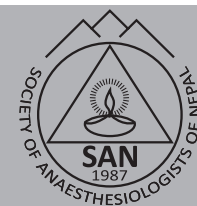
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Original Article

Comparison of endotracheal tube cuff inflation techniques by stethoscope and “just seal” method in patients undergoing surgeries under general anesthesia

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Abstract

Background: Overinflation of the endotracheal tube cuff affects tracheal mucosa blood supply that causes postoperative complications like cough, sore throat and hoarseness. There is no standard cuff inflation technique that produces appropriate cuff pressure. The aim of this study was to find out better technique of cuff inflation that will produce adequate pressure with limited complication using stethoscope guided and “just seal”.

Methods: This was prospective, randomized single blinded study of 100 American Society of Anesthesiologists Physical Status (ASA PS) I and II patients of 18-65 years undergoing elective surgery under general anesthesia requiring endotracheal intubation. Group J (n=50) received ‘just seal’ method of tracheal cuff inflation where air was introduced into cuff until audible leak at mouth disappeared and Group S (n=50) received stethoscope-guided tracheal cuff inflation where air was introduced into cuff until harsh breath sound changed to soft while listening with stethoscope bell over the thyroid cartilage. Volume of air in endotracheal tube cuff, cuff pressure following inflation and post-operative sore throat, hoarseness and cough at 24 hour were assessed.

Results: Demographic details, mean volume of air in cuff, mean cuff pressure and incidence of postoperative adverse effects like sore throat, hoarseness and cough at 24 hours between the groups were comparable.

Conclusion: Both the stethoscope guided and “just seal” cuff inflation techniques were equally effective in producing adequate cuff pressure of 20-30 cmH₂O with limited complication.

Keywords: Cough; endotracheal intubation; sore throat

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Introduction

Secure and patent airway is of vital importance in an anesthetized patient and is maintained by use of an endotracheal tube.¹ The cuffed endotracheal tube intubation provide positive pressure ventilation and prevent aspiration with the help of cuff inflation.^{1,2}

Cuff pressure must be high enough to seal the trachea for positive pressure ventilation and prevent aspiration of oropharyngeal secretions and low enough to allow adequate perfusion of the tracheal mucosa.³ A cuff pressure between 20 and 30 cmH₂O is recommended to provide an adequate seal and reduce the risk of complications.³ High-volume low-pressure cuffs were introduced in the early 1970s to enable tracheal wall pressure control.⁴ Despite the use of high-volume, low-pressure cuffs, certain patients remain at risk for cuff-induced laryngotracheal morbidity, even with short-duration anesthesia.⁴ Complications resulting from excessive cuff pressure include post-intubation tracheal pain, sore throat and hoarseness, tracheal necrosis and stenosis, tracheal perforation, vocal cord paralysis and tracheo-esophageal fistula.^{1,2} and women are more frequently affected by these symptoms. This study explores risk factors associated with postoperative sore throat and hoarseness in women following intubation. In this prospective cross-sectional study, 97 patients undergoing elective ear, nose, and throat surgery or plastic surgery were included. Eight different variables were analyzed to detect possible associations for the development of postoperative sore throat or hoarseness. For data analysis, the chi² test and the odds ratio were used. Three variables were found to be significant risk factors for postoperative sore throat: age greater than 60 years ($P = .01$

The incidence of sore throat after endotracheal intubation varies from 14.4-50%.⁵ It can lead to dissatisfaction and discomfort after surgery and can delay a patient's return to normal routine activities.⁵ Different factors have been implicated such as tracheal tube size, type of tube, cuff contours and pressure of the tube cuff, multiple attempts at endotracheal intubation, duration of intubation, and type of surgery.⁵ Excessive pressure exerted on the tracheal mucosa is an avoidable factor that has been implicated as a cause of damage after intubation of trachea with cuffed tubes.⁶

Although various cuff inflation methods have been used like palpation of pilot balloon, elimination of the leakage sound, direct measurement of endotracheal tube cuff pressure via a manometer and continuous pressure measurement, there is no standard identified in the literature addressing the method of cuff inflation or intracuff pressure maintenance in anesthetic practice.⁷ The use of a cuff pressure manometer for monitoring cuff pressure is recommended.⁸ However, it is not always routine in clinical practice. It would be helpful for clinicians to know how much air must be injected into the cuff to produce the minimum adequate pressure.⁹

The purpose of this study was to find out better technique of cuff inflation that will produce adequate pressure with limited complication using stethoscope guided and "just seal" method.

Methods

This was prospective, comparative, randomized, single blind study done in tertiary care hospital in Kathmandu. Following Institutional Review Board approval, informed written consents from patients were taken. Patients with age 18-65 years, ASA physical status I and II, undergoing elective surgery under general anesthesia requiring endotracheal intubation and duration of intubation 30-120 minutes were included. Exclusion criteria included patient refusal for consent, surgery requiring rapid sequence induction, anticipated difficult intubation, more than two attempts at intubation, laryngotracheal abnormalities and pathology, history of sore throat, cough and hoarseness, undergoing oropharyngeal surgeries and surgeries in lateral, prone and head down position.

The sample size was calculated based on the study done by McHardy et al¹⁰ taking alpha error as 1.96, beta error as 0.84 and to decrease incidence of sore throat of 50% to 30% with 80% power and 5% significant level. The sample size taken was 50 in each group.

Patients enrolled in the study were randomized into two groups (Group J and Group S) by lottery method. A box of 100 chits, 50 chits of each group were prepared by the researcher anesthesiologist. A trained staff, not involved in any part of the study, withdrew chit from the box. The anesthesiologist then enrolled the allocated patients and assigned them to intervention. Only the patients were blinded to the intervention and outcome.

Preoperative evaluations of patients were done a day before surgery. Patient was kept nil per oral of minimum six hours before surgery. On day of surgery, in the operating room, monitors (Noninvasive Blood Pressure, Electrocardiogram, and Pulse Oximeter) were attached to the patient. Intravenous access was done with appropriate size cannula. Premedication with intravenous midazolam (0.04mg/kg) and intravenous pethidine (0.75 mg/kg) were given. Pre-oxygenation was done for three minutes. Induction was done with propofol in titrating dose till verbal response loss followed by muscle relaxant vecuronium 0.1 mg/kg. Trachea was intubated with polyvinyl chloride high volume, low pressure endotracheal cuffed tubes (Mallinckrodt™ Oral/Nasal Tracheal Tube cuffed, Covidien) 7.5 millimeter internal diameter for male and 7.0 millimeter internal diameter for female patients after three minutes of assisted ventilation with oxygen and inhalation agent. Cuff was inflated by using the two methods of cuff inflation. Group J received the 'just seal' method of cuff inflation which involved connecting the tracheal tube to the anesthetic breathing circuit; the adjustable pressure limiting valve was fully closed, and oxygen was delivered to the lungs manually by slowly squeezing the

reservoir bag. During lung inflation, air was introduced with increment of 1 ml into the endotracheal cuff from a calibrated syringe connected to pilot balloon until all audible sounds from the mouth was abolished. Group S received the stethoscope-guided method of cuff inflation involved ventilation of the lungs in the same fashion as the “just seal” technique. The bell of a stethoscope (Littmann®) was placed over the right lamina of the thyroid cartilage, and air was introduced with increment of 1ml from a calibrated syringe connected to pilot balloon into the endotracheal cuff, until harsh turbulent breath sound was replaced by softly pitched sounds. The volume of air required was recorded. End tidal CO₂ monitoring was done for confirmation of tube placement. The pressure within the cuff was determined using an endotracheal tube cuff manometer (Mallinckrodt™), which measured endotracheal cuff pressure from 0 to 120 cmH₂O. The endotracheal tube was secured and connected to a mechanical ventilator. The standard general anesthetic technique was administered to all the patients. N₂O was not used during maintenance. At the end of the surgery, inhalation agent was discontinued and 100% oxygen was given to the patient. After observing spontaneous respiration, neuromuscular block was antagonized with Neostigmine 0.05 mg/kg and Glycopyrrolate 0.01 mg/kg. Oral suction was done and patient was extubated in deep anesthesia. The patient was transferred to the post-operative ward with full recovery. Post-operative sore throat, hoarseness and cough were assessed using a binary scale (yes or no) at 24 hour post operatively and recorded.

For each patient age, sex, weight, volume of air placed in endotracheal tube cuff, cuff pressure following inflation, duration of intubation which was defined as time from cuff inflation till extubation, type of surgery and post-operative sore throat, hoarseness and cough were assessed at 24 hour post operatively and recorded.

The primary outcome measure of the study was to compare incidence of sore throat post operatively at 24 hours between two groups. The secondary objectives were to compare volume of air in endotracheal tube cuff, endotracheal tube cuff pressure following inflation and post operative hoarseness and cough at 24 hours between the two groups.

Collected data were analyzed by means of statistical software SPSS 20. Independent t-test was used for continuous variables like age, weight, duration of intubation, volume of air, cuff pressure and Chi square test for proportions like sex, type of surgery, post-operative sore throat, hoarseness and cough. Overall significance level was maintained at $p < 0.05$.

Results

A total of 100 patients who met the inclusion criteria were enrolled in this study. None of the patients were excluded from the study. The details of the patients flow throughout the study have been shown in figure 1 below.

The patients in both the groups were comparable for age, weight, Female/Male ratio, ASA PS I and II and duration of intubation as shown in table 1. The types of surgery in both the groups were also comparable as shown in table 2.

Table 1: Demographic characteristics

Variables	Group J	Group S	p - value
Age (Years) (mean $\pm$ SD)	41.3 $\pm$ 11.3	39.8 $\pm$ 11.2	0.513
Weight (Kg) (mean $\pm$ SD)	56.2 $\pm$ 9.2	55.1 $\pm$ 10.1	0.563
Female/Male (Ratio)	39/11	40/10	0.806
ASA I/II(Ratio)	39/11	42/8	0.444
Duration of intubation (Minutes) (mean $\pm$ SD)	74.8 $\pm$ 24.7	72.6 $\pm$ 21.3	0.625

SD = Standard Deviation; ASA = American Society of Anesthesiologists

Table 2: Assessment of types of surgery in Group J and Group S

Types of surgeries	Group J	Group S	P- value
Abdominal	23	26	0.830
Laparoscopic	24	20	
Breast	2	2	
Orthopedic	1	2	

As shown in table 3, both groups had 14% incidence of sore throat while the incidence of cough was more in Group S (10%) than Group J (6%). However, it was not statistically significant. There was no hoarseness in both the groups.

Table 3: Assessment of incidence of postoperative sore throat at 24 hour between two groups. (Mean $\pm$ SD)

Variables	Group J No. of cases (n = 50)	Group S No. of cases (n = 50)	p-value
Sore throat	7(14%)	7(14%)	1.000

SD = Standard Deviation

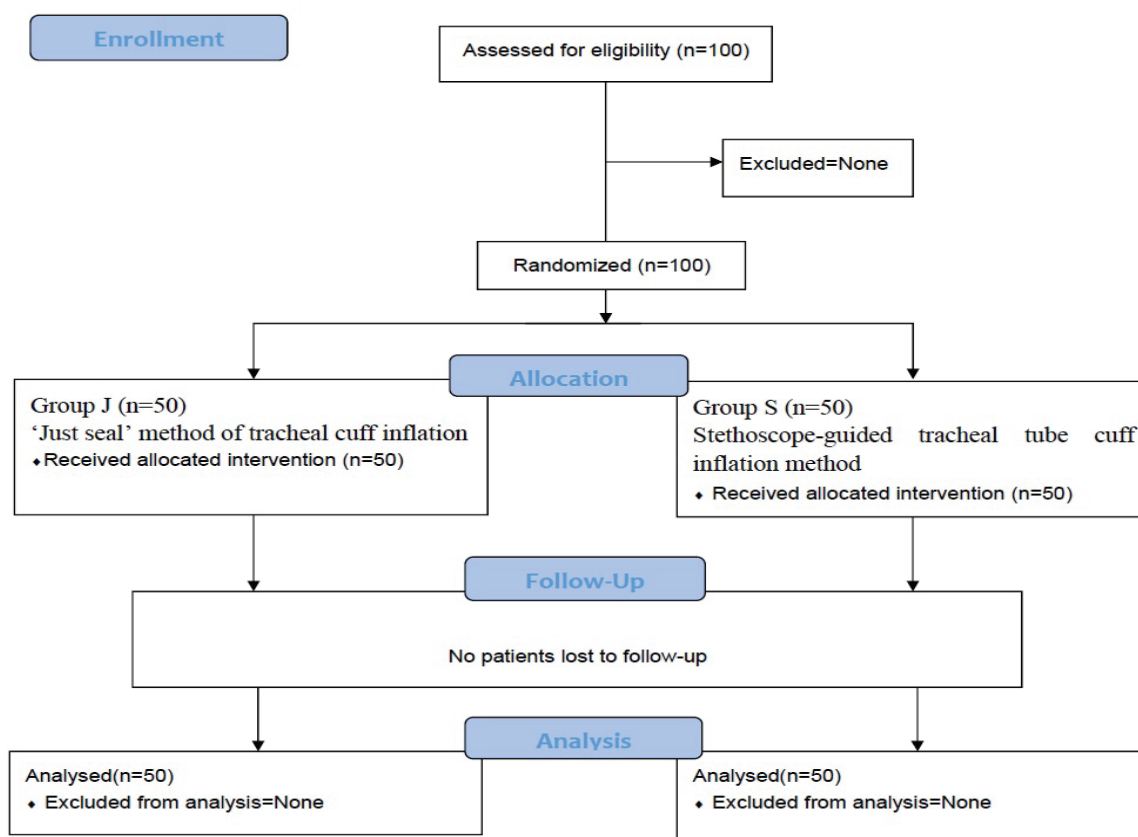


Figure 1: CONSORT 2010 Flow Diagram

Table 4: Assessment of incidence of postoperative cough and hoarseness at 24 hour between two groups. (Mean $\pm$ SD)

Variables	Group J No. of cases (n = 50)	Group S No. of cases (n = 50)	p-value
Hoarseness	0	0	
Cough	3(6%)	5(10%)	0.461

SD = Standard Deviation

There was no statistical significant difference in the volume of air placed in endotracheal tube cuff (p-value 0.095) and the cuff pressure (p-value 0.532) in both Just seal and stethoscope guided groups as shown in table 4 and 5 respectively.

Table 5: Assessment of volume of air placed in the endotracheal tube cuffs (ml) in two groups (mean $\pm$ SD)

Variable	Group J	Group S	p-value
Volume of air (ml)	4.82 $\pm$ 0.72	4.58 $\pm$ 0.70	0.095

SD = Standard Deviation

Table 6: Assessment of endotracheal tube cuff pressure (cmH₂O) in two groups (mean $\pm$ SD)

Variable	Group J	Group S	p-value
Cuff pressure (cmH ₂ O)	22.24 $\pm$ 2.16	21.96 $\pm$ 2.30	0.532

SD = Standard Deviation

Discussion

The incidence of sore throat in both Group J and Group S was 14% which was similar to the study by Christensen et al¹¹ where just seal technique was used to inflate the endotracheal tube cuff which was 14.4%. The incidence of cough in this study was more in Group S (10%) than Group J (6%), although it was not statistically significant (p 0.461). There was no hoarseness in both the groups. There were less incidences of sore throat; cough and no hoarseness in both groups in this study as endotracheal cuff pressure in all the patients were found to be the recommended range of 20-30 cmH₂O.

Studies have shown that an increase in cuff pressure leads to postoperative sore throat.^{1,2,10} Almarakbi et al study showed that with increased cuff pressure (33 cmH₂O) in just seal technique, the incidence of post intubation cuff related complications was significantly more frequent as compared with the pressure volume loop group patients

(18.25 cmH₂O).¹² Al-metwalli et al study also showed that with low cuff pressure in sealing group (20 cmH₂O) and control group (25 cmH₂O) there was low incidence of laryngotracheal complications whereas with high cuff pressure in finger group (48 cmH₂O) there was high incidence of sore throat as compared to sealing group and control group.¹³ Similarly in a study by Liu et al², the incidence of sore throat, hoarseness and blood-streaked expectoration 24 hours after extubation in study group where cuff pressure was adjusted to 20 ± 2.1 mmHg were significantly lower than in control group where no measurement of endotracheal tube cuff pressure was done. In their study, fiberoptic bronchoscopic examination showed that injury to the tracheal mucosa was more severe in the control group than in the study group ($P = 0.043$). Their study also showed that incidence of cough, sore throat, and blood-streaked expectoration increased with the increasing duration of endotracheal intubation (>180 minutes) in both group. Shorter duration of intubation (<120 minutes) in this study had also contributed for less incidences of complications.

However, a study done by Jaensson et al, found that a cuff pressure below 20 cmH₂O was associated with postoperative hoarseness.¹ and women are more frequently affected by these symptoms. This study explores risk factors associated with postoperative sore throat and hoarseness in women following intubation. In this prospective cross-sectional study, 97 patients undergoing elective ear, nose, and throat surgery or plastic surgery were included. Eight different variables were analyzed to detect possible associations for the development of postoperative sore throat or hoarseness. For data analysis, the chi² test and the odds ratio were used. Three variables were found to be significant risk factors for postoperative sore throat: age greater than 60 years ($P = .01$) The cause of hoarseness could be due to the movement of the endotracheal tube during controlled ventilation leading to irritation of the narrowest part of the airway, the vocal cords. This is more likely to occur when using an endotracheal tube with a low cuff pressure because the tube is probably not fixed in the tracheal lumen. This could be the reason why there was no hoarseness in any patients in both the groups in this study as the cuff pressure in both the group was above 20 cmH₂O.

N₂O was avoided in this study because N₂O in the inhaled mixture leads to its diffusion to inside the cuff especially when it is inflated with air, causing increase in cuff pressure and volume of cuff.¹⁴

The mean volume of air in endotracheal tube cuff in Group J was 4.82 ± 0.72 ml and Group S was 4.58 ± 0.70 ml which was comparable (p -value 0.095) in this study. Although the volume of air in study done by Kumar et al¹⁵ was higher in Just Seal group [5.4 ml (1.2)] and stethoscope guided [5.4 ml (2.0)] group than this study, it was not significant which is similar to this study. Studies by Sengupta et al⁹ and Bolzan et al¹⁶ showed similar volume of air 4.4 ± 1.8 ml

and 4.59 ± 0.45 ml respectively in the endotracheal tube cuff by just seal technique as in this study. The cuff volume in stethoscope guided in this study was less compared to studies of Almarakbi et al¹² 5 ml (4.8-5.5) and Kaki et al¹⁷, 5.26 ± 0.46 ml.

The mean endotracheal cuff pressure in Group J was 22.24 ± 2.16 cmH₂O and Group S was 21.96 ± 2.30 cmH₂O which was comparable (p -value 0.532) in this study. In study by Kumar et al¹³ cuff pressure measured in the Just seal group was significantly higher than that in the stethoscope guided group with p value of < 0.0001 which was in contrast to this study. The cuff pressure was higher in studies by Sengupta et al⁹ 35.3 cmH₂O (21.6) and Bolzan et al¹⁶ 36.78 ± 4.75 cmH₂O in just seal technique. The cuff pressure measured was higher in studies by Almarakbi et al¹⁷ 33 cmH₂O (32-35) and Kaki et al¹² 33.48 ± 3.49 cmH₂O in stethoscope guided technique.

Although the study has reached its aims, there are some unavoidable limitations. First, hemodynamic measurements of the patients at the time of cuff measurement were not recorded since severe hypotension can affect mucosal perfusion of tracheal and can affect incidence of postoperative sore throat. Second, total dose of postoperative analgesia received by the patients was not recorded as analgesia used can affect assessment of sore throat.

The study included patients undergoing elective surgery under general anesthesia requiring endotracheal intubation with duration of intubation of 30-120 minutes and age between 18-65 years. The result of the study can be applied to any patients requiring general anesthesia with endotracheal tube intubation where cuff pressure manometer is not available. With either of the cuff inflation technique, post operative sore throat can be minimized.

Monitoring of cuff pressure with cuff pressure manometer is always recommended. However, when cuff pressure manometer is not available either one of the cuff inflation techniques can be used since both techniques produced cuff pressure of recommended range and produced minimum complications.

In conclusion, both the stethoscope guided and "just seal" cuff inflation techniques were equally effective in producing adequate endotracheal tube cuff pressure with limited complication. Both techniques produced cuff pressure of 20-30 cmH₂O which was under recommended range.

Conflict of interest: The authors have filled the ICMJE conflict of interest form and have nothing to disclose.

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