Original Article

Comparative evaluation of three methods of endotracheal tube cuff inflation for adequacy of seal

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Abstract

Background and Aims: Intubation with cuffed endotracheal tube (ETT) is common in operation rooms, critical care, and emergency rooms. The pressure exerted by the cuff on the tracheal mucosa can lead to a reduction in blood flow to the tracheal wall and result in mucosal ischemia. There are many methods for ETT cuff inflation. Aim of the study was to compare the cuff pressures and volumes between the three methods of ETT cuff inflation.

Material and Methods: One hundred and twenty patients were randomized into three groups: Group SG (stethescope guided), group AL (audible leak), and group P (palpation). In group SG, the cuff was inflated by auscultating with the bell of the stethoscope over the thyroid cartilage for leak around cuff. In group AL, the cuff was inflated by listening for an audible leak around the cuff with observer's ear 5 cm away from the mouth of the patient. In group P, the cuff was inflated by palpating for a leak over the cricoid and trachea. The adequacy of the cuff seal was compared between the groups by assessing the volumes of additional air needed to stop the leak around the cuff as confirmed by supraglottic capnometry.

Results: The initial volumes needed to inflate the cuff were significantly more in the stethoscope (SG) and hearing (AL) groups than in the palpation (P) group (SG = 5.1 ± 1.4 ml, AL = 4.6 ± 1.6 ml, P = 3.1 ± 0.9 ml; SG and AL vs. P, $P < 0.001$). Additional cuff volumes required to achieve zero leak around cuff by supraglottic capnometry were 0.85 ± 1 ml in group SG, 1.3 ± 1.1 ml in group AL, and 2.237 ± 0.8 ml in group P (SG vs. P and AL vs. P; $P < 0.001$).

Conclusion: Out of the auscultation-guided, audible leak-guided, and palpation-guided methods of ETT cuff inflation, the auscultation-guided and audible leak-guided methods achieve significantly better tracheal seal than the palpation-guided method.

Keywords: Cuff inflation, endotracheal tube, EtCO2

Introduction

Guedel and Waters in 1928 added a cuff around the endotracheal tube (ETT) to prevent aspiration and this marked the birth of the modern ETT. The disposable cuffed ETT is commonly used to provide ventilation in emergency rooms, operation rooms, and intensive care units. The cuff in its inflated state serves to provide an effective seal between the ETT and the tracheal wall. This seal is useful in providing positive pressure ventilation without leak around the tube as well as preventing aspiration. The cuff pressure should be sufficient to prevent aspiration without compromising the tracheal blood flow. High pressures exerted by the cuff on the tracheal mucosa can lead to a reduction in blood flow to the tracheal wall steering to complications.[1,2] Clinical signs and symptoms of these complications can be postoperative sore throat, hoarseness of voice, dysphagia, etc.[3-5] A low cuff pressure (<20 cm H_2O) may cause aspiration.[6] This indicates that optimal inflation of the cuff is required to prevent complications related to the cuff. An acceptable cuff pressure ranges from 20 to 30 cm H2O.[7-9] This pressure limit is

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determined in part by capillary perfusion pressure supplying the trachea (48 cm H2O) and the minimum occlusive intra-cuff pressure required for positive pressure ventilation, to prevent aspiration (20 cm H2O).[1] Thus, the caregiver has to aim within this narrow range to prevent aspiration and maintain the integrity of the tracheal mucosa.

The common clinical practice of cuff inflation by injecting a fixed volume or by assessing inhaled-exhaled volume difference is imprecise, and evaluating leak by dye infusion is impractical.[10-12] It is recommended that a cuff pressure manometer be used during ETT cuff inflation so that the cuff pressures lie within the recommended range,[13] but they have yet to be widely adopted in most emergency rooms, operation rooms, and ICUs. Widespread use is prevented by the cost of procurement and reduced awareness about the device. Health care workers inflating the ETT cuff without the aid of a cuff pressure manometer use myriad methods to determine the adequacy of cuff seal.[3,10,13-15] Among published studies, very few address the assessment of the adequacy of cuff seal by supraglottic capnometry.[16-18]

Supraglottic capnometry is a novel method to check cuff seal adequacy. Recently many articles and guidelines are indicating that the adequacy of CPR can be checked by capnography and capnography-guided CPR can improve the outcome of CPR.[19,20] Capnography is a mandatory monitor to use during anesthesia.[21-23] This had prompted many institutions to acquire capnography. Capnography being readily available, we studied whether supraglottic capnometry can detect adequacy of cuff seal on par with cuff pressure monitoring while using different methods of cuff inflation.

This study was conducted to compare three commonly used methods of cuff inflation (auscultation, audible leak, and finger palpation guided) to determine which method will be the most appropriate in day-to-day practice (i.e. in the absence of supraglottic capnometry and continuous cuff pressure monitoring) to achieve adequate sealing of trachea with the cuff of ETT. SG method would serve as a practical approach to inflate the ETT cuff for adequate seal was the hypothesis of the study.

Material and Methods

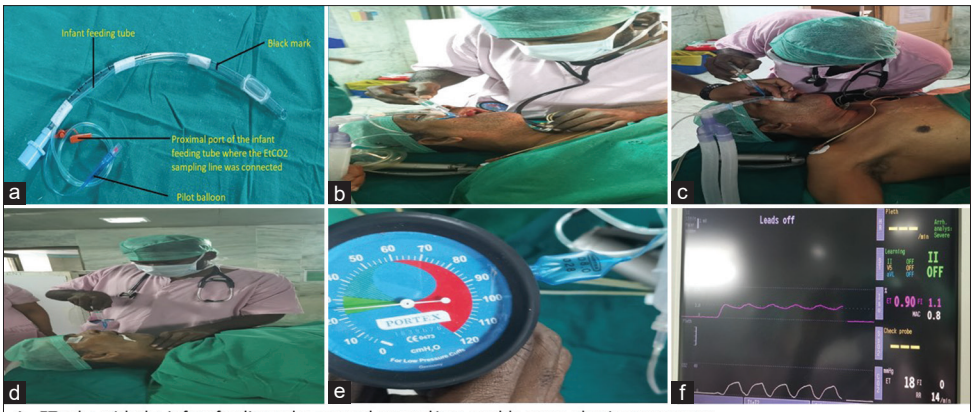
After approval from Institute Ethics Committee (JIP/IEC/2017/0439) and registration with Clinical Trials Registry of India (CTRI/2018/03/012600) (http://ctri.nic.in), enrolment of the patients began. Written informed consent was taken from 120 patients (ASA class 1 to 3 and between 18 and 60 years) posted for elective surgery under general anesthesia. Patients undergoing laparoscopic surgeries, requiring postoperative elective ventilation, preexisting laryngeal diseases, with risk of profound hypotension during surgery, for whom rapid sequence intubation is planned, patients with a high risk of aspiration (GI obstruction, Achalasia cardia, etc.) were excluded.

The preoperative assessment was done on the day before surgery. Written informed consent was sought. Appropriate fasting guidelines, premedication, and anti-aspiration measures were explained to the patient during this visit. On the day of surgery, patients were reviewed preoperatively and shifted inside the operating room. Monitors [electrocardiogram, non-invasive blood pressure, and pulse oximetry (SpO2)] were attached and the baseline parameters were noted. Portex™ ETT made of polyvinyl chloride of appropriate size with the standard radius of curvature of 14.6 cm for intubating the patient was slightly modified to allow for supraglottic capnography. An infant feeding tube was secured around the ETT, in such a way that the tip and suction ports of the infant feeding tube lie just above the black mark on the ETT as shown in Figure 1a.

The standard departmental protocol for induction and intubation was followed. The patient was intubated with the modified ETT under direct vision confirming the black mark just within the vocal cords. Intubation and data collection were carried out by a junior resident (the second author of this manuscript) who had successfully completed more than 100 intubations. This ensured that the tip of the infant feeding tube along with the sampling ports lay in the supraglottic region to be used for supraglottic capnometry. Patient was connected to the ventilator with settings: volume control mode with a fresh gas flow of 6 L/min, tidal volume of 8 ml/kg, PEEP of 5 cm H2O and with a respiratory rate of 14/min in all groups. Bilateral air entry was confirmed by five-point auscultation and the peak airway pressures were noted. The study subjects were randomized into three groups (group P, group AL, and group SG) based on a computer-generated block random number table. Sealed opaque envelopes were opened and cuff inflation technique was decided according to the particular randomized group.

In the stethoscope-guided method (group SG), the cuff was inflated while auscultating with the bell of the stethoscope (Welch Allyn Harvey™ Elite®) over the thyroid cartilage [Figure 1b]. The cuff was inflated until auscultatory leak stopped and the tube was fixed noting the depth of insertion.

In the audible leak method (group AL), the cuff was inflated while listening for an audible leak around the tube



A - ET tube with the infant feeding tube secured around it to enable supra-glottic capnometry
B - Stethoscope guided method of cuff inflation, C - Audible Leak method of cuff inflation,
D - Palpation method of cuff inflation, E - The Portex Cuff Inflator/Pressure Gauge,
F - Supra-glottic capnometry correlating with ventilator breaths

Figure 1: Materials and methods used in the study

with observer's ear as near as possible to the mouth of the patient (maximum 5 cm) depicted in Figure 1c. The inflation was stopped once the audible leak vanished and the tube was fixed noting the depth of insertion.

In the palpation method (group P), the cuff was inflated until no leak could be palpated by 3-4 fingers placed over cricoid and upper tracheal rings as shown in Figure 1d. Thereafter the tube was fixed noting the depth of insertion.

In all groups, the cuff inflation was done by 1 ml increments assessing for a leak during the inspiratory phase of controlled mechanical ventilation delivered by a ventilator. The volume required for inflation was documented. The initial cuff pressure was noted down in each method. The cuff pressure was measured using PORTEX™ cuff pressure manometer [depicted in Figure 1e].

The adequacy of the cuff seal was assessed using supraglottic capnometry by connecting the side-stream EtCO2 monitoring line to the proximal port of the infant feeding tube. This method picked up the respiratory gases present in the supraglottic region resulting out of leak around the cuff which were then sampled by side stream capnography. If any supraglottic capnometry waveform correlating with the ventilator breaths was detected [as shown in Figure 1f], further inflation in 0.5 ml increments was done till capnometry failed to detect EtCO2. An additional volume of inflated air was noted. If no supraglottic capnometry waveform was detected, deflation of cuff by 0.5 ml decrements was done until supraglottic capnometry showed minimal tracing and then reinflated just above this level to achieve zero EtCO2. The volume of air deflated from the cuff in the three groups was noted. Following this, the intra-cuff and peak airway pressures were noted again. The patient's head was maintained in neutral position throughout the study procedure. N2O free anesthesia was provided to all enrolled patients. Intraoperatively re-assessment of the leak was done if repositioning of the tube was necessary because of any unforeseen circumstance and it was documented.

Statistical analysis

A sample size of minimum 35 in each group was calculated using Open epi software, with the power of 80% and confidence interval of 95% based on the study by Borhazowal *et al.*[12] Sample size was calculated to estimate the mean difference in cuff pressures and volumes between three groups (P, SG, AL) using standard deviation (SD) of 2 ml for mean volumes and SD 12 cm H_2O for mean pressures.[12] Considering a dropout of 10%, a total of 120 patients were enrolled in the study. [Figure 2] Statistical analysis of the data was done using the software, IBM SPSS (Statistical Package for the Social Studies) Statistics for Windows, version 20 (IBM Corp., Armonk, N.Y., USA). Continuous variables were summarized using mean (SD) and analyzed using a one-way ANOVA test. Categorical variables were summarized as proportions and analyzed using Pearson's Chi-square/Fisher's exact test. Posthoc analysis was done using one-way ANOVA test whenever applicable.

Results

The baseline demographic parameters were comparable [Table 1]. The initial cuff volumes used for achieving zero-leak and intra-cuff pressures were significantly more in groups SG (stethoscope guided) and AL (audible leak guided) as compared to group P (palpation guided) ($P < 0.001$) [Table 2]. More volume was needed in group SG as compared to group AL but the difference was not significant ($P = 0.59$) [Table 2]. Further volumes needed for achieving zero-leak with supraglottic capnometry

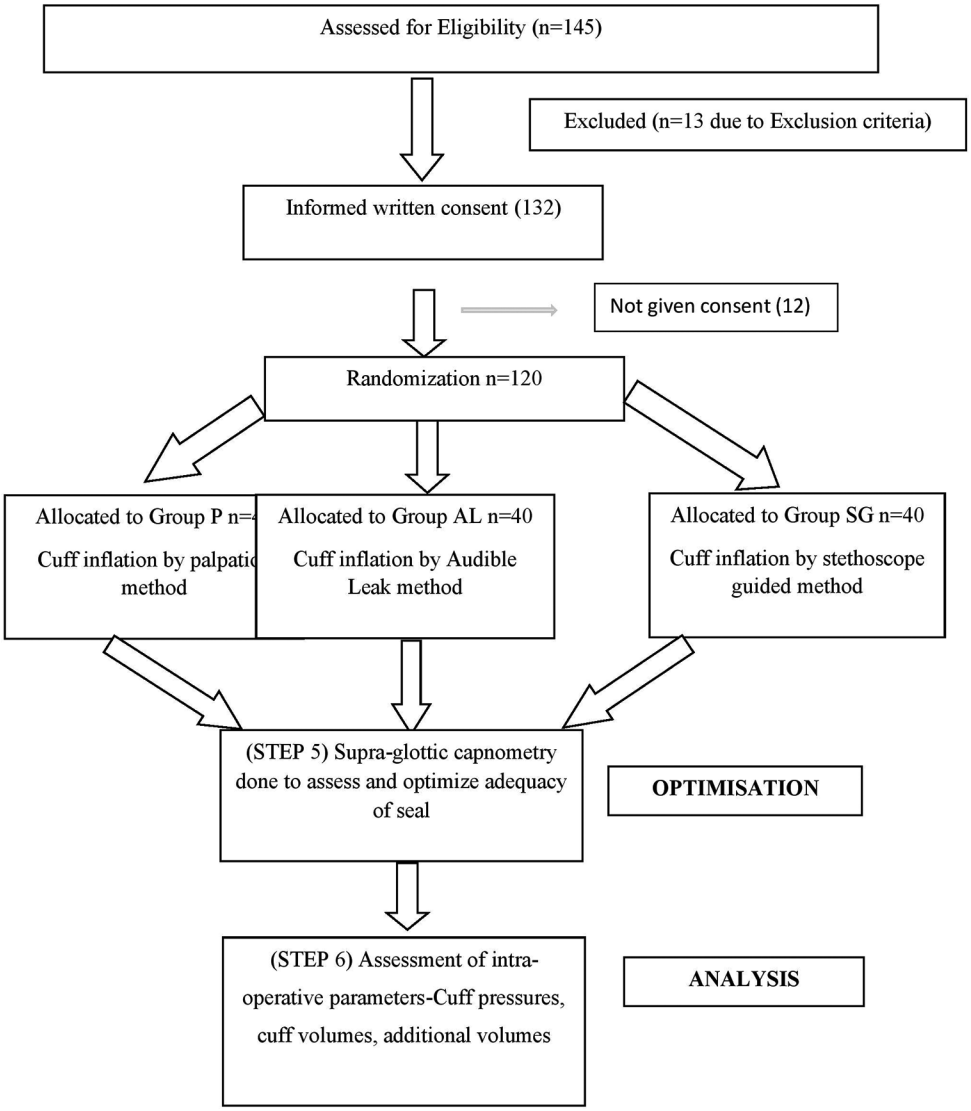


Figure 2: Flow chart

were significantly less in groups SG and AL as compared to group P (palpation guided) ($P < 0.001$) [Table 1]. Lesser volume was needed in group SG as compared to group AL but the difference was not significant ($P = 0.42$) [Table 2].

The cuff pressures reached after cuff inflation by auscultation guidance (SG) and audible leak guidance (AL) were significantly more than those after palpation guidance (P) ($P < 0.001$) but not significantly different between groups SG and AL ($P = 0.30$) [Table 2].

Discussion

Our study showed that the volumes needed to achieve cuff seal were significantly more when these were guided by either auscultation (group SG) or hearing (group AL) as compared to palpation (group P). This translated into a requirement of significantly less volumes in the groups SG and AL as compared to group P to achieve a complete seal that was confirmed by supraglottic capnometry.

We found that in most of the patients, in all three groups, there was a leak after the initial cuff inflation, shown by cyclical EtCO2 tracing correlating with the ventilator breaths. The additional volume inflated in each group had a statistical significance. Though additional volume was required to achieve adequate seal in most of the patients in all three groups, the SG and AL groups required significantly less additional volume to achieve an adequate seal than group P ($P < 0.001$). Six patients in our study did not require additional cuff volume with supraglottic capnometry method. Out of these six, five patients belonged to the SG group. This showed that inflating the ETT cuff with the SG method was more consistent in achieving adequate seal than even the audible leak method.

Table 1: Demographic parameters

Parameter	Group SG *n*=40	Group AL *n*=40	Group P *n*=40	*P*
Age in years (Mean±SD)	37.775 (14.56)	40.275 (13.609)	40.15 (15.414)	0.5966
Gender (male/female)	16/24	24/16	20/20	0.202
BMI in kg/m^2 (Mean±SD)	23.299 (3.546)	23.79 (2.768)	22.71 (3.093)	0.305
ASA Class (1/2/3)	25/14/1	26/14/0	28/12/0	0.667
ETT Size (7/7.5/8/8.5)	11/14/12/3	7/9/15/9	6/14/15/5	0.366

Table 2: Cuff volumes and pressures

Group/Parameters	Group SG (Mean+SD)	Group AL (Mean+SD)	Group P (Mean+SD)	*P*	*F*	Pair wise significance		
						SG and AL	SG and *P*	AL and *P*
Initial cuff volume (ml)	5.1±1.4	4.6±1.6	3.1±0.9	0.001*	26.8	0.59	<0.001*	<0.001*
Final cuff volume (ml)	5.9±1.6	5.9±1.9	5.3±1.3	0.214	1.6			
Additional cuff volumes required to achieve zero leak in supraglottic capnometry (ml)	0.85±1.0	1.3±1.1	2.237±0.8	<0.001*	20.9	0.42	<0.001*	<0.001*
Initial cuff pressures (cm H_2O)	25.4±6.7	22.7±5.5	16.2±3.3	<0.001*	30.0	0.30	<0.001*	<0.001*
Cuff pressures after achieving zero leak in supraglottic capnometry (cm H_2O)	31.1±8.9	28.2±6.1	25.5±6.1	0.023*	6.2	0.069	0.001*	0.096

The main aim of anesthesiologist is to prevent leak and aspiration. This can be achieved with zero EtCO2 tracing during supraglottic capnometry. We could achieve zero leak during supraglottic capnometry with least additional volume of air in SG group and a little more but comparable volumes in the AL group. Supraglottic capnometry cannot be practiced in every case; however, practically we can achieve our target more frequently with SG and AL guided methods.

In our study, the cuff pressures attained after initial cuff inflation were also significantly less in the palpatory group as compared to the other two groups. Surprisingly, the cuff pressures attained in palpatory method were below the recommended minimum value of 20 cm H2O. In the study performed by Borhazowal *et al.*,[12] the mean cuff pressure attained by SG method of cuff filling was 29.4 cm H2O. The mean cuff pressure in the audible leak group in their study was 38.80 cm H2O. This value is higher than the mean cuff pressure attained in the AL group in our study. Borhazowal *et al.* did not mention the distance from the mouth at which the audible leak was heard, whereas in our study we standardized the maximum distance as 5 cm from the mouth.[12] Also, the ambient noise would affect the efficacy of audible leak detection. These two factors might have contributed to the differences in mean pressures achieved in the AL groups.

In our study, the initial cuff pressures in SG group and AL group were in the recommended range of 20 to 30 cm H2O. But except 6 patients, others showed gas leak with the supraglottic capnometry method. This indicates the superiority of supraglottic capnometry over the cuff pressure manometer for determining adequacy of cuff seal.

Capnometry as a tool for identifying adequacy of cuff seal was first evaluated by Efrati *et al.*[16]. Efrati *et al.*[16] proposed that the capnometry sampling site was an important factor in assessing the adequacy of the cuff seal. In our study, we wanted to avoid any injury to the cords caused by the modified ETT. Hence, we chose to measure the capnometry close to the cuff, but just above the cords instead of between the cuff and the cords.

Efrati *et al.* also compared the cuff pressures attained by SG method of cuff inflation to the cuff pressures attained by the supraglottic capnometry method.[16] The mean cuff pressures in the capnometry group were lower than the cuff pressures in the SG group. On the other hand, in our study, the mean cuff pressure in SG group was lower than the cuff pressures attained after optimization by supraglottic capnometry. This could be because Efrati *et al.*[16] fixed EtCO2 >2 mmHg as a significant leak. This was based on their study on a porcine model that showed no iodine leak at EtCO2 <2 mm Hg, whereas we, in our study, considered any cyclical waveform of EtCO2 as significant leak and inflated the cuff until the cyclical waveform disappeared or supraglottic capnometry became zero. In other words, we intended to detect a leak by EtCO2 qualitatively and not quantitatively. To measure quantitatively, the area between the cords and the cuff would have been suitable for sampling EtCO2. But we wanted to avoid injury to the cord structures and hence we chose a site above the cords for EtCO2 detection. This may explain the higher cuff pressures attained in our study after optimizing by supraglottic capnometry.

We also compared the cuff pressures after optimizing to zero leak using supraglottic capnometry. Here we found a significant

difference between the SG group and the *P* group with a mean difference of 5.6 cm H2O, *P* value < 0.05. The mean cuff pressure in group SG was higher than the recommended 30 cm H2O. However, this has minimal clinical relevance as supraglottic capnometry is not commonly used to detect leaks around cuff.

Limitations

This study was solely performed in the operation theater setup for short period. Thus, the conclusions should not be extrapolated to intensive care settings. Common laparoscopic surgeries and acute intestinal obstruction patients were excluded from the study. Therefore, these methods of cuff inflation may or may not be adequate to achieve a seal in such conditions. Supraglottic capnometry should have been done in a safer manner than done in this study involving the use of two tapes that are inside patients' oropharynx.

Conclusion

Cuff inflation with the assistance of auscultation with stethoscope or listening to audible leak provides a significantly better cuff seal with the tracheal wall than the palpation-guided method. Auscultation-guided method appears to be marginally superior to the audible leak-guided method. Cuff inflation with the assistance of stethoscope and audible leak also achieves cuff pressures that are within the recommended range.

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Conflicts of interest

There are no conflicts of interest.

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