Original Research Paper

Volume-9 | Issue-2 | February-2019 | PRINT ISSN - 2249-555X

Anaesthesiology

ASSESSMENT OF EFFECTIVENESS OF CRICOID PRESSURE IN PREVENTING GASTRIC INSUFFLATION DURING BAG AND MASK VENTILATION: A RANDOMIZED CONTROLLED TRIAL

Dr Ashutosh Ranjan*	Senior Resident, Department of Anesthesiology, JLN Medical College, Bhagalpur, Bihar(India) *Corresponding Author
Dr. Veena Horo	MD,Head of Dept of Anaesthesia,Associate Professor,JLNMCH Bhagalpur

KEYWORDS :

Introduction

Rapid sequence induction and intubation (RSII) is practiced in patients at risk of pulmonary aspiration of gastric contents.[1] The conventional RSII includes adequate preoxygenation, rapid administration of predetermined dose of intravenous induction agent and depolarizing neuromuscular blocker, with simultaneous application of cricoid pressure (Sellick's maneuver). This is followed by laryngoscopy and tracheal intubation with a cuffed endotracheal tube (ETT).[2,3] Facemask ventilation (FMV) is avoided, prior to tracheal intubation, for fear of gastric insufflation. In scenarios like failed tracheal intubation and in patients with decreased functional residual capacity (such as morbid obesity and pregnancy, to name a few), avoiding FMV may increase the risk of hypoxemia.[2,4,5] Few surveys have shown that a significant number of anesthesiologists provide gentle FMV at some point of time during RSII; this is termed as "modified" RSII.[6,7]

High airway pressures may increase the risk of gastric insufflation during FMV.[8,9,10,11,12] Few studies have proven that CP is effective in preventing gastric insufflation. In these studies, the occurrence of gastric insufflation was identified by aspirating gastric contents using nasogastric tube or by auscultating with a stethoscope over the epigastrium.[9,13,14,15,16] Measurement of the gastric antral cross-sectional area (CSA) can be used to assess change in gastric volume.[17,18] The appearance of "comet tail" artifacts caused by the "shadow" of gas in the stomach indicates entry of gas into the stomach during FMV.[10,19] Therefore, this study was designed to use gastric USG to assess the effectiveness of CP in preventing gastric insufflation during FMV. The primary objective was to assess the effectiveness of cricoid pressure in preventing gastric insufflation during FMV by measuring the change in the gastric antral CSA and volume using USG. The secondary objective was to see the appearance of comet tail artifacts, which will indicate gastric insufflation and assess the correlation between peak airway pressure and the antral CSA measured after FMV.

Materials and Methods

After obtaining approval from Institute Ethics Committee and registering with Clinical Trials Registry, India(CTRI/ 2016/01/ 006478), a randomized controlled trial was conducted. Adults with American Society of Anesthesiologists (ASA) physical status 1 or 2 scheduled for elective surgeries under general anesthesia were included in the study. Patients with high risk of aspiration requiring RSII, patients with anticipated difficult airway, oro-gastric, or esophageal pathology were excluded.

Informed written consent was obtained from all participants and 84 patients were randomized to receive "cricoid pressure" (Group CP; n = 42) or "no cricoid pressure" (Group NCP; n = 42) based on a computer-generated block randomization table using variable block sizes. Allocation concealment was done using serially numbered opaque-sealed envelopes. A 2–5 MHz curvilinear ultrasound probe (Sonosite S-ICUbered opaque Inc, Bothell, WA, USA) was used for performing the gastric ultrasound, in all patients.

After verifying the adequacy of fasting status (8 h for solids and 2 h for clear liquids), patients were transferred to the operating room and ASA standard monitors were connected. Baseline gastric antral CSA was measured, using free tracing method, in supine and right lateral decubitus positions by an anesthesiologist trained in point-of-care ultrasound, who was not involved in anesthetizing or ventilating the patient. The antrum was imaged by placing the ultrasound probe in sagittal plane over epigastrium with left lobe of liver, aorta, and celiac artery as landmarks [Figure 1a].[20] The images were saved and verified by a radiologist later. After preoxygenation, anesthesia was induced with fentanyl 2 mcg•kg–1 and thiopentone 3–5 mg•kg–1 or propofol 2 mg•kg–1followed by appropriate dose of a non-depolarizing neuromuscular blocker at the discretion of the attending anesthesiologist.

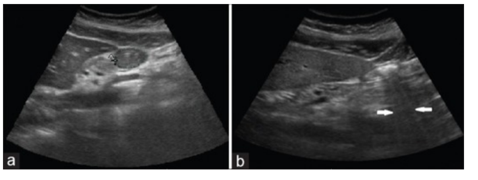

Figure 1

Ultrasonographic images of gastric antrum: (a) Gastric antral cross-sectional area measured by free tracing method before face mask ventilation (FMV); (b) Comet-tail artifacts (arrows) after FMV indicating gastric insufflation

In group NCP, FMV was initiated soon after loss of eyelash reflex. Trachea was intubated after 3 min of FMV. In group CP, cricoid pressure was applied after induction but before initiation of FMV, ensuring that the tips of the fingers applying cricoid pressure remained blanched. CP was released after endotracheal intubation. The appearance of comet tail artifacts during FMV, by keeping the probe in the same plane as described above, were noted [Figure 1b].[19] After confirming the position of the ETT, antral image was obtained and CSA was measured again in supine and right LDP positions. Highest achieved Paw during FMV was recorded. Any episode of desaturation or difficult FMV was also noted. Gastric volume (GV) in both supine and right lateral decubitus (RLDP) positions were calculated from measured antral CSA using the following formula, described in an earlier study:[18]

$$GV\,(ml) = 27.0 + 14.6 \times \text{right lateral CSA} - 1.28 \times \text{age}$$

Statistical analysis

Based on the study by Salem et al.,[13] it was predicted a minimum expected difference in gastric volume of 150 ml and standard deviation of 183 ml. A sample size of 42 was estimated for each group to provide a statistical power of 90% and significance level of 5%, given an anticipated noncompliance of 20% and attrition of 10%.

Continuous variables like gastric antral CSA and GV were expressed as mean (SD). Categorical variables like gender, ASA physical status class, incidence of comet tail artifacts were expressed as numbers (%). The IBM SPSS® Statistics for Windows, version 19 software (IBM Corp., Armonk, N.Y., USA) was used for statistical analysis.

The paired t-test was used to analyze the change in gastric antral CSA and GV within the groups. The changes in antral CSA and GV from baseline were analyzed between two groups using independent t-test. Linear relation between peak airway pressure and gastric antral CSA within each group was analyzed using Pearson's Correlation. The incidence of comet tail artifacts was analyzed using Chi-square test. P < 0.05 (two-sided) were considered significant.

Results

Eighty-four patients were recruited from January 2016 to June 2017 [Figure 2]. All the participants completed the study and the assimilated data were analyzed. The groups were comparable in terms of anthropometric data, Paw and baseline measurements of gastric antral CSA and GV [Table 1]. Trachea was intubated successfully in the first attempt, in all the patients.

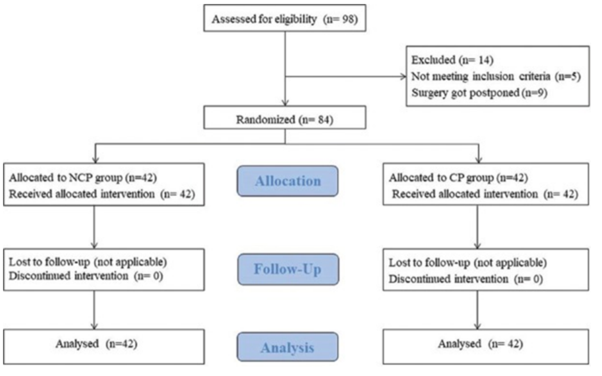

Figure 2 CONSORT diagram

Table 1
Baseline characteristics of study population

Parameters	Group NCP (n=42)	Group CP (n=42)
Age (years)	41.3 (16.6)	38.8 (17.2)
Sex (male/female)	19/23	15/27
Height (cm)	156.8 (7.3)	155 (8.3)
Weight (kg)	54 (11.5)	52.8 (12.2)
ASA physical status (I/II)	24/18	18/24
Baseline supine CSA (cm²)	2.36 (0.98)	2.64 (0.76)
Baseline right LDP CSA (cm²)	2.62 (1.08)	2.87 (0.96)
Baseline supine gastric volume (ml)	13.88 (14.58)	19.43 (16.1)
Baseline right LDP GV (ml)	17.33 (17.33)	21.74 (16.95)
Highest peak airway pressure (cmH$_2$0)	19 (3)	20 (4)
Highest tidal volume (ml)	411 (79)	391 (73)

Continuous data are presented as mean (standard deviation); categorical data are presented as counts. NCP: No cricoid pressure; CP: Cricoid pressure; ASA: American Society of Anesthesiologists; CSA: Cross-sectional area; LDP: Lateral decubitus position; GV: Gastric volume

The change in the gastric antral CSA and GV after FMV was found to be significant within group NCP and not in group CP [Table 2 and Figures Figures3,3, ,4].4]. The increase in gastric antral CSA after FMV was smaller in group CP than in group NCP in supine (0.02 [0.36] vs 0.36 [0.76] cm2; 95% confidence interval [CI]: 0.1–0.6 cm2; P = 0.012) and in right LDP (0.67 [0.80] cm2 vs 0.03 [0.29] cm2; 95% CI: 0.4–0.9, P < 0.001). The change in calculated GV showed similar differences [Table 3].

Table 2
Gastric antral cross-sectional areas and volumes before and after face mask ventilation in both the groups

Group	Parameters	Before FMV	After FMV	P
Group NCP	Supine CSA (cm²)	2.36 (0.98)	2.72 (1.05)	0.004*
	Right LDP CSA (cm²)	2.62 (1.08)	3.29 (1.29)	<0.001*
	Supine GV (ml)	13.88 (14.58)	18.22 (17.41)	0.003*
	Right LDP GV (ml)	17.33 (17.33)	26.06 (22.34)	<0.001*
Group CP	Supine CSA (cm²)	2.64 (0.76)	2.67 (0.78)	0.687
	Right LDP CSA (cm²)	2.88 (0.96)	2.91 (0.95)	0.512
	Supine GV (ml)	19.43 (16.1)	20.18 (16.65)	0.077
	Right LDP GV (ml)	21.74 (16.95)	22.41 (17.33)	0.178

Data are presented as mean (standard deviation). CSA: Cross-sectional area; LDP: Lateral decubitus position; GV: Gastric volume; FMV: Face mask ventilation; *P<0.05

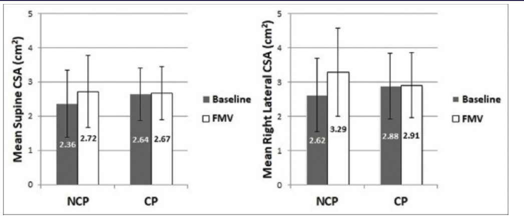

Figure 3

Mean gastric antral CSA in supine and right lateral positions before and after FMV. CSA = Cross-sectional area; NCP = No Cricoid Pressure; CP = Cricoid Pressure; FMV = Face Mask Ventilation

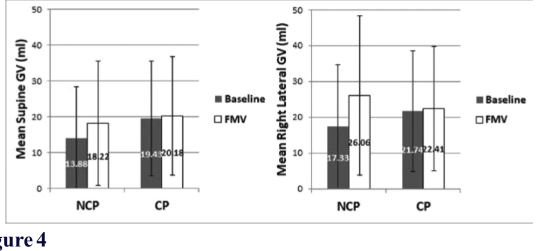

Figure 4

Mean gastric volume in supine and right lateral positions before and after FMV. GV = Gastric Volume; NCP = No Cricoid Pressure; CP = Cricoid Pressure; FMV = Face Mask Ventilation

Table 3
Change in gastric antral cross-sectional area and volume from baseline after face mask ventilation

Parameters	Group NCP (n=42)	Group CP (n=42)	Difference of the means	95% CI	P
Change in supine CSA (cm²)	0.36 (0.76)	0.02 (0.36)	0.34	0.1-0.6	0.012*
Change in right LDP CSA (cm²)	0.67 (0.80)	0.03 (0.29)	0.64	0.4-0.9	<0.001*
Change in supine GV (ml)	4.33 (8.78)	0.75 (2.67)	3.58	0.7-6.4	0.015*
Change in right LDP GV (ml)	8.73 (10.95)	0.67 (3.15)	8.06	4.5-11.6	<0.001*

Data are presented as mean (standard deviation). NCP: No cricoid pressure; CP: Cricoid pressure; CI: Confidence interval; CSA: Cross-sectional area; LDP: Lateral decubitus position; GV: Gastric volume; *P<0.05

There was no significant correlation between P_{aw} and antral CSA after FMV in group CP or NCP (correlation coefficient, r: 0.101 and 0.216, respectively). Comet tail artifacts were observed in more patients in group NCP than in group CP (30 [71%] vs 7 [17%], P< 0.001). The P_{aw} above which these artifacts appeared was higher in group CP than in group NCP (20 vs 14 cmH2O [Figure 5].

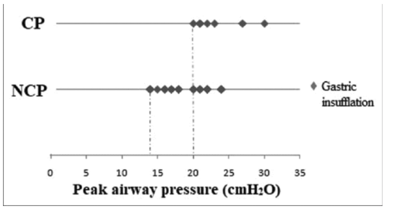

Figure 5

Incidence of gastric insufflation (Comet-tail artifacts) in relation to peak airway pressures (Paw). (♦) may represent one or more cases. Dotted line represents the lowest Paw at which artifacts appeared; 20 cmH$_2$O in group CP and 14 cmH$_2$O in group NCP. CP = Cricoid Pressure; NCP = No cricoid Pressure

Intraclass correlation coefficient (ICC) based on absolute agreement, two-way mixed model was used to assess the intra-rater reliability between two measurements of antral CSA measured in supine and right LDP. It was 0.89 for baseline measurements and 0.88 for measurements after FMV, suggesting good reliability.

There was no episode of desaturation in any of the patients. FMV was difficult in three patients, two in group CP and one in group NCP. Placement of an oropharyngeal airway, however, facilitated face mask ventilation in all three, suggesting that the difficulty was probably caused by upper airway obstruction rather than an improper application of cricoid pressure.

Discussion

The primary objective of this study was to find the effectiveness of CP in preventing gastric insufflation during FMV by gastric antralsonography. Gastric volume in both supine and right lateral decubitus positions were calculated in this study from respective gastric antral CSA measurement, using a formula validated by Perlas *et al*.[18] The validated model to calculate gastric volume from antral CSA was derived from right lateral CSA measured after fluid intake as it will make antrum the most dependent portion, thus making it larger and hence provide more accurate measurement than in supine position. In this study, we measured the antral area after possible gastric insufflation with air during FMV, hence position of the patient to measure the antral CSA was assumed not to play a major role. Moreover, it was easier and convenient to observe comet tail artifacts in supine position during FMV and to measure CSA after intubation. The ICC between supine and right lateral CSA measured at baseline as well as after FMV also suggested a good reliability between the measurements.

The increase in gastric antral CSA was less when cricoid pressure was used during FMV. However, the change in GV (derived from CSA) after FMV found in this trial was too trivial (18 and 26 ml, supine and right LDP, respectively), to be of any clinical significance. This is in contrast to earlier studies,[13,14] where higher GV was noted by aspiration of NG tube. This could be attributed to flawed estimation of GV from CSA by the formula, which was derived from measurements taken after ingestion of liquid.[18] Alternate site of measurement (other than antrum) or alternate mathematical model is required for quantitative estimation of change in GV caused by gaseous distension. There was no significant positive correlation found between P_{aw} and antral CSA after FMV in both the groups. This was in contrast with earlier studies.[8,9,10]

The comet tail artifacts denoting gastric insufflation occurred in group CP at airway pressures above 20 cmH_2O. This is much lower than what was found in earlier studies (Lawes *et al*.: 60 cmH_2O, Moynihan *et al*.: 40 cmH_2O, Asai *et al*.: 30 cmH_2O),[9,15,16] where alternate method of assessment like epigastric-auscultation was used. This could be because of variations in application of CP or higher sensitivity of ultrasound in detecting gastric insufflation. As this study was not sufficiently powered for comparing incidences of gastric insufflation at varying airway pressures, statistical analysis could not be performed on the data, thereby mandating further research.

The increase in gastric pressure associated with gastric insufflation during FMV can increase the risk of aspiration by transient relaxation of upper and lower esophageal sphincters.[21] There might however be exceptions, where the risk of desaturation and hypoxemia possibly outweighs the risk of aspiration, as in the morbidly obese, pregnant, COPD, and critically ill patients, and in unanticipated difficult airway or failed intubation. Face mask ventilation in these situations is likely to reduce morbidity and improve outcomes.[4]

The application of CP during RSII to prevent the risk of aspiration due to regurgitation of gastric contents has been practiced widely, since its demonstration in 1961, by Sellick,[22] which was followed by a systematic description of the technique by Stept and Safar.[3] Though its efficacy and safety have been called into question in the recent past and it continues to be an area of discussion and debate, it is still considered unethical to avoid using CP when it is deemed necessary.[23] Although the primary intent of cricoid pressure was to prevent regurgitation of gastric contents, it was also revealed to be effective in minimizing or even preventing gastric insufflation. The practice of providing FMV during RSII, termed as modified RSII, is being followed by several anesthesiologists, especially in situations enumerated above.[6,7]

The findings from this study would be applicable to healthy, nonpregnant, nonobese adult patients aged between 13 and 75 years belonging to ASA-PS classes 1 and 2 with normal gastric anatomy.

This study was not without limitations. First, the uniformity of the force used for applying cricoid pressure could not be ascertained objectively. Second, the gastric volume measurements derived from an established formula from a previous study was of questionable accuracy and reliability in measuring gas as gastric content. Thus, the comparison of GV for estimating insufflation was not absolutely devoid of error. Third, the probability of inaccuracy in locating and measuring the antral CSA using the free-tracing method cannot be overemphasized.

Summing up, cricoid pressure is effective and may be safely used during FMV to minimize gastric insufflation thus obviating the risk of regurgitation, especially so, when the airway pressures are restricted below 20 cmH_2O. There was no significant positive correlation noted between peak airway pressures and gastric insufflation. The increase in gastric antral CSA after FMV along with appearance of comet tail artifacts may be considered more reliable, to detect gastric insufflation using ultrasound rather than derived gastric volume. Based on these findings, further research including aforementioned high-risk patients even in emergent situations, maybe undertaken, to make modified RSII a standard clinical practice.

Financial support and sponsorship
Nil.
Conflicts of interest
There are no conflicts of interest.

REFERENCES

1. Stewart JC, Bhananker S, Ramaiah R. Rapid-sequence intubation and cricoid pressure. Int J Crit Illn Inj Sci. 2014;4:42. [PMC free article] [PubMed]
2. Hagberg CA, Artime CA. Miller's Anesthesia. In: Miller RD, Cohen NH, editors. Airway Management in the Adult. 8th ed. Philadelphia: Elsevier, Saunders; 2015. pp. 1655–56.
3. Stept WJ, Safar P. Rapid induction-intubation for prevention of gastric-content aspiration. Anesth Analg. 1970;49:633–6. [PubMed]
4. Clements P, Washington SJ, McCluskey A. Should patients be manually ventilated during rapid sequence induction of anaesthesia? Br J Hosp Med. 2009;70:424. [PubMed]
5. Brown JPR, Werrett G. Bag-mask ventilation in rapid sequence induction. Anaesthesia. 2009;64:784–5. [PubMed]
6. Ehrenfeld JM, Cassedy EA, Forbes VE, Mercaldo ND, Sandberg WS. Modified Rapid Sequence Induction and Intubation: A Survey of United States Current Practice. Anesth Analg. 2012;115:95–101. [PMC free article] [PubMed]
7. Brown JPR, Werrett GC. Bag-mask ventilation in rapid sequence induction: A survey of current practice among members of the Uk Difficult Airway Society. Eur J Anaesthesiol. 2015;32:446–8. [PubMed]
8. Ruben H, Knudsen EJ, Carugati G. Gastric Inflation in Relation to Airway Pressure. Acta Anaesthesiol Scand. 1961;5:107–14. [PubMed]
9. Lawes EG, Campbell I, Mercer D. Inflation pressure, gastric insufflation and rapid sequence induction. Br J Anaesth. 1987;59:315–8. [PubMed]
10. Bouvet L, Albert M-L, Augris C, Boselli E, Ecochard R, Rabilloud M, et al. Real-time Detection of Gastric Insufflation Related to Facemask Pressure–controlled Ventilation Using Ultrasonography of the Antrum and Epigastric Auscultation in Nonparalyzed PatientsA Prospective, Randomized, Double-blind Study. Anesthesiol J Am Soc Anesthesiol. 2014;120:326–34. [PubMed]
11. Weiler N, Heinrichs W, Dick W. As