

Predictive Performance of Gargle Test in Prediction of Successful Extubation in Patients Undergoing Head and Neck Surgery in ICU

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Abstract

Background

Improvement of predictive tools for recognition of airway edema is crucial for safe extubation and patient safety. This study aims to evaluate the efficacy of gargle test for assessment of airway edema and prediction of successful extubation in patients undergoing head and neck surgeries.

Methods

This is a prospective observational study on 118 patients that were undergone head and neck surgeries and been admitted to intensive care units. All the patients were weaned based on the same protocol. Initially, quantitative, and qualitative Cuff Leak Test were done and, the decision for extubation was made by employing them. Subsequently, gargling with purified water was implemented. Exclusion criteria were consisted of the impossibility of extubation due to reasons other than airway edema such as pneumonia. Independent sample t-test was applied to study the difference between quantitative variables between two groups, and Fisher's exact test was used for categorical variables. P-value < 0.05 was determined as a significant difference between the variables. To investigate the relationship between these two tests, sensitivity, specificity, positive and negative predictive values, and accuracy were calculated.

Result

One hundred eighteen were enrolled in this study. Sixty-seven patients (56.78%) male and 51 patients (43.22%) were female with a mean age of 54.7 ± 12.2 year. Due to surgical manipulations, and anatomical problems in the hypopharynx and larynx, 5 patients (4.2%) were not able to perform the gargle test. Six patients (5.1%) were facing extubation failure since they experienced respiratory distress and stridor. A measure of agreement (kappa) of gargle test with qualitative and quantitative CLT was low ($K = 0.21$, $k = 0.07$, respectively). The gargle test had higher specificity, negative predictive value (NPV), and accuracy compared to quantitative and qualitative CLT. Extubation failure in patients with positive gargle test was significantly lower than patients with negative gargle test (3.7% vs. 33.4 % respectively, $P = 0.032$).

Conclusion

The gargle test is simple, cheap, and does not require any equipment, and groups of nerves and muscles which control larynx function are being assessed in the gargle test. It provides better patients safety in difficult extubations.

Background

The decision to extubate the patients in the intensive care unit (ICU) is critical and challenging. On the one hand, delay in the removal of endotracheal tubes is associated with complications such as infection and increased mortality, on the other hand, inappropriate decision to extubate the patient with anatomical problems, trauma, head and neck surgeries, restricted mouth opening, and neck limited range of motion can result in difficult intubation which eventually can be life-threatening. (1) Thus, improvement of predictive tools and recognition of airway edema is crucial for safe extubation, and it is necessary to predict if the patient can tolerate extubation and if reintubation is still a possibility. (2, 3, 4). Improvement of these methods is required for patient safety, as it helps the intensivist to have a clearer evaluation and make a more appropriate decision for extubation in difficult situations. (3, 4)

Studies have reported the prevalence of laryngeal edema; 0.6–36.8%, reintubation; up to 80% (5), mortality; 30–40%, and increased pulmonary complications in difficult extubation. (6) This statistical discrepancy variabilities could be due to vocal cord dysfunction or laryngeal edema, reduced tracheal cross-sectional area, different study populations, and duration of intubation. (5, 6, 7)

Unlike tongue and pharynx edema, evaluation of laryngeal edema is difficult. Female gender, prolonged intubation, the severity of the airway edema, endotracheal tube size compared to larynx are associated with a higher risk of stridor after extubation and cause false negative or positive results in cuff leak test. (8, 9)

Considering the impacts of numerous confounding factors, false results, the discrepancy between the severity of clinical presentation of airway edema with the extent of tissue injury, and variable results in various measurements(9), it is essential to develop more reliable methods in airway evaluation. Based on this, physicians are attempting to employ various techniques to overcome this issue. These techniques include cuff leak test (quantitative/qualitative) (9), tracheal ultrasound (10), optic fibroscopy, direct laryngoscopy examination, and video laryngoscopy (11, 12), and flow-volume curves for extra-thoracic stenosis. (13)

Although tongue and pharyngeal edema can be easily evaluated via direct laryngoscopy, assessment of laryngeal edema and its severity in the presence of endotracheal tube is challenging. Airway studies with video laryngoscopy and fiberoptic bronchoscopy require patient extubation that can be life-threatening. (8) Cuff leak test is a simple method to predict the occurrence of complications. However, its result can be impacted by confounding factors, such as the ratio of the tube to trachea size, pulmonary mechanics, and rate of airflow. (7, 14) Optimally, the test should be used just before extubation for every patient. (8, 13) Due to numerous reasons, every single method mentioned above has limitations, as they require equipment, performer skills, and are associated with limited effectiveness or necessitate removal of the tube. Imaging techniques such as plain cervical radiography (15, 16), CT scan, and MRI can capture upper airway edema; However, they are expensive and impractical in clinical practice, and they are also accompanied by technical limitations. (13) Gargle is holding water in the back of the mouth and blowing air out from the lungs by utilization of groups of nerves and muscles in upper airways with a gurgling

sound. Thus, this study is conducted to evaluate the efficacy of the gargle test for assessment of airway edema and prediction of successful extubation in patients undergoing head and neck surgeries.

Methods

Study population and setting

After review and approval by the university ethics committee (IR.TUMS.IKHC.REC.1396.2004), a prospective observational study was conducted. One hundred eighteen patients were investigated; they had undergone head and neck surgeries and been admitted in general and surgical intensive care units in Imam Khomeini Hospital Complex of Tehran University of Medical Sciences. All patients were intubated and supported by mechanical ventilation for at least 12 hours.

Exclusion criteria were consisted of the impossibility of extubation due to reasons other than airway edema, pneumonia, or other reasons that prohibited ventilator weaning.

Weaning and airway assessment:

Airway management and monitor of the mechanical ventilator in the intensive care unit were accomplished under an intensivist's supervision. All the patients had endotracheal tubes with low pressure-high volume cuffs, and cuff pressure was monitored and maintained less than 25 cmH₂O every 4 hours. Weaning patients from the ventilator was on the grounds of a consistent protocol utilizing pressure support mode. Once the patient met all the criteria of ventilator weaning, the decision for extubation was made by employing Cuff Leak Test (CLT). Initially, quantitative, and qualitative CLT were done. Subsequently, gargling with purified water was implemented. Patients were given the essential explanations to mentally prepare them, improve their cooperation, and obtain their consent. Whenever it was necessary, an appropriate dose of a sedative was applied to enhance the patient's comfort and tolerance to an endotracheal tube. None of the patients were on corticosteroid drugs.

Quantitative CLT: Following suction of oral and tracheal secretions, the patient was placed in a sitting position. Prior to the test, the patient was put on the assist-control ventilation mode with a tidal volume of 6–8 ml/kg for 2 minutes. The average exhaled tidal volume was recorded over the next 5 respiratory cycles before and after cuff deflation. A difference of more than 15% in the tidal volume was associated with the absence of airway edema and warranted the removal of the tube. (17)

Qualitative CLT: First the patient was weaned from the ventilator. Then, the oral and tracheal secretions were suctioned. Subsequently given that the patient was comfortable and placed in a sitting position, the endotracheal cuff was deflated. Next, the opening of the endotracheal tube was blocked and the patient was asked to breathe through the mouth. If the patient was able to perform 5 respiratory cycles without any sign of suffocation or evidence of airway obstruction, it was deemed as an appropriate test.

Gargle Test (GT): Like the qualitative CLT method, the patient was weaned from the ventilator in the sitting position. After performing oral and tracheal suction, the patient did a relatively deep inspiration

and held his/her breath. Then, concurrent breath-hold, the endotracheal tube was occluded and about 3–5 ml of purified water was put in the patient mouth. Next, the patient was asked to gargle water at the back of his mouth with long and slow exhalation. This indicates that there is an appropriate air leak (in terms of volume, flow, and power) around the tube. Also, it demonstrates the ability of the patient in maintaining airway patency and prevention from aspiration. Then, the patient was asked to lean forward and spit the water out in a dish.

The extubation decision was based on the result of CLT. All tests were done by another anesthesiologist and he allowed extubation. Extubation was done by the patient's nurse. The investigator did not know the result of the gargle test and just recorded data immediately after extubation such as stridor, dyspnea, and the patient's ability for talking. The need for early reintubation in the next 12 hours due to respiratory distress caused by airway edema and stridor considered extubation failure.

Age, gender, type of the surgery, duration of anesthesia and surgery, comorbidities, duration of mechanical ventilation (from initiation of anesthesia to extubation), type of intubation, success, or failure of extubation, and results of quantitative, qualitative CLT, and gargle test were documented.

Statistical Analysis

A minimum value of the correlation coefficient between the gargle test and quantitative/qualitative CLT was defined as 0.6. Initially, Spearman's correlation coefficient and later kappa coefficient (with 95% confidence interval) were calculated to study Inter-rater reliability between gargle test and quantitative/qualitative CLT. To investigate the relationship between these two tests, sensitivity, specificity, positive and negative predictive values, and accuracy were calculated. Data are demonstrated in the form of mean \pm standard deviation. Frequency was used to describe qualitative variables. Independent sample t-test was applied to study the difference between quantitative variables between two groups, and Chi-square or Fisher exact test was used for categorical variables. P-value < 0.05 was determined as a significant difference between the variables.

A ROC curve was used to identify the cut-off value for the minimum percentage of an acceptable leak for removal of the endotracheal tube in this study.

Results

One hundred eighteen patients who had undergone head and neck cancer surgeries including thyroidectomy, neck dissection, glossectomy, mandibulectomy, maxillectomy were enrolled in this study. Sixty-seven patients (56.78%) male and 51 patients (43.22%) were female with a mean age of 54.7 ± 12.2 . Demographic characteristics of the patients are depicted in (Table 1). Seventy-six patients (64.4%) were nasally intubated, while 42 patients (35.6%) were orally intubated. Due to surgical manipulations, and anatomical problems in the hypopharynx and larynx, 5 patients (4.2%) were not able to perform the gargle test. These 5 patients were excluded from data analysis and 113 patients were enrolled for analysis. Six patients (5.1%) were facing extubation failure since they experienced respiratory distress

and stridor. Extubation failure was not statistically significant based on the result of quantitative and qualitative CLT (P = 0.647, P = 0.385, respectively) (Table 2). However, extubation failure in patients with positive gargle test was significantly lower than patients with negative gargle test (3.7% vs. 33.4 % respectively, P = 0.032) (Table 2). A measure of agreement (kappa) of gargle test with qualitative and quantitative CLT was low (K = 0.21, k = 0.07, respectively). The gargle test had higher specificity, negative predictive value (NPV), and accuracy compared to quantitative and qualitative CLT (Table 3).

According to ROC curve, cut- off value (Fig. 1: A point) in quantitative CLT was predicted 16.5% with sensitivity of 74.1%, and Specificity of 60% (AUC = 0.621, 95%CI: 0.378–0.865, P = 0.318).

Table 1
Demographic characteristics of patients

Variable	Mean ± SD
Age, yr	54.7 ± 12.2
Weight, kg	70.8 ± 12.4
Height, cm	169.3 ± 8.3
BMI	24.6 ± 3.1
ICU stay, day	3.1 ± 1.1
MV duration, hr	28 ± 19.1
surgery duration, hr	5.8 ± 1.9
Weaning time, hr	16.9 ± 19.2
BMI: body mass index, MV: mechanical ventilation,	

weaning time: time of ventilator discontinuation from anesthesia.

Table 2
Comparison of extubation failure based on quantitative/
qualitative CLT and gargle test results

Test	Extubation failure		P value
	Yes	No	
Quantitative CLT (%)	1 (4.2)	23 (95.8)	0.647
≤ 15	5 (5.3)	89 (94.7)	
>15			
Qualitative CLT	1 (11.1)	8 (88.9)	0.385
non-appropriate	5 (4.6)	104 (95.4)	
appropriate			
Gargle test	2 (33.3)	4 (66.7)	0.032
negative	4 (3.7)	103 (96.3)	
positive			
Fisher's Exact Test, CLT: cuff leak test			

Table 3
Comparison of sensitivity, specificity, PPV, NPV and accuracy between qualitative/quantitative CLT and gargle test

Test	Extubation failure		Sensitivity	Specificity	PPV	NPV	Accuracy
	Yes	No					
Quantitative CLT. %	1	23	16.6%	79.4%	4%	94.6%	76.27%
≤ 15	5	89					
≥ 15							
Qualitative CLT	1	8	16.6%	92.8%	11.11%	95.4%	88.98%
non-appropriate	5	104					
appropriate							
Gargle	2	4	33.3%	96.3%	33.3%	96.3%	92.92%
negative	4	103					
positive							
CLT: cuff leak test, PPV: positive predictive value, NPV: negative predictive value							

Discussion

Five patients out of 118 patients we investigated were excluded from this study, as the performance of the gargle test was not feasible due to their anatomical problems. One hundred thirteen patients were analyzed, and sensitivity, specificity, positive predictive value (PPV), NPV, and accuracy were calculated for them.

After extubation, incidents such as laryngeal edema, and reintubation were associated with extended mechanical ventilation and increased morbidity in ICU patients. (5) Up to 20% of reintubation, 24 to 72 hours after extubation has been reported in the ICU setting. (18) Reintubation increases up to 47% in head and neck trauma, after maxillofacial surgery, and extensive neck injuries. On the one hand difficult intubation, on the other hand, airway edema, critical conditions, and inappropriate measures can lead to irreversible damage and death. (19, 20)

Zhou et al. (5) reported that CLT can accurately identify the patients at risk of airway complications after extubation and decrease the rate of laryngeal edema after extubation. However, the rate of reintubation did not change. They also found that prolonged intubation could cause laryngeal edema after extubation.

Miller et al.(15) reported that with a cuff leak of 110 ml, the PPV for stridor after performing CLT was 80 %, and the specificity of the test was 99 %. In Jaber et al. study,(21) CLT with a cuff leak of 12% (130 ml), showed a sensitivity of 85%, specificity of 95%, PPV and NPV were respectively 69% and 98%. De Bast et al.(13) demonstrated that the best cut-off value for air leaks was 15.5%. The sensitivity of this test was 78%, specificity was 72.1%, PPV was reported as 25%, and NPV was 96.1%. They concluded that due to the low PPV of this test, it may not be used to delay extubation.

The rate of post-extubation stridor, laryngeal edema, and efficacy of the leak test varies in different studies. Our study, unlike Miller et al. and Jaber et al.'s studies, showed low sensitivity and PPV. Like these studies, the specificity and NPV of our study were also high. Low PPV in our study was consistent with De Bast's study. Although PPV was higher in the gargle test, it was generally low in all three tests; PPV of quantitative CLT, qualitative CLT, and gargle test was 4%, 11.11%, 33.3% respectively. In other words, when these tests indicate the presence of laryngeal edema, it does not necessarily mean that the extubation of the patient will be unsuccessful. Essentially, evaluation of laryngeal edema and the severity of it in the presence of endotracheal tube is difficult. Before the removal of the tube, tests have significant false results, and it is not possible to have a definitive verdict. Furthermore, it has been demonstrated that several measurements done by different individuals have just an average consistency in identifying the extent of the edema. (8) In our study, all of the parameters including, sensitivity, specificity, PPV, NPV, and accuracy were superior in the gargle test compared to CLTs (Table 3). According to high accuracy, NPV, and specificity (92.92%, 96.3%, 96.3%, respectively), the gargle test was more effective in detecting airway edema. Considering its nature, groups of nerves and muscles which control larynx function are being assessed in the gargle test. This special characteristic cannot be determined in quantitative and qualitative tests. Further, the gargle test was significantly better in the evaluation of the likelihood of successful extubation ($p < 0.032$) (Table 2).

Prinianakis et al. (7) demonstrated that CLT was associated with lower efficacy in critically ill patients who have undergone mechanical ventilation for at least 48 hours after surgery. They attributed this difference to increased leak due to reduced compliance or increased airway resistance in surgical patients.

The use of CLTs in selective patients is a higher value compared to non-selective patients. (9) CLT, regardless of measuring absolute volume or expiratory volume percentage, is a weak predictor for the diagnosis of airway edema and extubation. It is not recommended that CLTs be used as a reliable indicator for postponing extubation, or the initiation of specific treatments (14) Thus, researchers are trying to propose other reliable measures to detect airway edema. All proposed tests have their specific limitations. Ding et al. (10) have used ultrasound to diagnose airway edema. They observed that air-column width and air-column width difference (ACWD) were lower in the stridor group compared to the non-stridor group. However, Mikaeili et al. (22) did not support this finding. They concluded that concerning stridor prediction, air-column width, and ACWD have low sensitivity and specificity compared to CLT. Eventually, both studies concluded that both CLT and laryngeal ultrasound have low sensitivity and PPV in the prediction of stridor. Thus, they should be used with precautions. (22)

Conclusion

The gargle test is simple, cheap, and does not require any equipment. Assessment of the nerves and muscles of the larynx and pharynx is a unique point in the gargle test. This feature of the gargle test can also provide greater reliability for safe extubation and reduce adverse outcomes in difficult extubations compared to other tests, such as CLTs.

Abbreviations

ICU

Intensive Care Unit

CLT

Cuff Leak Test

GT

Gargle Test

PPV

Positive Predictive Value

NPV

Negative Predictive Value

ACWD

Air-Column Width Difference

Declarations

Ethics approval and consent to participate

This study protocol was approved by the Tehran University of Medical Sciences Research Ethics Committee (Approval number: IR.TUMS.IKHC.REC.1396.2004). Written informed consent was obtained from all the participants.

Consent for publication

Not applicable.

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests

None authors to be declared.

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Authors' contributions

M.T.B. performed study design. L.A. interpreted the data. A.A. supervised the statistical analysis. M.T.B. wrote the draft, and all the authors critically reviewed the manuscript and approved the final version of the manuscript. All authors read and approved the final manuscript.

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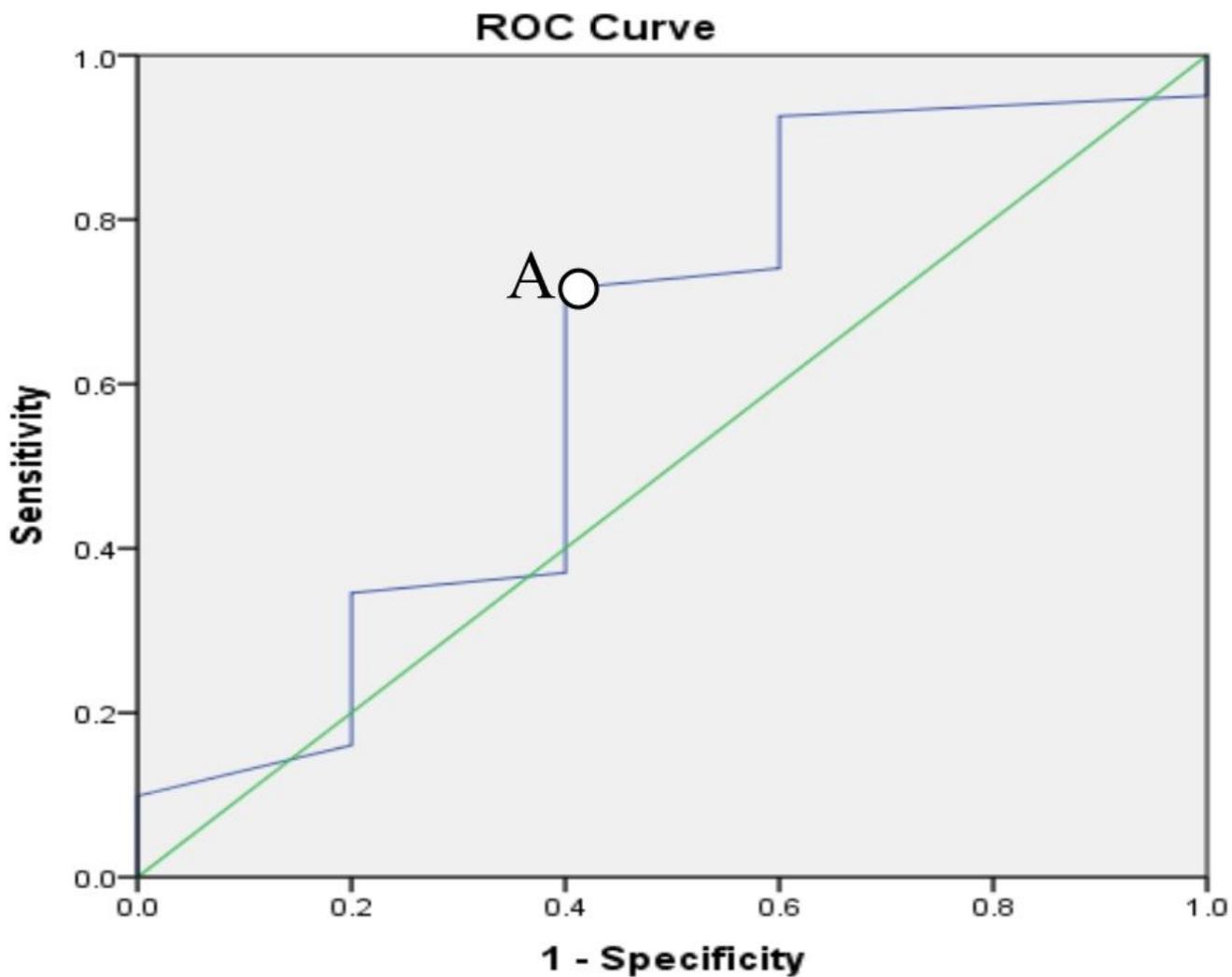
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Figures



Diagonal segments are produced by ties.

Figure 1

Appropriate cut off point (A) of quantitative cuff leak test for extubation failure