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Original Research Article

EVALUATING THE EFFECT OF CRICOID PRESSURE ON DIRECT LARYNGOSCOPIC VIEW AND EASE OF OROTRACHEAL INTUBATION IN ADULTS: A PROSPECTIVE, RANDOMIZED, DOUBLE-BLIND STUDY

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Abstract

Background: Cricoid pressure (CP) is an integral part of rapid sequence tracheal intubation and emergency airway management but its role and effects are controversial. This prospective, randomized, double-blind study aims to evaluate the effect of cricoid pressure on laryngoscopic view and ease of orotracheal intubation in adults. **Materials and Methods:** 100 patients of ASA I-III, posted for elective surgery requiring general anaesthesia with oral endotracheal intubation were randomly assigned to two equal groups CP (Cricoid pressure was applied) and NON CP (With sham cricoid pressure). Parameters recorded were Cormack and Lehan Grading, number of patients with single or double attempt of intubation, ease of Intubation scoring, time for successful intubation and complications like trauma and postoperative sore throat. Sample size of each group was determined by power analysis. Non-parametric data were analysed using Chi-square test and parametric data were analysed using unpaired student's t-test. **Result:** In this study, CP and NON CP groups were comparable with respect to demographic parameters, airway parameters, number of patients intubated with single attempt of intubation, number of easy and difficult intubation, time required for intubation and postoperative complications (trauma and sore throat). Contrary to the popular belief, Cormack-lehane grading improved with cricoid pressure (p=0.026). Increase in thyromental distance after applying cricoid pressure decreases time of intubation in cricoid pressure group (p=0.001). **Conclusion:** Cricoid pressure applied during intubation improved Cormack-lehane grading significantly and decreased the time of intubation in patients due to increase in thyromental distance, but it had no effect on ease of intubation.

INTRODUCTION

Cricoid pressure (CP) or Sellick's maneuver is the application of sustained digital pressure to the cricoid cartilage pushing it backwards and thus compressing the oesophagus between the posterior aspect of the cricoid and the body of C5-6. Sellick's report in 1961 transformed the practice of anesthesia and cricoid pressure became an integral part of rapid sequence tracheal intubation and emergency airway management due to it being intuitively helpful in preventing regurgitation of gastric contents.[1]

In regards to airway management and the prevention of aspiration as it relates to CP, the anatomical landmarks that we should focus on to identify the physical justification for CP surround the esophagus, cricoid cartilage, and trachea as well as their supporting structures. Rice et al (2009) used MRI to verify that the alimentary canal at the level of the cricoid ring is the post-cricoid hypopharynx and not the esophagus. Systemic reviews in the past have all pointed out that there are no published randomized controlled trials comparing the incidence of regurgitation on induction, with and without CP in patients at high risk of regurgitation.[2]

However, in recent years it has been reported that CP may alter the upper airway anatomy and compromise its patency.[3] Problems associated include difficult laryngoscope placement, pharyngeal compression, and laryngeal distortion.

Stand of cricoid pressure in ease of laryngoscopy and endotracheal intubation is controversial. In a recent study in 2016 by Komasawa et al,[4] evaluated how cricoid pressure impedes tracheal intubation with the

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Pentax-Airwayscope. On the contrary, in a study conducted by Koti et al,[5] showed that concerns about impending intubation are not justified because tracheal intubation can be achieved successfully with CP.

Henceforth we conducted a study in adult patients undergoing elective surgical procedures to evaluate the effect of cricoid pressure on laryngoscopic view, assessed by Cormack and Lehane grading (CL grade), using direct laryngoscope with rigid Macintosh blade as primary outcome, time of intubation and ease of orotracheal intubation as secondary outcomes. Complications like trauma and sore throat, resulted from cricoid pressure, were also noted in the postoperative period.

MATERIALS AND METHODS

Study was started in tertiary care teaching hospital after obtaining approval (letter no-204/GMC/IEC/04/2014) from institutional ethical committee. Well informed written consent was taken from all the patients. We followed declaration of Helsinki on ethical principles for medical research involving human subjects.

Hundred patients of either sex and American Society of Anaesthesiologists (ASA) grade I, II or III with age range of 20-80 years were randomly assigned in two groups Cricoid pressure (CP) and non-cricoid pressure (NON CP) with allocation ratio 1. All patients were posted for elective surgery requiring general anaesthesia with oral endotracheal intubation.

Patients excluded were patient under ASA grade IV, patients with anticipated difficult airway [cervical spine disorder, obstructive airway tumor, edentulous patients, anteriorly protruding incisors, obese (body mass index (BMI)>30) patients, fracture mandible, Mallampatti grade III and IV, mouth opening < 3.5cm, thyromental distance (TMD)< 6.5cm], patients with risk of pulmonary aspiration of gastric contents e.g. pregnant patients.

Online randomization by https://www.randomizer.org was used to generate a table of random numbers in set of two groups of 50 each. In Group CP cricoid pressure was applied and Group NON CP no cricoid pressure was applied but only mimicked (Sham cricoid pressure). This information was handed over to sister-in charge to allocate the patients. Intubating anaesthesiologist and patients were blinded to group assignment and the anaesthesiologist applying crioid pressure and recording data were not blinded.

Pre-anaesthetic evaluation was done. Monitoring included electrocardiogram (ECG), noninvasive arterial pressure, peripheral saturation probe (SpO2), and measurement of end-tidal carbon dioxide (ETCO2). Premedication was done with Inj. Ondansetron 0.1mgkg-1 i.v., inj.midazolam 0.05mgkg-1 i.v., inj.tramadol 1.5mgkg-1 i.v. and inj.glycopyrrolate i.v.0.01mgkg-1. Following preoxygenation with100% oxygen for 3 minutes, induction with fentanyl 1 µg/kg and propofol 2.5 mg/kg or thiopental 5 mg/kg was done. Neuromuscular blockade with succinylcholine 2 mg/kg was achieved and after onset of complete neuromuscular blockade, the patient's head and neck was placed in Magill position. Cricoid pressure was applied by an experienced anesthesia provider using a single handed technique. The thumb and middle finger were placed on either side of the cricoid cartilage and cricoid pressure was applied by the index finger. During the control condition (no cricoid pressure) the anesthesia provider placed their thumb, middle and index finger in the same manner without applying any pressure. Direct laryngoscopy was done using rigid Macintosh blade of size either 3 or 4 depending on patient's profile. A cuffed endotracheal tube (ETT), size depending on patients profile was then advanced through the glottis and into the trachea and confirmation of the ETT inside the trachea was done by capnography and auscultation of lungs. Now if the attempt was unsuccessful, then either optimal external laryngeal manipulation, stylet was used or the amount of cricoid pressure was decreased.

In case of unsuccessful first attempt, the patient was ventilated again for 3 mins and the same step was repeated again right from the i.v injection of succinylcholine to the confirmation of ETT placement. In case of unsuccessful 2nd attempt, the case was taken as failed case and would not be included in the analysis.

Parameters assessed were Cormack and Lehan Grading, number of patients with single/double attempt of intubation (maximum two attempts of intubation were taken), ease of Intubation scoring [Easy(0)- in first attempt, without manipulation or stylet use and Difficult(1)- two attempts/ either optimal external laryngeal manipulation (operator's right hand with simultaneous view of laryngoscopic view)/ stylet/ decreased the amount of cricoid pressure], time for successful intubation (In case of 2nd attempt, the time for ventilation in between two attempts was excluded) and complications (trauma and postoperative sore throat). Thyromental distance after applying cricoid pressure(PCTMD) in CP group was also measured before laryngoscopy.

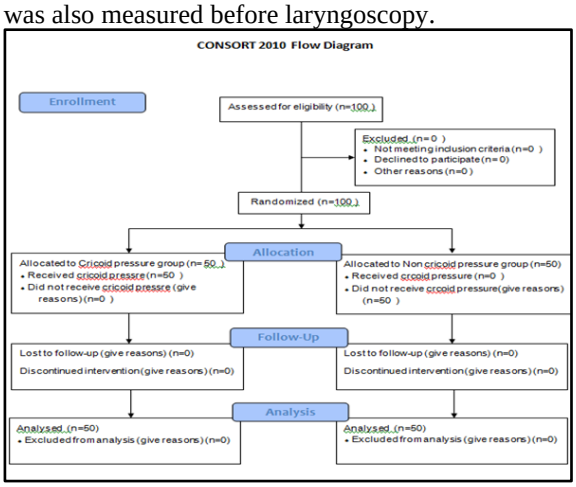

Figure 1: Flowchart of patients enrolled in the study.

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Sample size was calculated by power analysis, taking incidence of Cormack Lehane grade as primary parameter from previous study [6] with median (standard deviation, SD) of 1(0.67) and assuming type I error as 0.05 and power of study as 80%. So, the sample size was taken 100 patients with 1:1allocation ratio considering the possibility of drop out or failed intubation. Non-parametric data were analysed using Chi-square test and parametric data were analysed using unpaired student's t-test. Relationship between time of intubation and post cricoid pressure thyromental distance (CPTMD) in CP group was assessed by Pearson correlation and simple regression analysis. Statistical analysis was performed using SPSS software (version 24.0; SPSS Inc., Chicago, IL, USA). A P value < 0.05 was considered significant. Data are presented as Mean (SD) and number (percentage).

RESULTS

The flowchart of patients recruited and analysed is shown in Figure 1. In this study, CP and NON CP groups were comparable with respect to demographic parameters and airway parameters [Table 1].

Table 1: Demographic and airway parameters between the two groups. Data are presented as mean (SD) and number

Parameters	CP (n=50)	NON CP (n=50)	P value
AGE (years)	37.50 (14.40)	38.12 (12.16)	0.817
GENDER (M/F)	17/33	19/31	0.677
Weight (kg)	56.44 (8.49)	55.36 (7.01)	0.490
Height (cm)	163.98(6.69)	164.74(5.28)	0.529
ASA grading (I/II/III)	20/25/5	17/26/7	0.742
MPS (I/II)	12/38	16/34	0.373
TMD (cm)	6.97 (0.48)	6.94 (0.45)	0.732
IID (cm)	4.22 (0.43)	4.40 (0.56)	0.262

The number of Cormack-lehane grading for cricoid pressure and non-cricoid pressure groups was statistically significant with p value 0.026. Out of 50 patients in each group, numbers of patients with CL grade 1 were 25 and 11 in cricoid pressure group and non-cricoid pressure group respectively [Table 2]. Two groups were comparable with respect to the parameters- attempts of intubation, time of intubation and postoperative complications. [Table 3]

Table 2: Compariosn of Cormack-Lehane (CL) grading between the two groups. Data are presented as number(percentage)

Parameter	CP (n=50)	NON CP (n=50)	P VALUE
Cormack-Lehane Grading (I/II/III/IV)	25/16/9/0	11/26/12/1	0.026*

Table 3: Comparison of number of patients intubated with single/double attempt of intubation, time of intubation and postoperative complications (trauma and sore throat) between the two groups. Data are presented as number, mean (SD) and number (percent).

Parameter	CP (n=50)	NON CP (n=50)	P value
Number Of Patients And Attempts Of Intubation (1st /2nd)	47/3	48/2	0.312
Time of intubation (sec)	21.34 (4.43)	21.76 (4.41)	0.636
Trauma	5 (10)	3 (6)	0.46
Sore throat	11 (22)	14 (28)	0.48

In this study the parameter 'ease of intubation' was categorized as easy or difficult. On comparing ease of intubation between the two groups, number of easy intubation was 38 in cricoid pressure group in comparison to 29 in non-cricoid pressure group. Despite the difference in the number of easy intubations, it was statistically insignificant with p value 0.056 [Table 4].

Table 4: Comparison of ease of intubation between the two groups. Data are presented as number.

Parameter	CP (n=50)	NON CP (n=50)	P value
Ease of intubation (easy/difficult)	38/12	29/21	0.056

In this study, a relationship was observed between time of intubation and CPTMD when cricoid pressure was applied. This relationship was proved by correlation and regression analysis. Increase in thyromental distance decreases time of intubation in cricoid pressure group. A simple linear regression is calculated to predict time of intubation based on thyromental distance in cricoid pressure group. A significant p value 0.001 was found after analysis in cricoid pressure group. [Table 5 and Figure 2]

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Table 5: comparison of relationship between time of intubation and postcricoid pressure thyromental distance (CPTMD) in cricoid pressure group

	CP group			
	Time of Intubation (sec)		TMD (cm)	
	Pearson Correlation	P value	Pearson Correlation	P value
Time of Intubation (sec)	1		-0.471	0.001*
TMD (cm)	-0.471	0.001*	1	

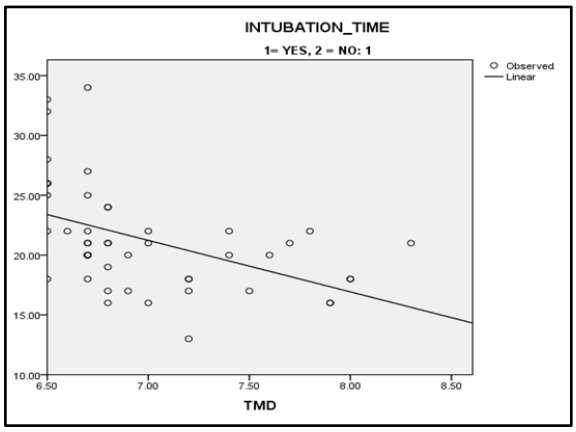

Figure 2: Correlation between time of intubation and thyromental distance (TMD) in cricoid pressure group.

DISCUSSION

The incidence of failed intubation using conventional laryngoscopy is believed to increase when cricoid pressure is applied.[7] This study was conducted to observe the effect of cricoid pressure on laryngoscopic view and ease of endotracheal intubation. In our study, Cormack-lehane grading improved with cricoid pressure. Airway obstruction associated with the use of cricoid pressure is well documented,[8,9] and most failed intubation guidelines now recommend graded release of cricoid pressure in the 'can't intubate, can't ventilate' situation. In previous studies by Vanner et al,[10] and Haslam et al,[11] showed that application of cricoid pressure at 30 N is likely to improve the laryngoscopic view and there is marked deterioration in laryngoscopic view as cricoid pressure increased.

In our study, a relationship was observed between time of intubation and postcricoid pressure thyromental distance (PCTMD). Increase in thyromental distance decreases time of intubation in cricoid pressure group. In cricoid pressure group, time of intubation (TOI) can be predicted by the equation:-TOI= [51.360 – 4.305 x (CPTMD)] seconds where CPTMD is measured in cm.

Prakash et al,[12] and Chou et al,[13] in their study identified TMD < 6.0 cm as a predictor of difficult laryngoscopy and intubation, though in a recent study by Krobbuaban et al,[14] on morbid obesity and tracheal intubation, TMD was found to be no different between easy and difficult intubations. In our study we observed average increase in TMD after applying cricoid pressure though we have not analysed exact relationship between TMD and PCTMD. We found significant relation between intubation time and increased PCTMD.

Rest other parameters, attempt of intubation, ease of intubation, time of intubation and postoperative complications were comparable between the two groups. All the previous studies showed that cricoid pressure either decreases or has no effect on the success of endotracheal intubation. This finding was observed in our study, irrespective of improvement in Cormack-lehane grading by cricoid pressure. The probable reason for this observation is major improvement observed in CL grading is between CL grade 1 and 2, which minimally affects the difficulty of laryngoscopy and intubation. In our study, difficulty in intubation was defined by use of adjuncts (stylet / bougie), second attempt of intubation and release of cricoid pressure. Increase ease of intubation in cricoid pressure group is explained by its improvement in CL grading and when difficulty was experienced during intubation, release of cricoid pressure helped. On contrary, number of times adjunct used in non-cricoid pressure group was higher, thereby, explaining the result. With respect to time of intubation, it was comparable in this study. In previous studies where direct laryngoscopy was done, mean time of intubation was much less than this study. This could be explained by the use of airway adjuncts, like stylet and bougie, in non-cricoid pressure group which summed up the time required for intubation.

Limited studies were done on the effect of cricoid pressure on airway trauma and sore throat. There is only one case report of laryngeal fracture due to cricoid pressure. In our study, the incidence of postoperative complications (trauma and sore throat) was comparable between the two groups and low in incidence.

This study should be interpreted with limitations that cricoid pressure applied in this study was as per 50 ml syringe training aid,[15] which neither assures accuracy of cricoid pressure nor rules out inter-patient variability in anatomy of cricoid cartilage and the force applied. Secondly, this study excluded emergency patients, ASA grade IV and with difficult airway, i.e the group of patients in which cricoid pressure is routinely applied. Thus, further studies are recommended to include both high-risk patients and those with anticipated difficult airway.

CONCLUSION

Cricoid Pressure is an invariable part of airway management, especially in emergency patients and patients with risk of aspiration. From this study, we can conclude that it improves cormack lehane grading, but has got no role in improving ease of

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intubation and duration of intubation. Moreover patients in whom intubation was easy post cricoid pressure, was mainly due to increase in thyromental distance (post cricoid pressure). This finding could be helpful especially in patients with TMD < 6 cm. However further research is required because many patients in whom cricoid pressure might be helpful (like TMD <6 cm, emergencies etc) were excluded from our study due to ethical reasons.

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