Cricoid Pressure Does Not Increase the Rate of Failed Intubation by Direct Laryngoscopy in Adults

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Background: **Cricoid pressure (CP) is applied during induction of anesthesia to prevent regurgitation of gastric content and pulmonary aspiration. However, it has been suggested that CP makes tracheal intubation more difficult. This double-blind randomized study evaluated the effect of CP on orotracheal intubation by direct laryngoscopy in adults.**

Methods: **Seven hundred adult patients undergoing general anesthesia for elective surgery were randomly assigned to have a standardized CP (n = 344) or a sham CP (n = 356) during laryngoscopy and intubation. After anesthesia induction and complete muscle relaxation, a 30-s period was allowed to complete intubation with a Macintosh No. 3 laryngoscope blade. The primary endpoint was the rate of failed intubation at 30 s. The secondary endpoints included the intubation time, the Cormack and Lehane grade of laryngoscopic view, and the Intubation Difficulty Scale score.**

Results: **Groups were similar for demographic data and risk factors for difficult intubation. The rates of failed intubation at 30 s were comparable for the two groups: 15 of 344 (4.4%) and 13 of 356 (3.7%) in the CP and sham CP groups, respectively (*P* = 0.70). The grades of laryngoscopic view and the Intubation Difficulty Scale score were also comparable. Median intubation time was slightly longer in the CP group than in the sham CP group (11.3 and 10.4 s, respectively, *P* = 0.001).**

Conclusions: **CP applied by trained personnel does not increase the rate of failed intubation. Hence CP should not be avoided for fear of increasing the difficulty of intubation when its use is indicated.**

CRICOID pressure (CP) was proposed by Brian A. Sellick in 1961 to prevent regurgitation of gastric content during induction of general anesthesia.[1] The so-called "Sellick's maneuver" is performed by the application of a backward pressure with the first three fingers of the dominant hand on the cricoid cartilage to collapse the esophagus on the body of the sixth cervical vertebra. Despite the lack of solid evidence of its efficacy, the Sellick's maneuver remains a standard of care for patients at high risk of aspiration of gastric content during induction of anesthesia.[2] However, it has been reported that CP may alter the upper airway anatomy and compromise its patency.[3,4] CP was first evoked as a cause of failed intubation in pregnant women,[5] and more cases have been reported during the last decade.[6–8] Difficult ventilation with a face mask or with a laryngeal mask airway,[4,9] difficult insertion of an orotracheal tube through the laryngeal mask airway,[10,11] and altered visualization of the larynx by fiberoptic bronchoscope[4] have also been reported with CP. Although the impact of CP on grades of laryngoscopic view has been studied,[12,13] the effect of CP on the success rate of tracheal intubation by direct laryngoscopy has not been evaluated in a randomized controlled study. Because the efficacy of CP to prevent pulmonary aspiration of gastric content has never been demonstrated and several observations have suggested that CP can make intubation more difficult, its effect on tracheal intubation should be studied. The objective of this study was to evaluate the effect of CP on the rate of failed orotracheal intubation and on the conditions of intubation in adult patients under general anesthesia. The study hypothesis was that CP may impede orotracheal intubation by direct laryngoscopy.

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Materials and Methods

This double-blind randomized controlled study was conducted at the Centre Hospitalier *Affilié* Universitaire de Québec (Hôpital de l'Enfant-Jésus) and was approved by the hospital ethics committee. Patients were evaluated for eligibility the day before or on the morning of surgery, and written informed consent was obtained. Patients older than 18 yr undergoing elective surgery under general anesthesia with orotracheal intubation were eligible. Exclusion criteria were contraindication to the medication used for induction, contraindication to a CP,[14] upper respiratory tract abnormalities, patients known to be impossible to ventilate by mask, history of a difficult intubation requiring an alternative to direct laryngoscopy, pregnancy, surgery requiring a double-lumen endotracheal tube, symptomatic gastroesophageal reflux, morbid obesity (body mass index >35 kg/m^2), and definite indications for a CP (*e.g.*, a full stomach). The following risk factors for difficult intubation were recorded: modified Mallampati class, dental status, presence of retrognathism, ability to prognate, interincisal distance (or intergingival in toothless patients), and thyromental and sternomental distances.[15–19]

Experimental Protocol

Immediately before the induction of anesthesia, patients were randomly assigned to receive either CP or a sham cricoid pressure (SCP). The randomization sequence was prepared with the Maple software (version 6.0; Maplesoft, Waterloo, Ontario, Canada) and sealed in prenumbered opaque envelopes. Standard monitoring was used for all patients. Neuromuscular blockade was monitored at the adductor pollicis by stimulating the ulnar nerve at the wrist. End-tidal carbon dioxide was sampled at the Y-piece of the breathing circuit. The patient's head was positioned in the sniffing position using a 7-cm thick uncompressible pillow.[14,20] After preoxygenation with 100% oxygen for 3 min by face mask, anesthesia was induced with propofol 1.0–3.0 mg/kg and sufentanil 0.2–1.0 μg/kg. Neuromuscular blockade was obtained either with rocuronium 0.6–1.2 mg/kg or with rocuronium 0.03 mg/kg followed by succinylcholine 1.5 mg/kg. Patient lungs were manually ventilated with 100% oxygen by mask until complete paralysis was achieved.

In the experimental group, a standardized CP was applied using the single hand technique as originally described by Sellick.[1] Seven anesthesia assistants took part in the study and were trained by one of the investigators (AFT) to correctly identify the cricoid cartilage and apply a pressure of 30 newtons (~3 kg) with the first three fingers of their dominant hand.[1,21] The pressure was applied with the thumb and the middle finger at 10 o'clock and 2 o'clock, respectively. The index finger was located above the cricoid cartilage to control the direction of the force. To optimize the learning of the correct pressure, a simulator was devised with a 20-ml syringe mounted on an electronic scale. Anesthesia assistants trained daily on this simulator. In every patient, correct identification of the cricoid cartilage and appropriate positioning of the fingers were confirmed by one of the investigators. In the SCP group, the cricoid cartilage was identified and the fingers were positioned as in the CP group but no pressure was applied. A screen was hung over the upper part of the patient's neck to keep both the anesthesiologist and the data collector unaware of the patient's CP or SCP status. In both groups, one of eight certified anesthesiologists who participated in the study intubated the trachea by direct laryngoscopy with a Macintosh No. 3 laryngoscope blade.

The intubation time was defined as the interval between the insertion of the laryngoscope blade into the mouth up to the inflation of the endotracheal tube cuff and was measured with a chronometer. Correct positioning of the tube was confirmed by capnography. A 30-s period was allowed to complete tracheal intubation. If capnography did not confirm tracheal intubation, the attempt could be resumed only if there was time remaining in this 30-s period. The anesthesiologist rated the grade of laryngoscopic view on the Cormack and Lehane scale[22] and the complexity of intubation on the Intubation Difficulty Scale[23] and was asked whether the larynx was in midline position or shifted laterally. If the intubation could not be completed within 30 s, the intubation attempt was aborted and recorded as a failure and the patient was entered in the crossover phase of the study. These patients were then ventilated for 30 s with 100% oxygen by mask. In the second intubation attempt, patients of the CP group had a SCP applied and patients of the SCP group had a CP applied. This was done following the same algorithm as the original attempt. The grade of laryngoscopy was again rated by the anesthesiologist. If the trachea could not be intubated within 30 s of that second attempt, the protocol was discontinued and the airway was managed following the difficult airway algorithm of the American Society of Anesthesiologists.[24] If arterial oxygen saturation decreased to less than 90% at any time during the study, CP or SCP was released and the protocol was terminated. This attempt was recorded as a failure, blinding was maintained at all times, and data were analyzed according to the patient's group allocation.

Data Analysis

The primary endpoint was the failure to intubate the trachea within the first 30-s attempt. Sample size was determined to identify an increase in the rate of failed intubation in the CP group compared with the SCP group. The incidence of failed orotracheal intubation by direct laryngoscopy within 30 s is unknown. However, Cormack grades III and IV are good predictors of failed intubation,[22] and it was decided to use their incidence as a surrogate in sample size determination. Wide variations of this incidence are reported in the literature (1.1–11.3%).[16,25,26] We considered that a reasonable estimate would be between 4% and 5%. Therefore, it was determined that a sample size of 350 patients per group would be required to identify an increase in the incidence of failed intubation to 10% with Type I and Type II errors of 5% and 20%, respectively. Continuous variables are reported as mean $\pm$ SD. Statistical analysis was performed with the Student *t* test or the Wilcoxon test for continuous data and with the chi-square test or the Fisher exact test for proportions. All tests were two-sided and $P < 0.05$ was considered significant.

Results

Over a 7-month period, 830 patients were evaluated for inclusion in the study. Of those, 700 were enrolled and randomly assigned to the CP or the SCP group (fig. 1). Groups did not differ for gender, age, ASA physical status, anthropometric characteristics, or risk factors for difficult intubation (table 1). The distribution of the anesthesiologists (n = 8) and the anesthesia assistants (n = 7) involved in the study was comparable between the two groups. All patients received the CP or SCP as determined by randomization.

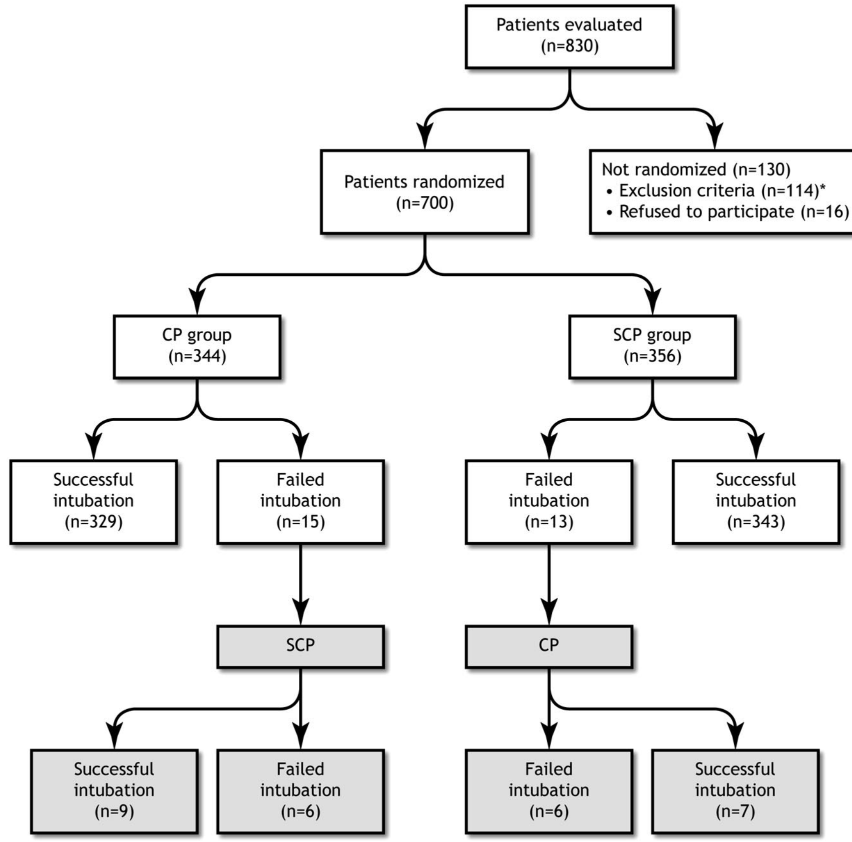

Fig. 1. Flow diagram of the experimental protocol. Patients who could not be successfully intubated within the first 30-s attempt were entered in the crossover phase of the study (shaded boxes). During the second intubation attempt, patients of the cricoid pressure group had a sham cricoid pressure applied while patients of the sham cricoid pressure group had a cricoid pressure applied. *Patients were excluded for the following reasons: symptomatic gastroesophageal reflux (n = 42), morbid obesity (n = 21), use of a laryngeal mask airway (n = 14), inability to give consent (n = 11), upper respiratory tract abnormalities (n = 8), contraindication to a cricoid pressure (n = 8), history of a difficult intubation requiring an alternative to direct laryngoscopy (n = 5), contraindication to any of the study medications (n = 3), other reasons (n = 2). CP = cricoid pressure; SCP = sham cricoid pressure.

The proportion of patients who could not be intubated within the first 30-s attempt was comparable between the CP and the SCP groups (4.4% and 3.7%, respectively; $P = 0.70$) (table 2). No difference was observed between groups for grade of laryngoscopic view or for Intubation Difficulty Scale score (table 2 and fig. 2). The intubation time for the successful intubations at the first attempt was slightly longer in the CP group compared with the SCP group (table 2). In patients who could not be intubated during the first intubation attempt and entered the crossover phase of the study (n = 28), the rate of failed intubation was again comparable for the two groups (table 2). Among these patients, no change was observed for grade of laryngoscopic view in 20 patients, whereas it was improved in four and three patients from the CP and the SCP groups, respectively (*P* = not significant). In one patient of the SCP group, glottic exposure worsened when CP was applied.

In one patient of the CP group, oxygen saturation dropped to less than 90% during the second intubation attempt. The patient was ventilated by mask and his trachea was intubated by direct laryngoscopy with a rigid hockey-shaped stylet. Intubation was recorded as unsuccessful for both attempts.

Discussion

In this study, CP had no influence on the rate of failed orotracheal intubation with a Macintosh No. 3 laryngoscope blade in adult patients. Furthermore, CP had no effect on glottic exposure during laryngoscopy or on the complexity of intubation as assessed by the Intubation Difficulty Scale score.

The clinical effectiveness of CP should be determined by weighing its efficacy in preventing pulmonary aspiration of gastric content against the risk of impeding tracheal intubation. The protection against pulmonary aspiration of gastric content provided by CP is very difficult to assess. Considering the low incidence of pulmonary aspiration, a huge number of patients would be required. Obvious ethical considerations would also be raised. On the other hand, this study shows that concerns about impeding intubation are not justified because tracheal intubation can be achieved as successfully with CP.

Two previous randomized studies evaluating the effect of CP on laryngoscopic view with a standard laryngoscope blade have yielded conflicting results. In a group of 100 patients, Brimacombe *et al.* reported no effect of CP on laryngoscopy grade.[12] In another study, 50 patients had a standard CP, an upward and backward CP, or no CP applied.[13] These authors concluded that laryngoscopic view, assessed in millimeters of visible vocal cords, was worse with standard CP than without CP. Other studies have evaluated the success of intubation with CP using devices other than a common laryngoscope blade. With a lightwand[27] and the Wu-Scope Sys-

Table 1. Baseline Patient Characteristics and Anesthetic Data

	Cricoid pressure (n = 344)	Sham cricoid pressure (n = 356)
Male gender	168 (48.8)	180 (50.6)
Age (yr)	42.3 ± 14.6	44.3 ± 15.4
Weight (kg)	71.5 ± 14.0	71.1 ± 14.4
Height (cm)	168.7 ± 8.9	168.5 ± 9.1
Body mass index (kg/m^2)	25.1 ± 4.2	24.9 ± 4.0
ASA physical status (I/II/III)	148/180/16	152/186/18
Modified Mallampati class (I/II/III/IV)	105/163/62/14	113/157/77/9
Mouth opening < 40 mm	15 (4.4)	15 (4.2)
Thyromental distance < 65 mm	10 (2.9)	15 (4.2)
Sternomental distance < 125 mm	1 (0.3)	5 (1.4)
Retrognathism	44 (12.8)	53 (14.9)
Inability to prognate	2 (0.6)	2 (0.6)
Dental status		
Complete dentition	236 (68.6)	221 (62.1)
Absence of dentition	46 (13.4)	57 (16.0)
Lack of all upper teeth	39 (11.3)	56 (15.7)
Partial lack of upper teeth	15 (4.4)	16 (4.5)
Other dental status	8 (2.3)	6 (1.7)
Drugs for anesthesia induction		
Propofol (mg)	193.4 ± 53.5	187.7 ± 54.0
Sufentanil (μg)	17.9 ± 6.4	18.0 ± 5.7
Rocuronium (mg)	51.2 ± 9.7	49.7 ± 9.3
Succinylcholine (mg)	117.5 ± 22.8	118.9 ± 22.9
Succinylcholine	87 (25.3)	94 (26.4)

Data are presented as number and percentage or mean ± SD. There was no significant difference between groups for all variables.

ASA = American Society of Anesthesiologists.

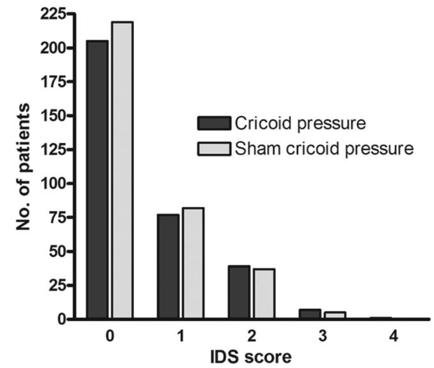

Fig. 2. The distribution of Intubation Difficulty Scale scores was not different between the two groups (P = 0.78). These data include only patients with a successful intubation during the first 30-s attempt. The Intubation Difficulty Scale score is calculated as the sum of the seven following parameters as described by Adnet *et al.*[23] N_1 = number of supplementary intubation attempts (0 if intubation is successful at the initial attempt); N_2 = number of supplementary operators; N_3 = number of alternative intubation techniques; N_4 = Cormack and Lehane grade of glottic exposure minus 1; N_5 = lifting force required during laryngoscopy (0 if normal force, 1 if increased force); N_6 = external laryngeal pressure (0 if no laryngeal pressure, 1 if laryngeal pressure was applied, Sellick's maneuver adds no point); N_7 = vocal cord mobility (0 if vocal cords are in abduction, 1 if in adduction). Because of the design of this study, N_2, N_3, and N_6 always counted 0. A higher Intubation Difficulty Scale score indicates a more difficult intubation. IDS = Intubation Difficulty Scale

tem (Pentax Precision Instruments, Orangeburg, NY),[28] a lower success of tracheal intubation was reported with the application of CP. Using the fiberoptic bronchoscope, the rate of successful intubation was increased in one study and decreased in another.[29,30] Finally, one study has reported that the success of intubation with the Bullard laryngoscope is not altered by CP.[29]

Although most previous studies used laryngoscopic view as their primary endpoint, we elected to use the rate of failed intubation within a fixed time period. This was preferred because orotracheal intubation is the final objective of direct laryngoscopy. Moreover, it is an objective binary variable, as opposed to more subjective variables such as the grade of laryngoscopic view. However, the duration of a reasonable intubation attempt is not well defined. The choice of a 30-s duration was made

Table 2. Intubation Data

	Cricoid pressure (n = 344)	Sham cricoid pressure (n = 356)	*P* value
Failed intubation			
1st attempt	15 (4.4)	13 (3.7)	0.70
2nd attempt (crossover)	6 (40.0)	6 (46.2)	1.00
Intubation time (s)			
Mean ± SD	12.4 ± 4.3	11.4 ± 4.0	
Median (25th–75th percentile)	11.3 (9.3–14.6)	10.4 (8.7–13.3)	0.001
Cormack and Lehane grades			
I	233 (67.7)	234 (65.7)	0.85
II	100 (29.1)	110 (30.9)	
III	11 (3.2)	12 (3.4)	
IV	0	0	
Lateral shift of the larynx	43 (12.5)	9 (2.5)	< 0.0001

Data are presented as number and percentage unless otherwise noted.

1st attempt: number of failed intubations within the first 30-s attempt; 2nd attempt (crossover): number of failed intubations within the second 30-s attempt among the patients who had failed the first intubation attempt (see text for more complete explanation). Intubation time: time to intubation for successful intubations during the initial 30-s attempt. Cormack and Lehane scale of glottic exposure: grade I, complete visualization of the vocal cords; grade II, visualization of the posterior portion of the glottis; grade III, visualization of the epiglottis only; grade IV, inability to visualize the epiglottis.[22]

a priori because it represents a reasonable duration for an intubation attempt based on experts' opinion.[31,32] Allowing a longer period for intubation would probably have resulted in a few more successful intubations, but it is doubtful that it would have favored one group over the other. The application of a cricoid pressure had two minor adverse effects on laryngoscopy. First, median intubation time was slightly increased by 0.9 s in the CP group. Second, lateral shift of the larynx was more frequent in the CP group (table 2). However, these effects had no influence on the failure rate of intubation or on the Intubation Difficulty Scale score and are probably not clinically significant.

The results of this study are in contradiction with the common clinical impression that CP impedes visualization of the larynx and with case reports of difficult intubation.[5–8] This discrepancy might be explained by the frequent use of a less than optimal technique for the application of CP in the usual clinical setting. Indeed it has been reported that anesthesia personnel have a limited knowledge of CP and that most of them are not aware of any recommendation on the force to be applied on the cricoid cartilage.[33,34] Herman *et al.* reported that a wide variation in the actual force was applied when the personnel were not previously trained for this task.[35] However, they have also shown that, with training on a simulator, performance is reproducible within a range of 2 newtons with a good retention time. It can be presumed that excessive force, wrong (lateral) direction of the force or, more importantly, application of the pressure on the larynx rather than on the cricoid ring would make visualization of the larynx and intubation difficult or impossible. In our study, the anesthesia assistants were taught the correct CP technique and they trained daily on a simulator to apply the recommended pressure of 30 newtons. Thus it is possible that different results might be obtained in a clinical setting where the application of CP is not correctly done. It must also be mentioned that a Macintosh laryngoscope blade was used in our study and that the use of a straight laryngoscope blade might yield different results.

In conclusion, our results indicate that CP, when applied by trained personnel, does not increase the rate of failed orotracheal intubation and has no impact on the difficulty of laryngoscopy and intubation in an adult surgical population. Therefore the application of CP should not be avoided for fear of increasing the difficulty of intubation by direct laryngoscopy when its use is indicated.

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