of the 60 patients enrolled in the study. Time taken for laryngoscopy (T_L) and intubation (T_I) was clinically similar in both the groups of patients. However, in the stylet group, successful ET intubation was achieved in 12.4 sec in the easy subgroup as against 16.3 sec in the restricted subgroup ($p< 0.05$, S). Total intubation time was about 7 sec less in the stylet group when compared to the bougie group in both subgroup of patients. The difference of the time was statistically significant ($p< 0.05$). However, it was in the clinically acceptable range (*Tables 4 and 5*).

Table 4: Intubation time (in seconds) in bougie and stylet group

Time (seconds)	Subgroup	Easy subgroup n= 50	Restricted subgroup n= 10	p value
T_L	Bougie	7.7 ± 3.08	10.18 ± 3.9	0.127 • (NS)
	Stylet	7.99 ± 3.17	8.38 ± 2.19	0.799 • (NS)
T_I	Bougie T_B	5.2 [2.5, 16.9] $	6.7 [5, 23] $	0.051 ‡ (NS)
	Bougie T_R	15 ± 4.24	13.9 ± 5.23	0.582 • (NS)
	Stylet	12.4 [8, 20.8]$	16.3 [14.9, 17.3]$	0.007 ‡ (S)
Total time	Bougie	28 [20.5, 40] $	31.1 [27.7, 58] $	0.232 ‡ (NS)
	Stylet	21.42 ± 4.45	24.44 ± 3.02	0.161‡ (NS)

$ - Range in seconds • - Unpaired *t*-test ‡- Mann – Whitney U test NS - Not significant T_B- Time for bougie insertion T_R- Time for railroading the ET tube over the bougie

Table 5: Comparison of Total intubation times (in seconds) between the Bougie and Stylet group

	Group Bougie n = 30 median and range	Group Stylet n = 30 median and range	p value
Easy subgroup n=25	28 [20.5-40]	21 [27.7-58]	0.001‡ (S)
Restricted subgroup n=5	31 [12.2-29]	24 [21.8-28]	0.016‡ (S)

‡ Mann – Whitney U test S- Significant

Ease of intubation using the aid of stylet or the bougie was compared using the Visual Analogue Scale (VAS) Score and we did not find any statistically significant difference between the two groups (*Table 6*).

Table 6: Ease of intubation as assessed using the VAS score

VAS Scores (mean±SD)			
	Easy subgroup n= 25	**Restricted subgroup n=5**	**p value**
Group bougie n=30	17.32±2.79	24±7.41	0.087# (NS)
Group stylet n=30	17.92±3.25	23±2.73	0.087# (NS)
p value	0.514# (NS)	0.514# (NS)	

NS- Not significant SD: Standard deviation

Repeated-measure analysis of ANOVA

Discussion

Application of cricoid pressure is an important component of emergency intubations and rapid sequence intubation during general anaesthesia in patients presenting with full stomach. The purpose of rapid sequence induction is to quickly seal the airway by the introduction of a cuffed endotracheal tube with the least delay. Quick, atraumatic intubation of the trachea requires optimal visualisation of the glottis. It has been shown that applying cricoid pressure causes anatomical distortion of the upper airway and makes airway management more difficult. Furthermore external laryngeal pressure to improve the view of the larynx may not be performed concurrently with cricoid pressure.[6] Hence, during rapid sequence intubation, it is recommended that the endotracheal intubation must be performed with a styleted endotracheal tube or by using a gum elastic bougie as an aid.[7]

We have observed that the time taken for intubation was seven seconds longer, when gum elastic bougie was used as an intubation aid as compared to stylet in both easy and restricted groups of patients. Even though there is statistically significant increase in intubation time, we could not attribute any clinical significance to this finding.

Takashi *et al*, [3] had similar findings in the stylet group, while there was no statistically significant difference in the bougie group. Gataure *et al*,[5] had demonstrated that intubation using the gum elastic bougie was faster than using the stylet in simulated difficult intubations. The observed variations in our study as compared to the above two studies may be due to regular use of stylet as an intubation aid during rapid sequence induction in our institution. A bougie is used secondarily when intubation with styleted endotracheal tube fails. Also, successful intubation with bougie involves two phases: endotracheal placement of the bougie, and railroading the tracheal tube over the bougie into the trachea whereas intubation with stylet is done in one phase which involves the passage of a styleted endotracheal tube into the trachea. Hence intubation with bougie may take longer duration than with a stylet.

All patients could be successfully intubated in first attempt in both the bougie and stylet groups. This can be attributed to fewer grade 2b and 3a laryngoscopic views and also absence of any grade 3b or 4 view. In bougie group *clicks* sensation was elicited in twenty seven patients. In the remaining three patients, of whom one had grade 3a and two had grade 2b laryngeal views, the bougie had to be introduced further down into the trachea till *distal hold up* was felt.

The laryngeal view after cricoid pressure application remained the same or improved in 73% of patients while worsening by one grade occurred in 21.6% of patients. Takashi *et al*[3] observed that cricoid pressure had worsened the laryngoscopic view by one grade in 17 of 60 patients (28.3%), worsened by two grades in 14 of 60 patients (23.3%) which was clinically and statistically significant. Vanner *et al*[8] found an improvement in laryngoscopic grade, after application of cricoid pressure. Cricoid pressure, if properly applied would not cause major distortion of the laryngeal view that could worsen intubating conditions.

We attempted to standardise the cricoid pressure application by practicing it on a weighing scale before each intubation. This could have enabled consistent and correct application which in turn has resulted in minimising airway distortion. Limitations in the study included less number of participants, not

appropriately powered to difference in the intubation time and the study could not be blinded.

We conclude that, both gum elastic bougie and stylet are equally effective intubation aids during rapid sequence intubation. Intubation aided by bougie takes more time than that of a stylet, even though it is clinically trivial. Cricoid pressure does not affect the laryngoscopic visualisation of glottis in majority of patients.

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