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Original Article

Anaesthesia Section

Intubation Performance with Stylet and Preloaded Bougie for Rapid Sequence Intubation in Patients undergoing General Anaesthesia: A Randomised Clinical Trial

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ABSTRACT

Introduction: Rapid sequence induction requires quick and single attempt intubation to secure airway without any untoward complications. As the number of attempts increase, risk of desaturation and aspiration increase which is potentially life threatening. In such circumstances, miscalculation may cost loss of time which may prove fatal. Various adjuncts and techniques have been devised to prevent such calamities.

Aim: To compare ease of intubation with angulated stylet versus distally preloaded bougie for rapid sequence intubation in elective general anaesthesia procedures.

Materials and Methods: This randomised clinical trial was conducted in 100 patients belonging to 18-60 years of age from November 2019 to October 2020. Patients were intubated using rapid sequence including cricoid pressure by either styletted endotracheal tube (group S) or distally preloaded bougie (group B), for surgeries performed under general anaesthesia. The primary outcome was to determine mean Time to Intubation (TTI) and number of attempts, while secondary outcomes were haemodynamic responses to intubation and complications. Data comparison between independent groups in this normally distributed data was done using student -t test while intragroup analysis was done using chi-square test.

Results: A total of 100 patients were randomised into two groups-group S (mean age: 41.12 years) and group B (mean age: 37.34 years), of 50 patients each. Number of intubation attempts with stylet were single in 82%, two in 18% cases while with preloaded bougie, it was 80% and 14%, respectively (p-value=0.196). Time to intubation was 22.16 seconds (group S) versus 33.78 seconds (group B) (p-value <0.05). The haemodynamic assessments revealed that tachycardia, hypertension and increased End tidal carbon dioxide ($EtCO_2$) was seen for 10 minutes immediately post induction in both the groups, though the intergroup difference was non significant. The incidence of sore throat was higher with stylet than bougie, though non significant (p-value=0.118).

Conclusion: Stylet should be preferred for ease of intubation in rapid sequence inductions. However, the insertion and removal of stylet must be done cautiously to prevent post-operative sore throat.

Keywords: Aerosol, Anaesthesiology, Haemodynamics, Sore throat

INTRODUCTION

The community spread of Coronavirus Disease (COVID-19) infection called for essential modifications in existing norms of intraoperative conduct of anaesthesia. All airborne precautions along with minimum time devoted for high-risk procedures were contemplated as necessary for the safety of perioperative team. In this regard, use of Personal Protective Equipment (PPE) and protocolising Rapid Sequence Intubation (RSI) in every case whether elective or emergency was advocated by the national guidelines [1].

In elective Operation Theatre (OT) settings, during RSI, physicians may encounter difficult airway situation leading to a state of panic and chaos. So, in such critical scenarios, efficient techniques are required to facilitate intubation in first attempt and in minimal time. Various techniques and/or adjuncts have been studied but without any conclusive result [2,3].

Tracheal tube introducer, also known as bougie, has been used extensively in difficult airway scenarios especially in RSI to ensure first pass success [4]. Another technique for the same is the use of angulated stylet. However, it has been seen that usage of gum elastic bougie leads to less airway trauma in comparison to stylet as less force needs to be applied during airway manipulation [5]. The use of different angulations in stylet (30,45,75,90) have been used with miminal time to intubation with 75 degree and post operative sore throat being a major drawback [6]. All in all, many have advocated use of bougie/stylet based on one's expertise and experience.

During this COVID-19 era, emergency surgeries and RSI for intubation was mandated in national guidelines wherein need to minimise TTI lead us to this research hypothesis [7]. With use of PPE and importance to intubate with minimum trials and time, hyperangulated stylets and bougies were experimented, specifically with regards to TTI, number of attempts, while secondarily looking on the haemodynamic changes and adverse effects. The results of this study can be interpreted by experienced anaesthesiologists dealing with frontline COVID-19 intubations and translated into clinical practice with favourable TTI and attempts with stylet.

Therefore, the randomised clinical trial was conducted to elucidate the better method for improving intubation performance with stylet or preloaded bougie in RSI settings. The primary outcome of the study was to gauge time to intubation and mean number of attempts at intubation. The secondary outcome was recorded as haemodynamic changes, incidence of airway trauma and other complications (desaturation, oesophageal intubation and sore throat [3].

MATERIALS AND METHODS

This randomised clinical trial was conducted in Department of Anaesthesiology and Critical care medicine, at Maharishi

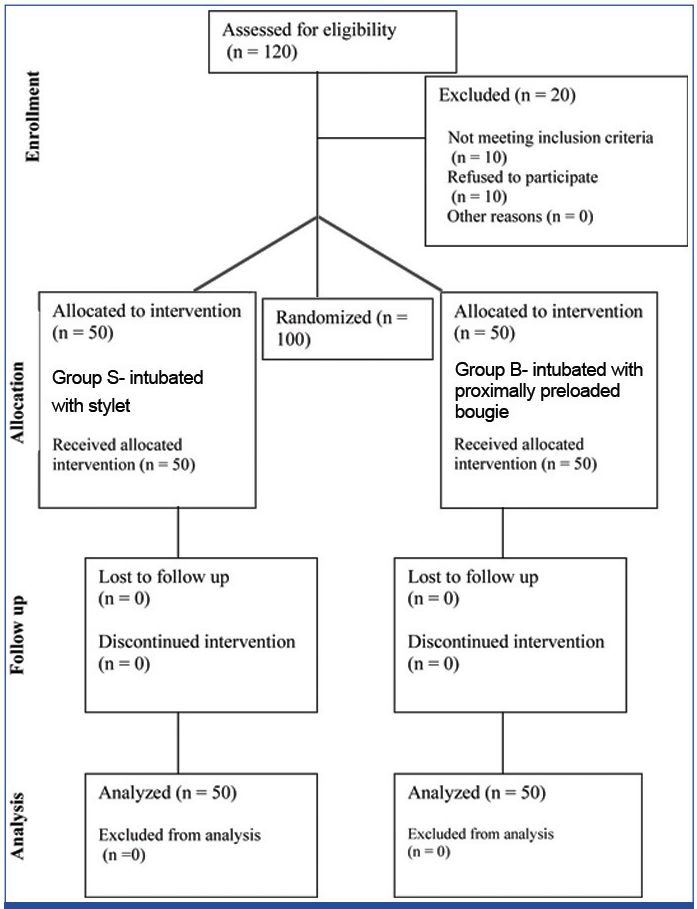
Markandeshwar University, Ambala, Haryana, India, from November 2019 to October 2020. Written and informed consent and approval was taken from Institutional Ethics Committee (IEC No./ MMU/1888).

Sample size calculation: The hypothesis to be studied in this randomised trial was that use of preloaded bougie not only would reduce time to intubation in RSI better than stylet but also lead to lesser pharyngeal trauma and sore throat. As a minimum 20% difference was hypothesised to obtain power of 80% with alpha error 0.05. The sample size for each group was found to be 50 [8].

Inclusion criteria: Patients between 18 to 60 years of age with American Society of Anaesthesiologists (ASA) status I or II planned for elective/emergency surgeries under general anaesthesia with RSI were included in the study.

Exclusion criteria: Patients with ASA status III or above, pregnancy, with raised intracranial pressure and with known history of distorted upper airway were excluded from the study.

Considering 10% drop-outs due to inclusion criteria and refusal to participate, 120 patients were enrolled. The CONSORT flow diagram depicted in [Table/Fig-1].



[Table/Fig-1]: CONSORT flow diagram.

Hundred patients undergoing elective/emergency surgery under general anaesthesia with rapid sequence induction were randomised into two groups of 50 each. Group S- intubated with stylet, group B- intubated with proximally preloaded bougie. Randomisation was done by means of sealed opaque envelopes opened by anaesthesiologist not involved in recording the observations.

Study Procedure

Preoperative management: Following a detailed preanesthetic check-up and optimisation, patient were kept nil per-oral six hours to solids and two hours to clear fluids. Single COVID-19 Reverse Trancriptase-Polymerase Chain Reaction (RT-PCR) test within 72 hours of surgery was performed and only after a negative report, patient was admitted and planned for surgery. A single RT-PCR had significant chances of being falsely-negative, hence all airborne precautions were taken in every elective and emergency procedure. Operation theatre was prepared according to the national COVID-19 guidelines where the central air conditioning was replaced by window air conditioners and number of air exchanges was set at 12/hour [9]. The informed consent was taken from all patients where they were explained the nature of anaesthesia to be given, all potential complications associated with the technique and precautions being taken to prevent transmission of COVID-19 infection. Tablet (Tab) alprazolam 0.25 mg was administered orally night before and 6 am on the morning of surgery. On the day of surgery, the patient was transported to the designated theatre ensuring that he/she was wearing triple-layer mask along with the transporting personnel.

Operating procedure: In the Operating Room (OR), no more than seven members were allowed in a surgery consisting of two surgeons, two nurses- one who assisted in surgery and the other being floor nurse, one anaesthesiologist, one anaesthesiology resident (the one who intubated had more than 12 months of experience) and one OR technician. The entire perioperative team followed COVID-19 protocol. Monitors including an electrocardiogram, pulse oximeter, $ETCO_2$ and non invasive blood pressure were attached and baseline haemodynamic parameters recorded. Intravenous cannula was secured and Ringer lactate solution 500 mL started. Following preoxygenation with 100% oxygen for three minutes, patients were given premedication in the form of injection glycopyrrolate 0.01 mg/kg, nalbuphine 0.1 mg/kg, and propofol 2-2.5 mg/kg till there was a loss of response to verbal commands. A wet gauze piece was kept as an interface between the mouth and the face mask to reduce aerosol transmission during induction. After confirming ability to mask ventilate and initiation of cricoid pressure by an assistant, 2 mg/kg succinylcholine was administered. Mask ventilation was avoided or done using lower Tidal volumes (Tv) if required (modified RSI) till the disappearance of fasciculations from great toe and laryngoscopy performed with C-Macintosh (Mac) videolaryngoscope in both the groups. In group 'S', patients were intubated with an appropriate-sized styletted endotracheal tube shaped in the form of "hockey-stick", where as in group 'B', a gum-elastic bougie with an endotracheal tube loaded at the distal part used for endotracheal intubation by rail-road technique. The anaesthetist intubating the patient was wearing eye goggles/ face shield as an extra protection while intubation. The tube was clamped after insertion and only after connecting the circuit and inflating the cuff, clamp was released. The confirmation of correct placement of endotracheal tube was done with end-tidal capnography and 5-point auscultation, following which cricoid pressure was withdrawn Patients were mechanically ventilated using A/C Volume Control Ventilation (VCV) mode with Tv-10 mL/kg, frequency 14 and pressure settings to achieve end-tidal carbon dioxide 30-35 mmHg. Maintenance of anaesthesia was done with isoflurane ($EtCO_2$) titrated to MAC-1 in O_2-N_2O mixture 1:1.

Postprocedure assessment: The ease of intubation was assessed by an anaesthesiologist who was unaware of group allocation as per number of attempts taken, time to intubate and manipulation required to aid intubation. Time to intubation was noted from introduction of the laryngoscope into oral cavity to appearance of correct end-tidal carbon dioxide waveform. This was monitoredby the second anesthetist who was present in OT. The secondary parameters assessed were haemodynamics namely- heart rate, systolic, diastolic, and mean arterial pressure (MAPs) documented before intubation, immediately after intubation, and thereafter at 1, 3, 5 and 10 minutes after intubation. Any complications occurring during intubation like desaturation, oesophageal intubation or trauma and sore throat were also noted.

STATISTICAL ANALYSIS

Statistical analysis was performed using Statistical Package for Social Sciences (SPSS) version 21.0 of windows. For categorical

variables, numbers or percentages were used for representation while numerical variables represented using mean and standard deviation. Data comparison between independent groups in this normally distributed data was done using student-t test while intragroup analysis done using Chi-square test. The results were considered statistically significant at p-value <0.05.

RESULTS

All baseline parameters (age, gender, and ASA grading) were similar in both the groups (p-value >0.05) [Table/Fig-2]. Total 82% of the patients could be intubated with stylet in a single attempt. Whereas, 80% could be intubated in the first attempt in the other group using preloaded bougie (p-value=0.196) [Table/Fig-2]. The time to intubation was 22.16 seconds versus 33.78 seconds in group S and group B, respectively (p-value <0.001) [Table/Fig-3].

Demographic data		Group S (n=50)	Group B (n=50)	p-value (Chi-square)
Age (Mean in years)		41.12	37.34	0.245
Gender	Male	31	31	1.000
	Female	19	19	
ASA status	I	28	35	0.147
	II	22	15	

[Table/Fig-2]: Demographic data.
ASA: American society of anaesthesiologists

No. of attempts	Group S (n=50)	Group B (n=50)	Total	p-value
1	41	40	81	0.196
2	9	7	16	
3	0	3	3	
Mean TTI (sec) (mean±SD)	22.16±6.65	33.78±20.49		**<0.001**

[Table/Fig-3]: The number of attempts required for intubation and TTI.

The incidence of pharyngeal trauma, oesophageal intubation, desaturation was similar in both the groups (p-value >0.05). The percentage of patients experiencing sore throat in the immediate post-operative period was 24% in Group S versus 12% in group B, respectively, although it was statistically insignificant (p-value >0.05) [Table/Fig-4]. Mean Heart Rate (HR) before and after Intubation till 10 minutes in both the groups are calculated [Table/Fig-5]. SpO_2 (Partial pressure of Oxygen) and Mean Arterial Pressures (MAP) showed no significant difference between before and after intubation values recorded till 10 minutes [Table/Fig-6,7].

Complications	Group S (n=50)	Group B (n=50)	Total	Chi square value	p-value
Oesophageal intubation	1	0	1	1.010	0.315
Desaturation	0	1	1	1.010	0.315
Sore Throat	6	12	18	2.439	0.118

[Table/Fig-4]: Incidence of complications during intubation in both groups

Heart rate (beats per minute)	Group S (n=50)		Group B (n=50)		t	p-value
	Mean	SD	Mean	SD		
Baseline	83.66	12.40	89.06	16.71	-1.835	0.070
Pretreatment time	84.72	12.70	89.80	14.93	-1.832	0.070
Post treatment time	89.68	14.31	92.96	17.25	-1.035	0.303
After 1 minute time	87.22	14.10	92.80	15.96	-1.853	0.067
After 3 minutes time	86.16	13.75	92.04	14.33	-2.094	**0.039**
After 5 minutes of time	85.60	12.92	90.90	13.02	-2.043	**0.044**
After 10 minutes of time	83.10	17.07	90.58	13.89	-2.403	**0.018**

[Table/Fig-5]: Mean Heart Rate (HR) before and after intubation till 10 minutes in both the groups.

MAP (mmHg)	Group S (n=50)		Group B (n=50)		t	p-value
	Mean	SD	Mean	SD		
Baseline	96.28	13.55	94.02	13.29	0.842	0.402
Pretreatment time	93.96	14.30	95.06	15.00	-0.375	0.708
Post-treatment time	93.86	16.12	94.64	14.63	-0.253	0.800
1 minute time	92.86	13.19	92.48	15.00	0.135	0.893
After 3 minutes time	93.16	12.17	94.36	14.12	-0.455	0.650
After 5 minutes time	93.80	16.28	93.12	15.07	0.217	0.829
After 10 minutes time	91.54	14.28	94.08	14.47	-0.883	0.379

[Table/Fig-6]: Mean Arterial Pressures (MAP) before and after intubation till 10 minutes in both the groups.

Partial Pressure of Oxygen (SpO_2) (%)	Group S (n=50)		Group B (n=50)		Z	p-value
	Mean	SD	Mean	SD		
Baseline	99.80	0.86	99.84	0.65	-0.263	0.793
Pretreatment time	99.64	1.10	99.86	0.53	-1.270	0.207
Post-treatment time	99.72	0.78	99.66	1.08	0.318	0.751
After 1 minute time	99.92	0.40	99.36	2.13	1.831	0.070
After 3 minutes time	99.86	0.57	99.66	1.76	0.765	0.446
After 5 minutes time	99.92	0.40	99.86	0.76	0.497	0.620
After 10 minutes time	99.92	0.40	99.96	0.28	-0.581	0.562

[Table/Fig-7]: Mean Spo_2 before and after induction till 10 minutes after intubation in both the groups.

The haemodynamic assessments revealed that, in the first 10 minutes, after intubation patients exhibited tachycardia and hypertension (both systolic and diastolic) and increased $EtCO_2$, within 20% of the baseline values, which returned to normal by 10 minutes. Intergroup comparison being statistically insignificant (p-value >0.05) [Table/Fig-8]. Total 82% of the patients could be intubated with stylet in a single attempt, whereas 80% could be intubated in the first attempt in the other group using preloaded bougie (p-value=0.196).

End Tidal Carbon Dioxide ($EtCO_2$) (mmHg)	Group S (n=50)		Group B (n=50)		Z	p-value
	Mean	SD	Mean	SD		
Baseline	26.06	3.36	26.88	2.78	-1.329	0.187
Pretreatment time	29.00	2.45	29.62	2.59	-1.229	0.222
Post-treatment time	31.38	3.14	31.76	2.37	-0.684	0.496
After 1 minute time	32.30	3.18	33.14	2.49	-1.471	0.144
After 3 minutes time	32.66	2.84	33.60	1.82	-1.971	0.052
After 5 minutes time	32.70	2.94	33.56	1.63	-1.807	0.074
After 10 minutes time	32.90	1.46	33.26	1.56	-1.190	0.237

[Table/Fig-8]: Mean $EtCO_2$ before and after induction till 10 minutes after intubation in both the groups.

DISCUSSION

As an anaesthesiologist, securing the airway safely holds all the more significance in emergency surgeries where the time constraints do not allow for elaborate thinking before proceeding, rather depend upon your swift decision making and experience especially in current COVID-19 scenario. Such case scenarios have been dealt more efficiently by RSI, which saves time from decision to intubate till successfully secured endotracheal tube. Numerous adjuncts and external manipulations in patient's position as well as laryngeal position have been attempted to overcome this problem and improve Cormack-Lehane (CL) grading [10] and intubation success with use of rapid sequence. Amongst these, different designs of stylets and bougies have been deviced and compared for ease of intubation. This study was initiated as literature mentions of stylets and preloaded bougies being equivalent in terms of intubation

success, although none of them have analysed the differential efficacy of the two in rapid sequence inductions with application of cricoid pressure [11].

Results have shown that number of attempts at intubation especially the first-time attempt success frequency was similar in both the groups (p>0.05). Similar results have been documented by Ömür D et al., [12] and Juergens AL et al., [13] where D-shaped stylets (anteriorly angulated) and gum elastic bougies performed equivalently in context to first-pass success and number of attempts. Kingma K et al., [8] demonstrated 86.6% first-pass success with stylet compared to 89.7% with preloaded bougie, both being superior to without adjunct intubation (37%) as well as rail-roaded bougie (75%). Thus, distally preloaded bougies make up for the time lost in rail-roading and could be adopted as first line for rapid sequence inductions proposed in majority of cases in COVID-19 era.

In contrast, Driver BE et al., stated that bougie had better first attempt success than stylet, especially in emergency/out of hospital settings [14]. One of the reasons for stark difference with this study is that the resuscitators were more familiar with use of bougie than stylet, which made a difference in the performance with the two equipment.

Time to intubation which was significantly lesser in stylet group as compared to bougie (p-value <0.05). Thus, preformed stylets took lesser time for intubation as compared to distally preloaded bougie despite the tube already being loaded on the bougie. Moreover, with regards to number of attempts, 82% patients could be intubated in first attempt with stylet as compared to 80% patients in preloaded bougie group. It was also observed that no patient required third attempt in group S and three patients (6%) were intubated in third attempt with preloaded bougie.

In a study by Batuwitage B et al., [11] on simulation models, stylets and bougies performed similarly in difficult intubation scenarios with time taken for intubation being lesser but not statistically significant in stylet group as compared to bougie group. Hence, simulation studies do give an idea of how the hypothesis might translate in human studies, but cannot precisely corroborate with the latter. Studies done in the setting of real-time scenarios are most precise for incorporation in clinical practice.

The haemodynamic response to intubation with preloaded bougie and stylet was also evaluated as a secondary outcome, with heart rate, systolic, diastolic and mean blood pressures and oxyhaemoglobin levels respectively. It was found that the haemodynamic response to laryngoscopy resulted in hypertension and tachycardia which returned to normal in 10 minutes post intubation, although the intergroup comparison was statistically insignificant [Table/Fig-6-8]. Thus, ease of intubation in terms of associated haemodynamic disturbances was similar in stylet and bougie group. It was hypothesised that as previous studies took lesser time to intubation with stylet and overall performance, it might lead to lesser haemodynamic alterations. However, the trends of heart rates, blood pressures, $EtCO_2$ and SpO_2 levels suggested that both the equipment lead to similar and insignificant changes in haemodynamics [Table/Fig-6-8]. Also, the use of good pre-emptive analgesia and appropriate propofol doses during induction helped in preventing excessive haemodynamic derangement [15]. The incidence of visible pharyngeal trauma, and other complications like esophageal trauma and desaturation was minimal in both the groups. However, the incidence of sore throat was comparatively higher (12/50) in stylet group in comparison to bougie (6/50), although it was statistically insignificant. Thus, bougie can be preferred to stylet as an airway adjunct in patients with reactive airway.

Kusunoki T et al., and Ono Y et al., demonstrated that extraction force used while removing the stylet was directly linked with increased incidence of sore throat, which could be the reason in present case as well [5,16]. However, Yoon HK et al., showed similar sore throat incidence with or without stylet in elective lumbar or thoracic spine surgeries when C-Mac videolaryngoscope was used [17].

Limitation(s)

Limited number of people were allowed in OT, and hence the time to intubation was recorded by the second anaesthetist which might have added to the bias in the study. The study used the conventional McIntosh blade for intubation. However, in situations like the COVID-19 pandemic video laryngoscopes are better [18]. There is a lack of long term follow-up (>24 hours) of patients for sore throat.

CONCLUSION(S)

Both stylet and preloaded bougies perform equivalently when used during rapid sequence induction. However, stylet reduces time to intubation, and can be preferred by the residents when the patient has extremely reduced reserves of alveolar oxygen before intubation. Also, it can be opined that the incidence of sore throat can be decreased in patients with reactive airway if bougie is used in place of stylet. Thus, use of adjuncts can be varied according to availability, experience and clinical situations with both preloaded bougie and stylets being equally good in terms of ease of intubation.

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