The Effectiveness of Cricoid Pressure for Occluding the Esophageal Entrance in Anesthetized and Paralyzed Patients: An Experimental and Observational Glidescope Study

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BACKGROUND: In the last 2 decades, the effectiveness of cricoid pressure (CP) in occluding the esophageal entrance has been questioned. Recent magnetic resonance imaging studies yielded conflicting conclusions. We used real-time visual and mechanical means to assess the patency of the esophageal entrance with and without CP in anesthetized and paralyzed adult patients.

METHODS: One hundred seven, nonobese ASA physical status I and II patients were recruited for the study. A cricoid force of 30 N was used. This force was standardized by using a weighing scale before application of CP in each patient. After oxygen administration, anesthetic induction, neuromuscular blockade, and establishment of manual ventilation with F_{IO_2} = 1.0, the view of the glottis and esophageal entrance was visualized, and video recordings were obtained by using a Glidescope video laryngoscope. Attempts to insert 2 gastric tubes (GTs), size 12 and 20 F, into the esophagus were made by a "blinded" operator without and with CP, the timing of which was randomized. A successful insertion of a GT in the presence of CP was considered evidence of a patent esophageal entrance (ineffective CP), whereas an unsuccessful insertion of a GT was considered evidence of an occluded esophageal entrance (effective CP). After the attempts to insert the GTs were completed, tracheal intubation was performed while CP was applied. The position of the esophageal entrance in relation to the glottis (midline versus lateral) was assessed from the video recordings, with and without CP.

RESULTS: We stopped the study when 79 patients (41 men and 38 women) qualified for and completed the study (2-sided Clopper-Pearson confidence interval (CI) 95% to 100%, n = 72). Advancement of either size GT into the esophagus could not be accomplished during CP in any patient but was easily done in all subjects when CP was not applied. This occurred whether the esophageal entrance was in a midline position or in a left or right lateral position relative to the glottis. Esophageal patency was visually observed in the absence of CP, whereas occlusion of the esophageal entrance was observed during CP in all patients. Without CP, the esophageal entrance was in a left lateral position in relation to the glottis in 57% ([95 % CI, 45%–68%)] of patients, at midline in 32% (CI, 22%–43%), and in a right lateral position in 11% (CI, 5%–21%). The position did not change with CP.

CONCLUSIONS: The current study provides additional visual and mechanical evidence supporting a success rate of at least 95% by using a cricoid force of 30 N to occlude the esophageal entrance in anesthetized and paralyzed normal adult patients. The efficacy of the maneuver was independent of the position of the esophageal entrance relative to the glottis, whether midline or lateral. (Anesth Analg 2014;118:580–6)

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Accepted for publication November 11, 2013.

Funding: Support was provided solely from institutional and departmental sources.

The authors declare no conflicts of interest.

This work was presented in part at the Annual Meeting of the American Society of Anesthesiologists, Chicago, Illinois, October 16–19, 2011.

Reprints will not be available from the authors.

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DOI: 10.1213/ANE.0000000000000068

In 1961, Sellick[1] introduced cricoid pressure (CP) to "control regurgitation until intubation with a cuffed endotracheal tube was complete." The maneuver consisted of "occlusion of the upper esophagus by backward pressure on the cricoid ring against the bodies of the cervical vertebrae to prevent gastric contents from reaching the pharynx." CP was met with an enthusiastic reception worldwide and rapidly became an integral component of the rapid sequence induction/intubation technique.

Over the last 2 decades, the effectiveness of CP in occluding the upper esophagus and, therefore, its necessity have been questioned.[2–4] Some suggested abandoning it altogether.[5,6] Studies in awake volunteers by using magnetic resonance imaging (MRI) yielded conflicting conclusions concerning the effectiveness of CP. Smith et al.[7] presented findings, suggesting that CP is unreliable at producing midline esophageal compression without distorting the airway

anatomy. However, Rice et al.[8] reported that CP consistently produced compression of the postcricoid hypopharynx. The effectiveness of CP remains a matter of intense debate.[4,9]

Accordingly, the current study was performed in which real-time visual and mechanical means were used to assess the effectiveness of CP in obliterating the esophageal entrance. This approach also provided assessment of the functional status of the upper esophageal lumen, information which may not be obtained by using MRI images. The patency of the esophageal entrance during CP was directly visualized by using the Glidescope® video laryngoscope (GVL; Verathon Medical Canada ULC) in anesthetized and paralyzed patients with and without CP. This device has been shown to improve laryngeal visualization, enhance tracheal intubation, and facilitate gastric tube (GT) insertion.[10,11] We theorized that mechanical evidence of closure of the esophageal lumen during CP could be confirmed by the inability to introduce a GT in the esophagus under direct vision. To our knowledge, the functional patency of the esophageal entrance during CP under direct vision has not been previously studied. Our use of anesthetized and paralyzed healthy patients was an advance over the previous studies in awake volunteers.

METHODS

The investigation was approved by the Research and Ethical Committee of Procare Riaya Hospital, Al-Khobar, Saudi Arabia. Four anesthesia providers (operators) participated in the study: the first operator was in charge of the overall anesthetic management and directed the study; the second operator performed CP; the third operator performed both laryngoscopy by using GVL and the GT insertion trials. The fourth operator reviewed the video recordings for the position of the esophageal entrance in relation to the glottis. The 4 investigators maintained the same role throughout the study. Training of the 2 operators performing CP and GT insertions commenced 3 months before the study began. Competence in the application of CP was assured by 20 consecutive successful applications of 30 N force (± 2 N) on a weighing scale. The operator performing the GT insertions was trained to use the same force in the absence and presence of CP. Training of the GT insertion trials was completed after the demonstration of successful insertion of GTs of 2 sizes (12 and 20 F) in the esophagus with the aid of the GVL in 20 patients.

Airway assessment (Mallampati classification, thyromental distance, mouth opening, assessment of range of cervical spine motion, and upper lip bite test) was performed beforehand. Patients in whom an airway assessment suggested a difficult airway were excluded from the study. Written informed consent was obtained from 107 patients: 49 men, 58 women; 19 to 60 years, ASA physical status I and II, body mass index <28 kg/m^2, scheduled to undergo surgical procedures, requiring general anesthesia and endotracheal intubation. The patients were free from cardiac or respiratory diseases and did not have symptoms suggestive of gastroesophageal reflux disease. In the operating room, standard American Society of Anesthesiologists monitors were applied. The patient's head was placed in a sniffing position. Horizontal alignment of the external auditory meatus with the sternum was used as an indication of proper positioning.[12] After the administration of midazolam (2–3 mg), oxygen administration was begun by using a flow at 10 L/min in a semiclosed circle absorber system. When maximal oxygenation was achieved (end-tidal oxygen ≥90%), anesthesia was induced with propofol 2 mg/kg, fentanyl 2 μg/kg, and sevoflurane in oxygen. Cisatracurium 0.2 mg/kg was given to maintain muscle relaxation. Gentle mask ventilation (peak airway pressure <20 cm·H_2O) was begun after an oropharyngeal airway placement. CP was applied by the same anesthesiologist in all patients with his back toward the video monitor. The cricoid cartilage was first identified and then held between the thumb and middle finger, and the pressure was applied by the index finger with a force that could be tolerated by the patient. After loss of consciousness, the force was increased to 30 N. The cricoid force was standardized by reproducing 30 N (± 2 N) before application in each patient.

Neuromuscular blockade was monitored by eliciting mechanically evoked responses (thumb adduction) during ulnar nerve stimulation at the wrist by using Neuromuscular Transmission Module E-NMT (Datex-Ohmeda-GE healthcare monitor). Disappearance of 3 twitches by using the train-of-four mode or a decrease in twitch height by 90% was indicative of adequate relaxation. After manual ventilation with F_{IO_2} = 1.0 was established, direct laryngoscopy by using GVL (blade size 4) was performed, and the view of the glottis and esophageal entrance was video recorded. The first operator, who was standing behind the patient, signaled to the second operator to apply or release CP. Application of CP was done with the operator standing to the right side of the patient by using his dominant right hand. The hand was maintained in the same position, whether or not CP was applied.

Attempts to insert the GTs were performed by the third operator, who was not aware of whether or not CP was performed. To increase the rigidity of the GTs, they were placed in cold saline for 15 minutes before insertion attempts were made. To blind the operator attempting the GT insertions, a screen separated this operator from the operator applying CP. Visualization of the esophageal entrance was a prerequisite for attempting cannulation. In each patient, 4 trials were made to introduce 2 lubricated GTs: size 20 F and size 12 F (SMMP Co, Riyadh, Kingdom of Saudi Arabia), without and with CP, the timing of which was randomized by using a computer-generated sequence. Randomization was performed by using SPSS statistics 17.0 (IBM, New York, NY). The sequence of randomization was concealed by using sequentially numbered envelopes provided to the first operator.

A successful insertion of the GT, indicative of a patent esophagus, was defined as the insertion of the GT 15 cm beyond the esophageal inlet. When this occurred in the presence of CP, it was considered evidence of ineffective CP. An unsuccessful insertion of the GT in the presence of CP was considered evidence of effective CP. In each patient, 4 trials were conducted (2 trials with 20 F [1 with and 1 without CP] and 2 trials with 12 F [1 with and 1 without CP]). Each trial included up to a maximum of 3 attempts (5 seconds/attempt). Once the esophagus was cannulated, no more attempts were performed. After the insertion trials were completed, the cricoid force was reapplied, and tracheal intubation was performed with either a 7.0 or 7.5 mm

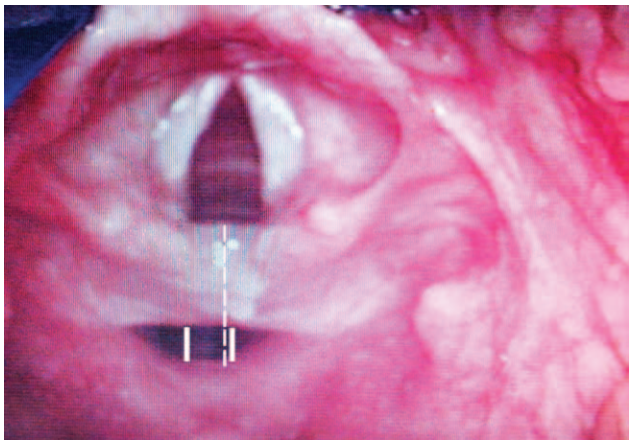

Figure 1. Assessment of the position of the esophageal entrance relative to the glottis (Cricoid pressure was not applied.) A vertical line was drawn from the middle of the posterior border of the glottis. If the line crossed the middle third of the esophageal entrance, it was considered in a midline position, whereas if the line crossed to the right or to the left of the middle third of the esophageal entrance, it was considered in a left lateral or right lateral position.

(ID) endotracheal tube (ETT), and the surgical procedure was begun.

The position of the esophageal entrance relative to the glottis was determined from the video recordings with and without CP. A vertical line from the middle of the posterior border of the glottis was drawn on the photographs obtained. If the line crossed the middle third of the esophageal entrance, it was considered to be in a midline position, whereas if the line was to the right or to the left of the middle third of the esophageal entrance, it was considered to be in a left lateral or right lateral position, respectively (Fig. 1).

Statistics

A power analysis was performed by using the Clopper-Pearson (quasi-exact) method. Based on our preliminary observations in 20 patients, we hypothesized that the success rate of CP in occluding the esophageal entrance would be 100%. Considering an a priori 95 % confidence interval (CI) of this proportion, 72 patients would be needed for the study.

Because we estimated that approximately 35% of the patients would be excluded, we recruited 107 patients for the study. We planned to exclude patients when one of the following situations arose: difficult ventilation or intubation; a change in heart rate or mean arterial blood pressure of >30%; occurrence of arrhythmias requiring treatment; oxygen saturation by pulse oximetry (Spo_2) decreasing to <95%; inability to visualize the esophageal entrance; when it became apparent that the study period would require >3 minutes for completion.

Data are reported as count or proportion (95 % CI) or mean ± standard deviation (SD). CIs were calculated by using the Clopper-Pearson method. Relevant observations and complications were recorded.

RESULTS

The study was stopped when 79 patients (41 men and 38 women) qualified for and completed the study (2-sided Clopper-Pearson CI, 95%–100%, n = 72). The glottis and esophageal entrance were visualized with the GVL in the 79 patients (41 men and 38 women) studied. The total number of trials was 316 (158 trials with 20 F [79 with and 79 without CP] and 158 trials with 12 F [79 with and 79 without CP]). In all 79 patients, cannulations with 20 and 12 F were successful on the first attempt when CP was not applied. These cannulations were accomplished easily in <5 seconds. This occurred whether the esophageal entrance was in a midline position or in a left or right lateral position relative to the glottis. During the application of CP, all trials to cannulate the esophagus (237 attempts with 20 F and 237 attempts with 12 F) were unsuccessful. Esophageal patency was observed visually when CP was not applied, whereas occlusion of the esophageal entrance was observed during application of CP in all patients (Figs. 2–4).

Without CP, the esophageal entrance was in a left lateral position in relation to the glottis in 57% (CI, 45%–68%) of patients, at midline in 32% (CI, 22%–43%), and a right lateral position in 11% (CI, 5%–21%). The position did not change with CP. In 30 patients, slight narrowing of the laryngeal entrance and an apposition of the vocal cords were noted during the application of CP. The 30 N cricoid force used did not compromise tracheal intubation in any patient. Tracheal intubation was accomplished with either a 7.0 or 7.5 mm (ID) ETT while CP was applied in the sniffing position. There were no serious complications related to the anesthetic management, tracheal intubation, application of CP, or placement of the GTs. The time required to obtain the data was <3 minutes in all patients studied.

Twenty-eight of the 107 patients who began in the study were excluded because of difficulty in visualizing the esophageal entrance. Manual ventilation was accomplished after placement of an oropharyngeal airway in all patients. Peak airway pressure was ≤20 $cm{\cdot}H_2O$. There were no instances of difficult tracheal intubation in the participants. Demographic data of the patients studied are presented in Table 1.

DISCUSSION

The current investigation provides visual and mechanical evidence for the effectiveness of CP in occluding the esophageal entrance in anesthetized and paralyzed patients. The use of the GVL allowed real-time visualization of both the glottis and the esophageal entrance and an assessment of the functional status of the upper esophageal lumen during CP. Occlusion of the esophageal entrance was observed during CP, whereas esophageal patency was observed when CP was not used. In all 79 patients studied, 30 N cricoid force resulted in the inability to introduce 2 sizes of GTs (12 F and 20 F) into the esophagus. Conversely, it was possible to cannulate the esophagus by using either GT when no cricoid force was applied. These results were consistent whether the esophageal entrance was in a midline or in a lateral position in relation to the glottis.

The effectiveness of CP, when initially described by Sellick[1], was based on the observed obliteration of the esophageal lumen in a cadaver model. He also confirmed the value of CP in preventing saline (run into the esophagus from a height of 100 cm H_2O) from reaching the pharynx in a patient undergoing gastroesophagectomy. Furthermore, Sellick[1] reported on the use of CP in 26 high-risk patients. In

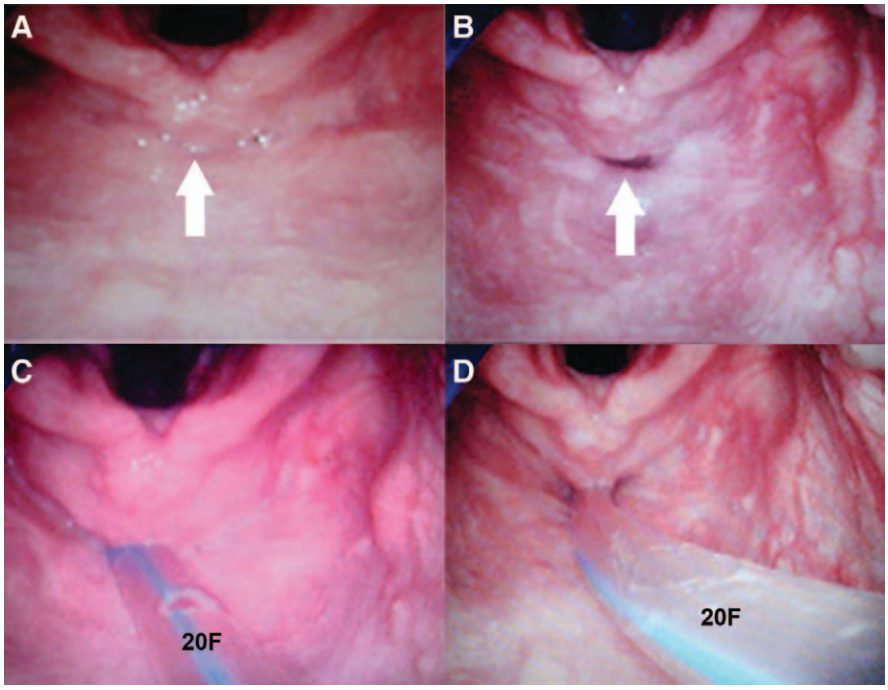

Figure 2. Images demonstrating the effectiveness of cricoid pressure (CP) when the esophageal entrance is in a midline position: A, Esophageal entrance occluded with CP. B, Patent esophageal entrance without CP. C, Inability to introduce gastric tube (GT) (20 F) into the esophagus with CP. D, Easy insertion of the GT without CP. The arrow points to the esophageal entrance.

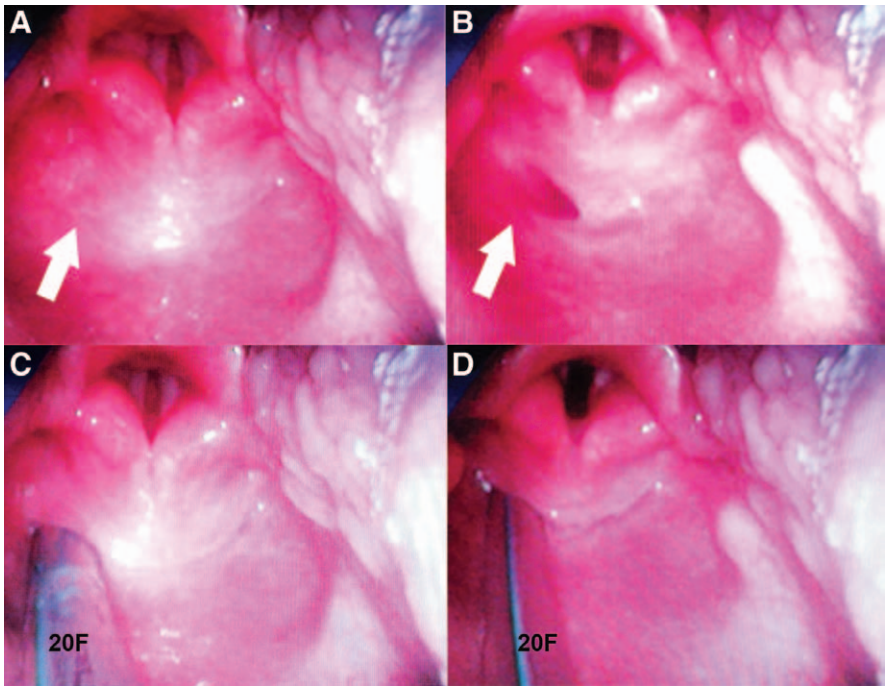

Figure 3. Images demonstrating the effectiveness of cricoid pressure (CP) when the esophageal entrance is in a left lateral position: A, Esophageal entrance occluded with CP. B, Patent esophageal entrance without CP. C, Inability to introduce gastric tube (GT) (20 F) into the esophagus with CP. D, Easy insertion of the GT without CP. The arrow points to the esophageal entrance.

23, no regurgitation or vomiting took place. In the remaining 3 patients, release of CP after intubation was followed by reflux of gastric or esophageal contents into the pharynx, suggesting that in these patients, CP had been effective. Further studies in infant and adult cadavers confirmed Sellick's earlier findings.[13–15] The use of CP has been questioned on the following grounds[9]: (1) Its efficacy has been demonstrated only in cadavers.[13–15] (2) There have been reports of aspiration of gastric contents despite CP.[16] (3) The esophagus may not be directly posterior to the cricoid cartilage, and therefore, the maneuver may not be reliable in producing midline esophageal compression.[7] and (4) The use of CP has been associated with complications, including relaxation of the lower esophageal sphincter, nausea and vomiting, and, very rarely, esophageal rupture.[4,9,16,17]

With the use of MRI, Smith et al.[7] evaluated the position of the esophagus relative to the vertebral body in awake volunteers with and without CP, while the head was in a neutral position. They found that the esophagus, without CP, was displaced laterally relative to the cricoid cartilage in 52.6% of subjects. They also found that CP further displaced the esophagus laterally in 90.5% of subjects relative to its

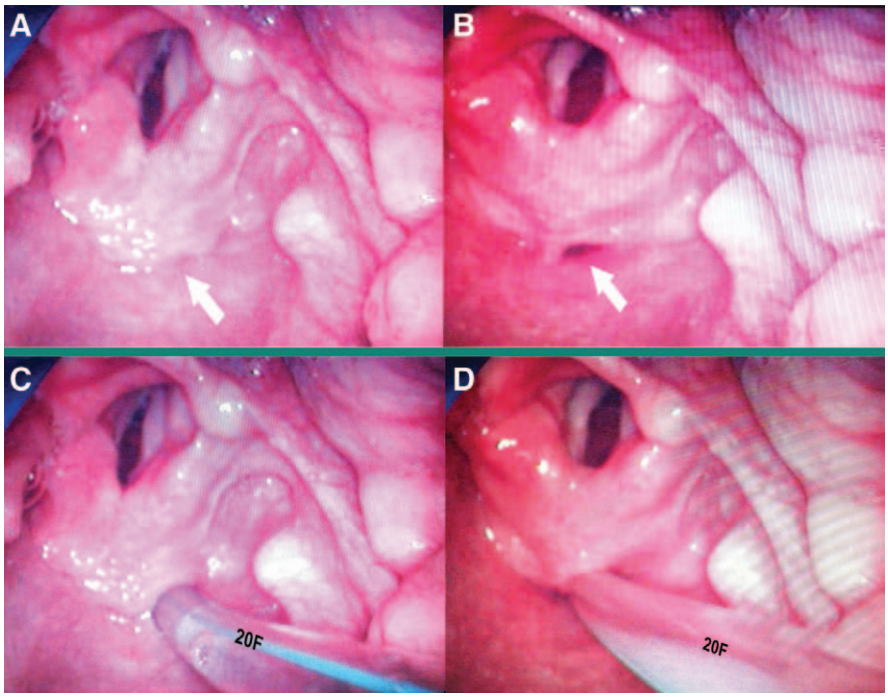

Figure 4. Images demonstrating the effectiveness of cricoid pressure (CP) in the rare situation in which the esophageal entrance is in the right lateral position: A, Esophageal entrance occluded with CP. B, Patent esophageal entrance without CP. C, Inability to introduce gastric tube (GT) (20 F) into the esophagus with CP. D, Easy insertion of the GT without CP. The arrow points to the esophageal entrance.

Table 1. Demographic Data

No. patients (after exclusions)	79
Age	31 ± 11 y
Men/women	41/38
Body mass index	25.5 ± 3.2 kg/m^2
ASA I/II	45/34
Mallampati classification	
Class 1	28
Class 2	51
Cormack-Lehane grading	
Grade 1	42
Grade 2	45
Esophageal entrance position with or without CP:	
Left	45
Middle	25
Right	9

Values for age and body mass index are presented as mean ± SD.

initial position, to the left in 69.4%, and to the right in 21.1% of subjects. With the use of different reference points (the glottis and the esophageal entrance), we also demonstrated that, in the absence of CP, there was a predominant left lateral position of the esophageal entrance relative to the glottis. However, in our study, regardless of the initial position (whether lateral or midline), the relationship between the glottis and esophageal entrance did not change when CP was imposed. With the use of the Glidescope, we could not determine whether movement of the glottis and the esophageal entrance in relation to the vertebral body occurred. Our findings concur with the MRI study of Rice et al.,[8] which demonstrated that CP does not cause lateral displacement of the alimentary tract (the postcricoid hypopharynx) relative to the cricoid cartilage in any of the neck positions investigated.

Smith et al.[7] proposed that lateral displacement of both the esophagus and larynx in relation to the vertebral body during CP can result in less effective compression of the esophagus. However, Rice et al.[8] clearly demonstrated that such lateral displacement does not reduce the effectiveness of the maneuver. Because the cricoid cartilage moves as the "CP unit" with the postcricoid hypopharynx, they concluded that lateral displacement of the esophagus is irrelevant. Rice et al.[8] also demonstrated that the lumen of the alimentary tract posterior to the cricoid cartilage was indeed compressed during CP. The compression of the postcricoid hypopharynx occurred regardless of the position of the cricoid cartilage (midline or lateral) relative to the vertebral body. Consistent with the findings of Rice et al.,[8] our investigation demonstrated that the efficacy of CP was independent of the position of the esophageal entrance.

The anatomy of the cricoid cartilage and the surrounding area may explain the effectiveness of a 30 N cricoid force regardless of whether the esophagus is in a midline or in a lateral position in relation to the glottis. Vanner and Pryle[18] calculated that when a 30 N force is applied to the cricoid cartilage, and the 2 convex structures of the cartilage and the cervical vertebral body are pressed together, a pressure in excess of 200 mm·Hg is generated posterior to the 10 cm^2 area of the lamina of the cricoid cartilage. However, the same investigators demonstrated experimentally that a 30 N cricoid force could only prevent regurgitation of esophageal fluid up to 40 mm·Hg.[16] The reason for this apparent discrepancy is that the pressure generated posterior to the cricoid cartilage is not evenly distributed with esophageal areas in the midline receiving greater compression than the lateral areas. When the esophagus is in a lateral position, the esophageal lumen may be pressed against the longus colli muscle rather than the vertebral body during CP, and thus would be receiving less force than if it were in a midline position.[18] However, because the intragastric pressure rarely exceeds 25 mm·Hg, a 30 N force is still more than adequate to prevent regurgitation in spite of lateral displacement.[19]

Although some studies found that CP does not increase the rate of failed intubation,[20–22] others demonstrated that cricoid force, especially if >30 N, can compromise airway patency and can cause difficulty with tracheal intubation.[23–25] Application of CP can make mask ventilation more difficult,[26] interfere with the placement of an ETT, and alter laryngeal visualization by a flexible bronchoscope.[26,27] However, many of these problems may be attributable to improper application of CP and lack of training in performing the maneuver.[28,29] The slight narrowing of the larynx and the apposition of the vocal cords during CP that we observed in some patients did not compromise tracheal intubation. This may have been due to limiting the cricoid force to 30 N and the use of the GVL. Our observations are compatible with a study that demonstrated no impediment to tracheal intubation with a cricoid force of 40 N. In fact, in that study, there was an improved view of the glottis when the Trueview EVO2™ laryngoscope was used as compared with the standard Macintosh blade.[30]

The current investigation has limitations that should be recognized. The study was conducted in normal adult nonobese patients, and thus, the findings cannot be extrapolated to different populations, such as children, morbidly obese patients, or patients with an abnormal esophagus such as esophageal pouch and achalasia. Only a cricoid force of 30 N (the force recommended by most investigators in adult patients)[20] was tested, and thus, we cannot exclude the possibility that less force would have been equally effective in occluding the esophageal entrance. It may be argued that it would have been preferable to have >1 operator performing CP. However, to minimize the variability in the application of CP and to provide an accurate and consistent force, we, like some previous investigators,[7,31,32] used a single operator trained to apply a cricoid force of 30 N. Our findings were in agreement with those of Herman et al.,[33] who demonstrated that with proper training, the cricoid force was reproducible within a range of 2 N. The use of GVL allowed us to easily visualize the glottis, to locate the esophageal entrance, and to test the success of insertion of the GT with and without CP. In the current investigation, the sniffing position was used during CP application and tracheal intubation. This may seem to be in contradiction to the original maneuver by Sellick,[1] who used extreme extension of the head and neck to stretch the esophagus behind the cricoid cartilage. However, in a second publication, Sellick[34] changed his view and recommended "slight" extension. Because the sniffing position is believed to enhance both laryngeal visualization and tracheal intubation, investigators concur that this position should also be used during CP.

We hypothesized that the inability to introduce a small GT into the esophagus during CP could serve as a "surrogate" indicative of effective occlusion of the esophageal entrance. In the current study, 2 sizes of GTs, with external diameters of 6.7 and 4.0 mm, were used. GTs with an external diameter smaller than 4.0 mm could not be tested because of lack of rigidity. Regurgitated gastric contents that traverse the esophagus to the pharynx can be liquids, solids, or a combination of liquids and solids. Our findings support the notion that solids equal to or larger than 4.0 mm in diameter cannot reach the pharynx when a cricoid force of 30 N is applied. However, they do not exclude the possibility of regurgitated fluid passing via an esophageal opening <4.0 mm in diameter despite application of CP.

In conclusion, the current investigation provided visual and mechanical evidence supporting the effectiveness of a cricoid force of 30 N in occluding the esophageal entrance in anesthetized and paralyzed normal adult patients. The efficacy of the maneuver was independent of the position of the esophageal entrance relative to the glottis, whether midline or lateral. ■

DISCLOSURES

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Attestation: Ahed Zeidan has seen and reviewed the data, approved the manuscript, and is the author primarily responsible for the study.
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Attestation: George Crystal has seen the original data, reviewed the data, and approved the final manuscript.
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