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Original Research Article

Entropy Changes in Response to Bimanual Cricoid Pressure during Induction of General Anaesthesia: A Randomised Control Trial

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Abstract:

Background and Objective: There is an increasing interest in methods for monitoring the depth of anaesthesia and especially an emphasis on detecting intraoperative awareness. The use of entropy to track the level of consciousness in patients receiving general anaesthesia or sedation is a relatively new monitoring approach. Entropy measures the degree of disorder or the lack of synchrony or consistency in a system. Cricoid pressure is a simple method to protect the subjects from regurgitation of gastric contents during the time of intubation in full stomach patients. Since it is the first step of clinical practice of anaesthesia, cricoid pressure has been considered for its efficacy, safety and its hemodynamic effects. No previous studies have been specifically performed to evaluate the anaesthetic depth by entropy monitoring when applying cricoid pressure. This study has been undertaken to assess the entropy and haemodynamic responses after application of cricoid pressure.

Methods: After obtaining approval from institutional ethical committee, patients who consented were randomly allocated into two groups. Group CP received bi-manual cricoid pressure of 44N two minutes after the induction of anaesthesia lasting 1 minute. Group nCP had hands placed simply without exerting pressure. Entropy, NIBP, heart rate was recorded at baseline, after induction, before and after application of cricoid pressure, before laryngoscopy and intubation and every one minute after intubation until 2 minutes, every 2 minutes till 10 minutes and every 15 minutes till end of surgery.

Results: The entropy values of RE & SE during induction were higher in the group CP (RE 68±3; SE 67±3) compared to group nCP (RE 58±2; SE 58±2) and was statistically significant. The haemodynamic parameters during induction like heart rate (CP 84±8; nCP 72±7), SBP (CP 132±8; nCP 123±8), DBP (CP 86±5; nCP 75±4) and MAP (CP 101±7; nCP 93±6) were higher in the group receiving cricoid pressure.

Conclusion: Entropy values of response and state entropy were higher in patients receiving bimanual cricoid pressure during induction of general anaesthesia.

Keywords: Entropy; Cricoid Pressure; Depth Of Anaesthesia, Induction Of Anaesthesia.

Introduction

Clinical evaluation has poor sensitivity and specificity in measuring the depth of anaesthesia. It requires knowledge of the dose-response relationship between anaesthetic agents and their pharmacodynamic effects. [1]

There is an increasing interest in methods for monitoring the depth of anaesthesia, and especially an emphasis on detecting intraoperative awareness. The most successful have used either a parameter derived from the electroencephalogram (EEG) or sensory-evoked responses. [2]

The use of entropy to track the level of consciousness in patients receiving general anaesthesia or sedation is a relatively new monitoring approach. Entropy measures the degree of disorder or the lack of synchrony or consistency in a system. The Entropy monitor reports two entropy numbers to aid in interpreting EEG analysis. The first is the response entropy (RE) and the second is the state entropy (SE). The RE tracks the changes in the EEG power in the higher frequency range 0.8 to 47Hz, whereas the SE tracks the changes in the EEG power in the lower frequency range of 0.8 to 32Hz. The relative changes in the RE and the SE make it possible to distinguish between real brain state changes versus those that are due to muscle activity on the electromyogram. Monitoring entropy is consistent with changes with the bispectral index (BIS). Like the BIS and narcotrend, the entropy scores correlate with level of consciousness. [3]

The application of pressure to the cricoid cartilage has become routine practice for the prevention of gastric regurgitation since its introduction into clinical practice by Sellick in 1961. [4] Cricoid pressure is a simple method to protect the subjects from regurgitation of gastric contents during the time of intubation in full stomach patients. Since it is the first step of clinical practice of anaesthesia, cricoid pressure has been considered for its efficacy, safety and its hemodynamic effects. [5]

An essential goal of all anaesthesiologists is to maintain an optimal level of anaesthesia. No previous studies have been specifically performed to evaluate the anaesthetic depth by Entropy monitoring when applying cricoid pressure.

Hence this study was undertaken to assess the entropy and haemodynamic responses after application of bimanual cricoid pressure.

Objectives:

1. To assess the entropy responses after application of cricoid pressure during induction of general anaesthesia.
2. To assess the haemodynamic responses after application of cricoid pressure during induction of general anaesthesia.

Methodology:

A Prospective randomized control study was conducted on fifty patients undergoing elective surgeries under general anaesthesia at hospitals attached to Bangalore medical college and research institute, Bengaluru. The study was conducted over period of two years from October 2016 to September 2018.

Sample Size Calculation

We hypothesized that entropy values would increase on application of bimanual cricoid pressure. To detect a minimum of 10% increase in entropy values after cricoid pressure from post induction entropy values, a minimum of 16 patients would be required in each group, keeping confidence interval at 95% and power of study at 80%. To obtain better results we decided to take 25 patients in each group and hence sample size of 50.

Inclusion Criteria

1. Patients who have given written informed consent. (ANNEXURE-1)
2. Patients aged 18-60 years.
3. Sex- males and females.
4. Patients scheduled for elective surgery under general anaesthesia.
5. Patients with ASA grade I & II.

Exclusion Criteria

1. Patients refusing to participate in the study.
2. Patients undergoing rapid sequence intubation.
3. Patients with current history of respiratory tract infections.
4. Patients with anticipated difficult airway.
5. Patients with hypertension, type 2 diabetes mellitus, ischaemic heart disease.
6. Pregnant women.

Results

A study entitled “entropy changes in response to bimanual cricoid pressure during induction of general anaesthesia- a randomised control study” was undertaken in hospitals attached to Bangalore Medical College and Research Institute, Bangalore, to evaluate the depth of anaesthesia on administering cricoid pressure during induction of anaesthesia along with haemodynamic changes associated with it. To detect a minimum of 10% increase in entropy values after cricoid pressure, a minimum of 16 patients would be required in each group, keeping confidence interval at 95% and power of study at 80%. To obtain better results we decided to take 25 patients in each group and hence sample size of 50.

Table 1: Age distribution of patients.

Age in years	GROUP			
	CP		nCP	
	No. of patients	%	No. of patients	%
21-30	1	4.0%	4	16.0%
31-40	5	20.0%	6	24.0%
41-50	14	56.0%	11	44.0%
51-60	4	16.0%	2	8.0%
61-70	1	4.0%	2	8.0%

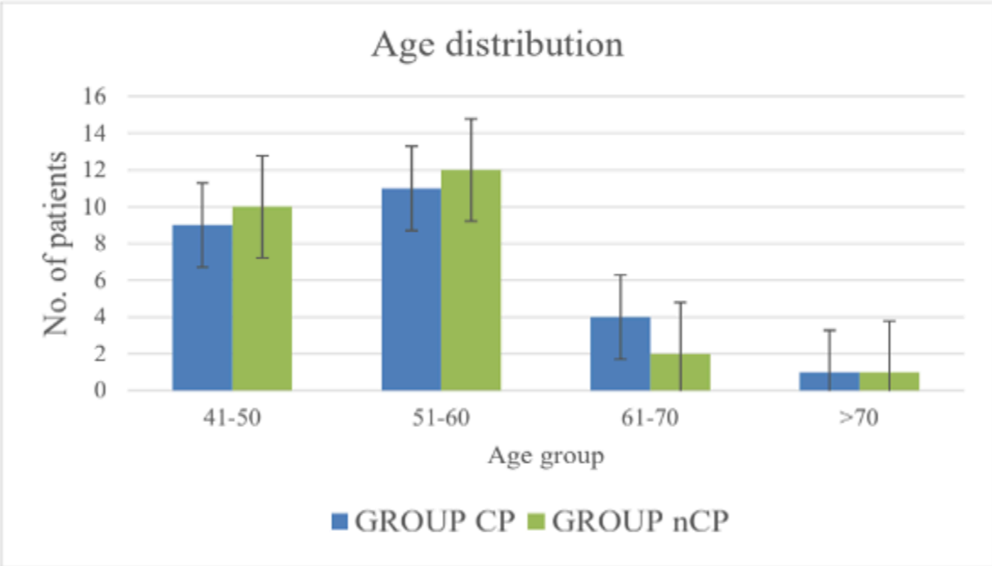

Figure 1: Age distribution of patients.

In both group CP and group nCP, majority of subjects were in the age group 41 to 50 years. There was no significant difference in age distribution between two groups (p=0.6).

Table 2: Mean Age of Patients

	GROUP			
	CP		nCP	
	Mean	Standard Deviation	Mean	Standard Deviation
Age in years	44.4	7.7	44.0	10.9

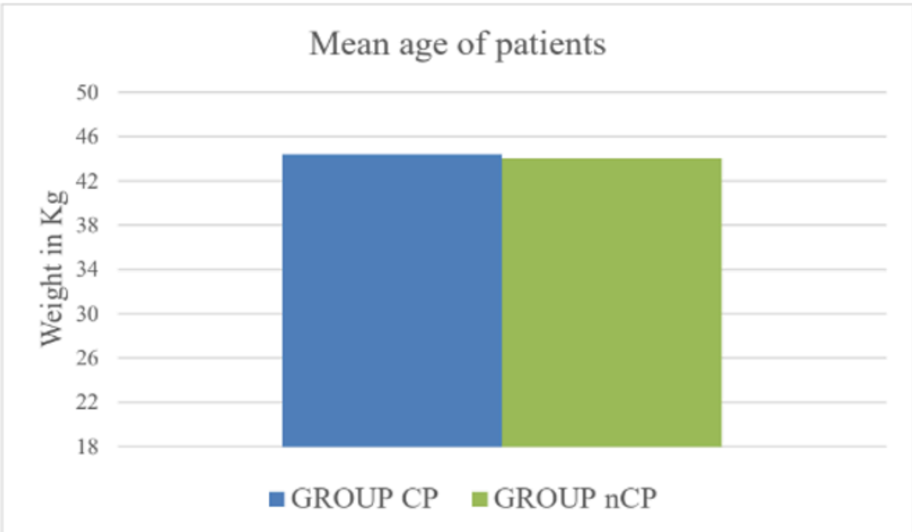

Figure- 2: Mean age of patients.

Mean age of subjects in group CP was 44.4 ± 7.7 years and in group nCP was 44 ± 10.9 years. There was no significant difference in mean age between two groups (p=0.8).

Table 3: Type of surgery.

Surgery	GROUP			
	CP		nCP	
	No. of patients	%	No. of patients	%
Laproscopic appendicectomy	5	20.0%	7	28.0%
Laproscopic cholecystectomy	8	32.0%	3	12.0%
Mesh repair	7	28.0%	8	32.0%
Modified Radical Mastectomy	5	20.0%	7	28.0%

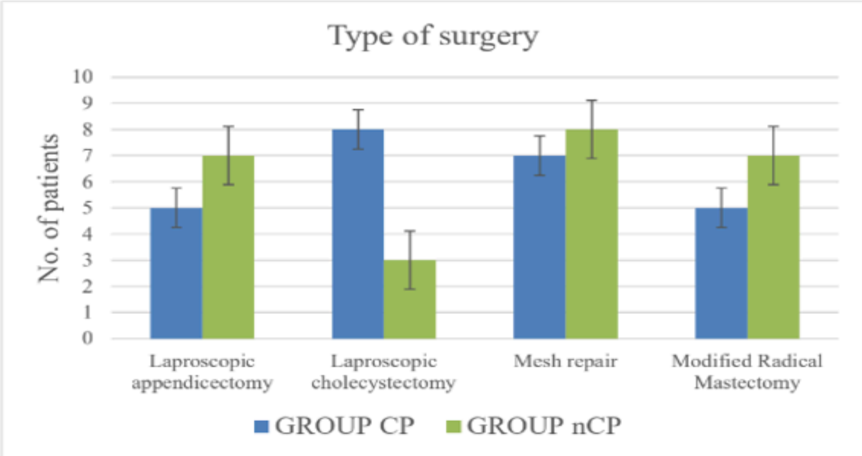

Figure 3: Type of surgery.

Majority of patients underwent Laproscopic cholecystectomy (32%) in group CP, whereas in group nCP majority of patients underwent mesh repair (32%). It was not statistically significant (p=0.4).

Table 4: Gender distribution of patients.

Gender	GROUP			
	CP		nCP	
	No. of patients	%	No. of patients	%
Female	14	56.0%	13	52.0%
Male	11	44.0%	12	48.0%

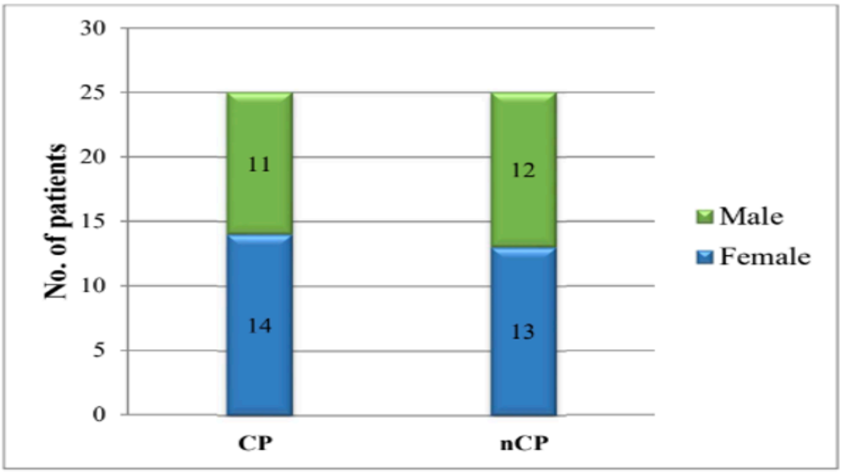

Figure 4: Gender distribution of patients.

In group CP and group nCP majority of subjects were females i.e. 56% and 52% respectively. There was no significant difference in gender distribution between two groups (p=0.8).

Table- 5: Weight distribution of patients.

Weight in Kg	GROUP			
	CP		nCP	
	No. of patients	%	No. of patients	%
41-50	9	36	10	40
51-60	11	44	12	48
61-70	4	16	2	8
>70	1	4	1	4

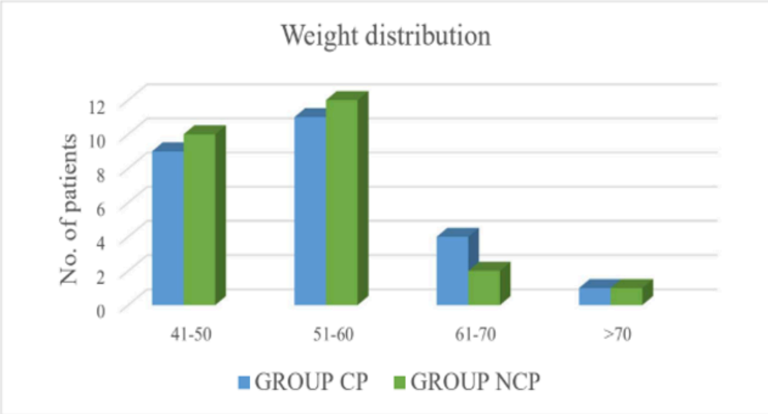

Figure 5: Weight distribution of patients.

Majority of the patients in both groups were between 51-60 Kg. The mean weight of patients in group CP was 53.91±7.07 Kg and in group nCP it was 51.06±5.09 Kg and it was not statistically significant.

Table 6: ASA grade comparison in both groups.

Weight in Kg	GROUP			
	CP		nCP	
	No. of patients	%	No. of patients	%
41-50	9	36	10	40
51-60	11	44	12	48
61-70	4	16	2	8
>70	1	4	1	4

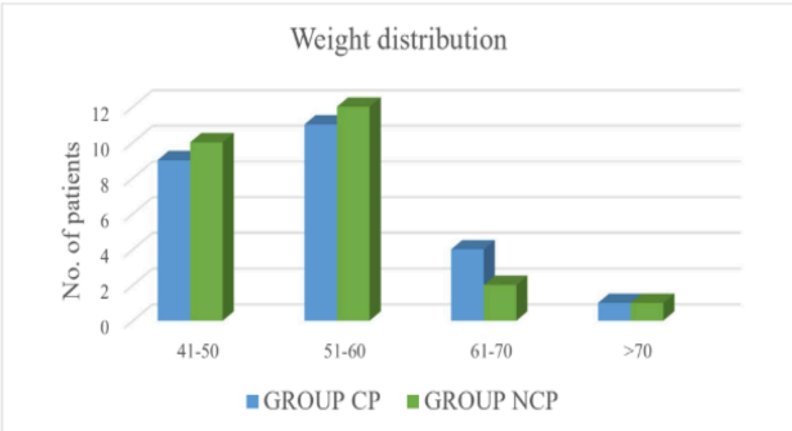

Figure 6: ASA grade comparison in both groups.

In group CP and Group nCP majority of subjects had ASA grade of 1 i.e. 72 and 68% respectively. There was no significant difference in ASA grade between both groups.

Table 7: Comparison of Heart rate (beats/min) between two groups.

HR/min	GROUP						p value b/w groups
	CP			nCP			
	Mean	SD	p value Intra group	Mean	SD	p value Intra group	
Baseline	80	8		78	8		0.40
Before CP	75	8	0.13	73	7	0.08	0.23
After CP	84	8	0.001*	72	7	0.07	0.00*
Before Intubation	83	9	0.007*	73	7	0.08	0.00*
After intubation	88	9	0.001*	79	7	0.15	0.00*
1min	87	9	0.001*	78	7	0.935	0.00*
2min	85	8	0.001*	78	7	0.248	0.00*
4Min	84	8	0.06	77	7	0.124	0.00*
6Min	82	8	0.052	76	7	0.11	0.00*
8Min	81	7	0.501	75	7	0.13	0.01*
10Min	79	7	0.239	74	8	0.14	0.02*
25Min	78	7	0.054	73	7	0.09	0.06
40Min	78	7	0.168	73	7	0.08	0.06
55Min	79	7	0.174	74	7	0.07	0.07
70Min	80	6	0.894	75	7	0.08	0.06
85Min	82	7	0.489	78	7	0.657	0.15
100Min	83	10	0.66	84	9	0.166	0.81
115Min	85	7	0.079	86	10	0.098	0.94

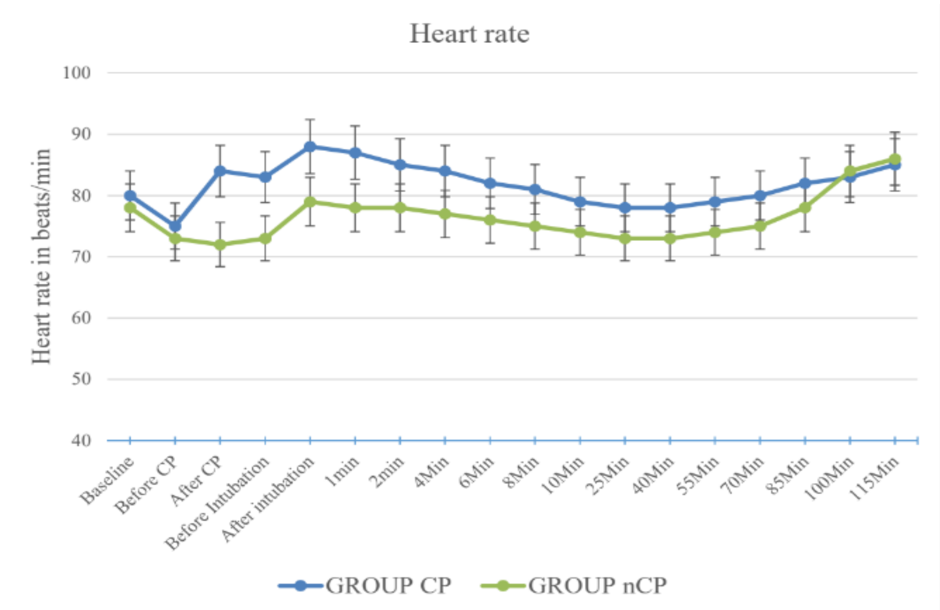

Figure 7: Comparison of Heart rate (in beats/min) between two groups.

In the study, heart rate was higher in group CP than group nCP from after application of cricoid pressure upto 10 minutes after intubation and was statistically significant.

Within group CP, significant increase in heart rate was found immediately after application of cricoid pressure till upto 2 minutes after intubation.

Within the group nCP increase in heart rate was observed immediately after intubation, but was not statistically significant.

Discussion

Cricoid pressure was first used as a protective measure against gastric regurgitation during the rapid-sequence induction of general anaesthesia in patients suspected to have a full stomach. This manoeuvre was also later used for the prevention of gastric insufflation during cardiopulmonary resuscitation. The beneficial effects of cricoid pressure seem to be due to an occlusion of the upper oesophageal sphincter by the force of external cricoid pressure. Since its advent into the clinical practice of anaesthesia, cricoid pressure has been investigated for its efficacy and safety. The hemodynamic effects of cricoid pressure have rarely been assessed in studies related to the rapid-sequence induction of anaesthesia. [5]

Several studies have demonstrated an increase in BIS as well as heart rate and arterial blood pressure associated with laryngoscopy and tracheal intubation in patients receiving intravenous or inhalational anaesthesia. [6]

Although the development of a relatively strong presser response after cricoid pressure application is demonstrated, the assessment of anaesthetic depth in patients receiving cricoid pressure remains a challenge for anaesthesiologists in order to avoid under sedation and awareness phenomena during induction of anaesthesia.

An essential goal of all anaesthesiologists is to maintain an optimal level of anaesthesia. No previous studies have been specifically performed to evaluate the anaesthetic depth by entropy monitoring when applying cricoid pressure. This prospective study was designed to assess the entropy values after application of CP in adult patients during the routine induction of general anaesthesia.

Our study demonstrated that bimanual cricoid pressure causes increase in entropy and hemodynamic responses during general anaesthesia. Several studies have shown that tracheal intubation is associated with increases in BIS as well as heart rate and arterial blood pressure, but no previous study has specifically addressed the entropy changes with bimanual cricoid pressure independent of laryngoscopy and tracheal intubation.

In our study, arterial pressures and heart rate increased after intubation in both groups, but was greater after applying cricoid pressure. This is because of stimulation of the autonomic nervous system which occurs due to compression of laryngeal and perilaryngeal structures. Also, we found that application of cricoid pressure alone, after induction of anaesthesia and before intubation, significantly increased entropy values and the combination of laryngoscopy and cricoid pressure tend to further increase the entropy values as well as the arterial pressures and heart rate.

It is suggested that a reflective response to a lethal stimulus due to intubation is mediated at the sub cortical level. However, peripheral noxious stimuli reach the brain through the ascending reticular activating systems of the brainstem and may cause EEG activation. So, the anaesthetic effect of drugs during induction of anaesthesia may be not enough to decrease the hypnotic responses. [5]

We hypothesized that entropy values would increase on applying cricoid pressure during induction of general anaesthesia, associated with increase in haemodynamic parameters suggesting inadequate depth of anaesthesia.

Demographic data comparing age, sex, weight, ASA grade, surgical procedure show no statistically significant difference among both the groups.

In our study the entropy values were higher post application of cricoid pressure in group CP (RE 68±3; SE 67±3) as compared to group nCP (RE 58±2; SE 58±2) and was statistically significant ($p = 0.00$ for both RE and SE).

This was similar to the findings of Saeed Abbasi et al (2011) where they found that BIS values after application of cricoid pressure were higher in group CP (42.7±3.8) than group nCP (38.4±5.2).

Our study also showed higher entropy values before intubation (post cricoid pressure) in group CP (RE 65±3; SE 64±3) than group nCP (RE 58±2; SE 57±3) and was statistically significant ($p = 0.00$ for RE and $p = 0.03$ SE).

In a study conducted by Saeed Abbasi et al (2011) demonstrated identical result that BIS values were higher in group CP (55.7±3.01) than group nCP (37.6±6.9) before laryngoscopy and intubation and was statistically significant ($p < 0.05$).

Also, in our study the entropy values immediately after intubation upto 4 minutes were higher in group CP than group nCP and were statistically significant ($p < 0.05$). The values of entropy immediately after intubation were- group CP (RE 73±3; SE 73±3); group nCP (RE 68±2; SE 64±3) and was statistically significant ($p = 0.00$ for both RE and SE).

In the study conducted by Saeed Abbasi et al (2011) showed similar result that BIS values were higher in group CP as compared to group nCP from immediately after intubation upto 2 minutes and was statistically significant ($p<0.05$).

However, in a study conducted by Chryssoula Staikou et al (2012), found no increase in BIS values after application of cricoid pressure ($p=0.91$) and at other intervals after intubation.

In our study heart rate after cricoid pressure was higher in group CP (84±8) as compared to group nCP (72±7) after application of cricoid pressure and was statistically significant ($p = 0.00$). This was similar to the findings of Saeed Abbasi et al (2011) where they found that heart rate after application of cricoid pressure was higher in group CP (96.2±18.6) than group nCP (85.8±17) and was statistically significant ($p<0.05$).

Our study also showed higher heart rate before intubation (post cricoid pressure) in group CP (83±9) than group nCP (73±7) and was statistically significant ($p = 0.00$).

In a study conducted by Saeed Abbasi et al (2011) demonstrated identical result that heart rate was higher in group CP (101.2±14.7) than group nCP (85.7±18) before laryngoscopy and intubation and was statistically significant ($p<0.05$).

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