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Original Research Article

Clinical Method of Estimating Endotracheal Tube Cuff Pressure with the Manometer

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Abstract

Objective: To compare the manometer method with the cuff sealing pressure method to assess the cuff pressure and study the incidence of post operative morbidity and correlate it with the duration of anesthesia. Whether existing method of assessing endotracheal cuff pressure is acceptable or a better monitoring modality (manometer) is needed for assessing endotracheal cuff pressure.

Methods: Hundred ASA grade 1, 2 or 3 adult patients of either sex scheduled to undergo elective surgeries under general anesthesia requiring endotracheal intubation were enrolled for the study. They were randomly divided into two groups (N= 50 in MM as well as the CSP group In MM group the cuff pressure was regulated by using the manometer and in CSP group by the clinical auscultation and recording the cuff pressure at the end of each hour. The incidence of post operative respiratory complications were assessed in the PACU and 24 hours post operative. The post operative respiratory complications were quantified according to the scoring system.

Results: Oxygen and nitrous oxide mixture is most suitable for inflation of endotracheal tube cuff as it maintains stable intra cuff pressures throughout the surgery. Excessive intra cuff pressures increases the incidence of laryngotracheal morbidity. Keeping the intracuff pressures within normal limits is very important aspect of maintaining general anesthesia with endotracheal tube intubation.

Conclusion: The two methods – cuff sealing pressure and manometer method are both equally effective in maintaining the intra cuff pressure to the prescribed limits. Ideally all patients who have been intubated should have cuff pressure monitoring. Because of the cost involved, it may not be possible to have a cuff pressure monitor in every operating room. Our study seems to suggest that the Cuff Sealing Pressure Method which requires no equipment may be quite effective in maintaining intra operative cuff pressure.

Keywords: Laryngotracheal Morbidity, Cuff Sealing Pressure Method.

Introduction

Endotracheal intubation remains the gold standard for securing the airway in patients prone to aspiration risk. The cuff of an endotracheal tube facilitates positive pressure ventilation and protects the airway from aspiration. However among the hazards inherent to the use of cuffed endotracheal tube is the damage inflicted to the trachea by an over inflated cuff [1] The cuff volume and intra cuff pressure increase due to nitrous oxide diffusion into the cuff when air is used to fill the cuff for satisfactory initial sealing [2] The tracheal mucosa becomes ischemic when the pressure exerted by the endotracheal tube cuff exceeds capillary perfusion pressure. This may lead to postoperative discomfort in the form of sore throat and hoarseness with incidence as much 15-60% [2.3.4]. Sometimes it may lead to more serious complication such as acute tracheal rupture, exsanguinating hemorrhage or development of tracheal stenosis and tracheal fistula [2]

The optimal method of monitoring endotracheal cuff pressure is yet a matter of debate. Although the use of a manometer would be ideal-but lack of widespread availability and convincing evidence that it is essential have prevented its adoption as standard of care. Many studies have also put forth the use of clinical methods to decide the cuff pressure in absence of a manometer. There are two methods of clinically assessing cuff pressure – manual palpation of pilot bulb and use of sealing volume of cuff (checked by auscultating for leak and preventing it at end inspiration with inflation pressure capped at 20 cm H_20).

We decided to conduct this study to compare the manometer method with the cuff sealing pressure method to assess the cuff pressure in patients anaesthetized using N_2O. By studying the incidence of relevant post operative morbidity and correlating it with the duration of anesthesia, we want to conclude whether our existing method of assessing endotracheal cuff pressure is acceptable or a better monitoring modality (manometer) for assessing endotracheal cuff pressure the need of the hour.

Materials and Methods

A thorough preoperative evaluation of each patient will be done. All routine biochemical, hematological and radiological investigations will be done. After obtaining written and informed consent, the patients will be randomly allocated into one of the two groups by the sealed envelope method:

Group I (Cuff seal pressure; CSP): Patients will be intubated and the endotracheal cuff will be inflated using the minimum amount of anaesthetic mixture of O_2+N_2O(50:50) to stop an audible auscultatory leak with the inflationary pressures capped at 20 cm H_2O.

Group II (Manometer method; MM): Patients will be intubated and the cuff will be inflated with the volume of anaesthetic mixture of O_2+N_2O (50:50) required to produce a cuff pressure of 25 cm H_2O.

Monitoring: The important parameters to be monitored during intra-operative period will consist of: Pulse, Blood Pressure, Electrocardiogram, Oxygen saturation, End Tidal CO_2 and End Tidal agent concentration as per standard institutional protocol.

Study Area: Batra Hospital and Medical Research Centre, New Delhi (A Tertiary Care Center and a multispeciality centre). It is a 400 bedded hospital with intensive care units.

Inclusion criteria: After approval by the Hospital Ethics and Thesis Committee, one hundred adult patients of either sex, of ASA status I, II or III, undergoing elective surgeries under General Anesthesia with

endotracheal intubation will be studied in this randomized study protocol.

Exclusion criteria:

Pregnant or lactating females

Patients with emergency intubations, difficult intubations or multiple attempts at intubation

Patients with higher risk for aspiration(e.g., full stomach, history of Gastro-esophageal reflux, etc.)

Patients with known anatomical laryngo-tracheal abnormalities

Patients with ASA physical status grade > 3

Obese patients (BMI>30)

Patients requiring nasogastric tube insertion

Sample Size and Sample Technique: 100 patients

Methodology: General anesthesia will be induced by intravenous bolus of induction agent, and paralysis will be achieved with a non-depolarizing muscle relaxant. Male patients will be intubated with an 8 or 8.5 mm internal diameter endotracheal tube, and female patients will be intubated with a 7 or 7.5 mm internal diameter endotracheal tube. This is a standard practice at our hospital. Patients who will be intubated with sizes other than these will be excluded from the study. Anesthesia will be maintained with a mixture of oxygen and nitrous oxide (50:50) along with isoflurane. We will record endotracheal tube size and morphometric characteristics including age, sex, height, and weight.

In the manometer group (MM), the cuff will be progressively inflated by injecting air in 0.5-ml increments until a cuff pressure of 25 cm of H2O will be achieved. We will note the total volume required to achieve the desired cuff pressure using a manometer that will be connected to the pilot balloon of the endotracheal tube cuff through a 3-way stop cock(to prevent the drop in cuff pressure that may occur with detaching and reattaching the manometer.

In the CSP group, an anesthesia provider will insert the endotracheal tube, and the incubator or the assistant will inflate the cuff using the minimum volume of gas mixture(50% O_2+50% N_2O) required to stop an audible leak on auscultation at an inflationary pressure capped at 20 cm of H_2O. An independent investigator will measure the cuff pressure at the time of initial cuff inflation. If the pressure is greater than 40 cm of H_2O at any stage, the pressure would be adjusted between 20-30 cm of H_2O and patient will be excluded from the study.

In both the groups, the cuff pressure will be measured every hour by an independent observer .In the MM group, at each such measurement the pressure would be adjusted to 25 cm of H_2O. In the CSP group, every hour the cuff would be deflated after oral suction and reinflated with the minimum amount of anesthetic gas mixture to obviate the seal. An independent observer would note the cuff pressure by manometer.

CSP Group

(a) Volume of anaesthetic gas mixture injected to eliminate air leak by auscultation.

(b) Cuff Pressure will be measured by aneroid manometer in group 1 (CSP group) and noted every hour.

MM Group

(a) Volume of anaesthetic gas mixture injected to achieve desired cuff pressure.

(b) In MM group cuff pressure will be checked every hour with manometer and adjusted to 25 cmH_2O if cuff pressure is outside 20-30 cmH_2O range.

(c) Leak is present or not in Group 2 (MM group) will be noted. If a leak is found, the cuff pressure will be checked. If within 20-30 cm of H_2O,the minimum increase of cuff

pressure that will stop the leak will be noted.

Postoperative respiratory complications - cough, sore throat , hoarseness and blood stained secretions will be assessed at the time of transfer from PACU and then at 24 hours post operative and quantification of post operative problem

Observation Chart

Table 1: Duration of surgery

Group	N	MEAN±SD	Range	P Value
MM	50	129.60±58.92	90-300	
CSP	50	127.80±46.79	90-300	0.87

Base line preoperative hemodynamic parameters:

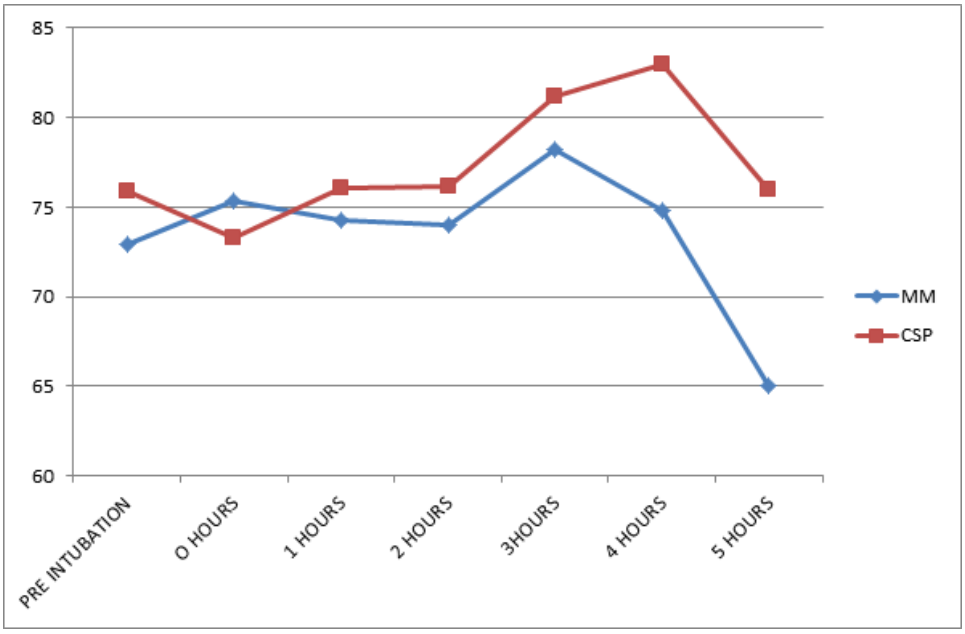

Figure 1: Line Diagram for Mean heart rate at different time intervals

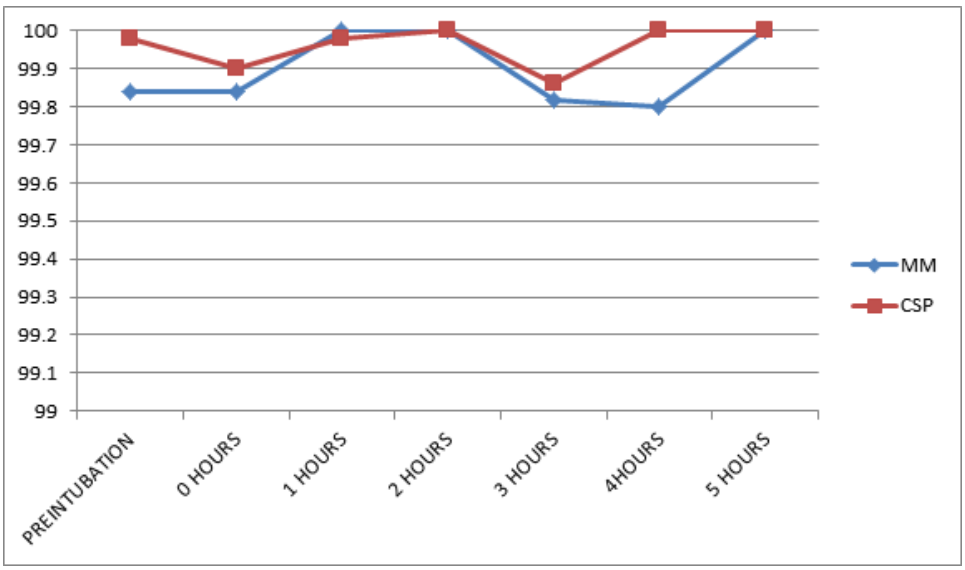

Figure 2: Line Diagram for Mean SPO_2 at different time intervals

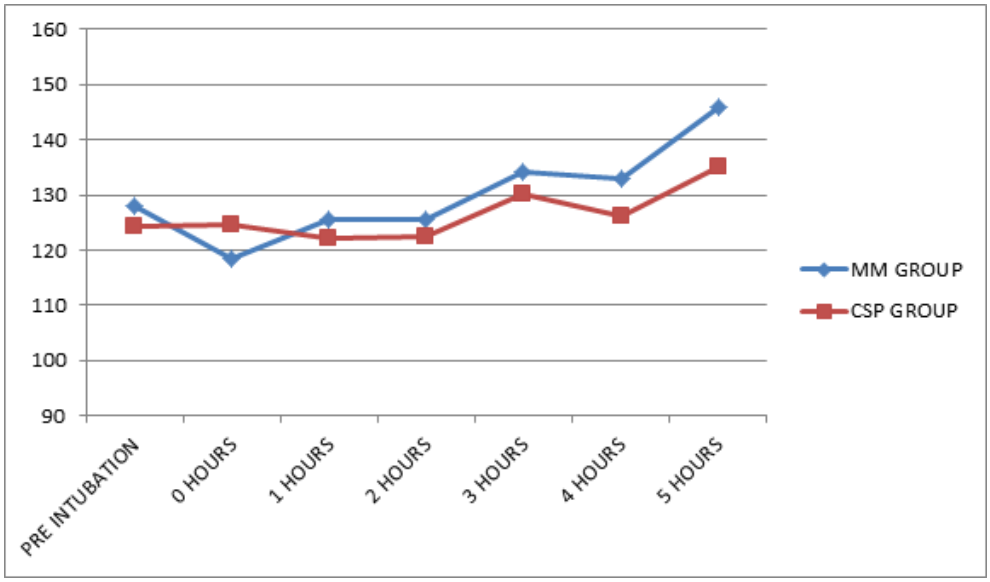

Figure 3: Line Diagram for Mean systolic blood pressure at different time intervals

Table 2: ETT size in patients

Group	ETT Size Females				ETT Size Males			
	7.0		7.5		8.0		8.5	
	Frequency	%	Frequency	%	Frequency	%	Frequency	%
MM	19	38	04	08	19	38	08	16
CSP	19	38	05	10	18	36	08	16

Table 3: Mean cuff pressure at different time intervals

Cuff Pressure	MM Group		CSP Group		P Value
	MEAN±S.D.	RANGE	MEAN±S.D.	Range	
0 Hours	25.66±0.92	22-30	26.08±1.52	20-30	0.10
1 Hours	25.44±0.99	23-29	25.7±1.47	22-30	0.30
2 Hours	25.51±1.32	22-30	25.62±1.05	22-30	0.67
3 Hours	24.33±1.53	24-30	25.23±0.93	22-30	0.06
4 Hours	25±0.71	22-30	27±1.41	22-29	0.27
5 Hours	25±0.56	22-30	26.5±2.12	20-30	0.08

Table 4 Volume of gas mixture injected at the time of intubation

Group	Volume of Gas Mixture Injected (Ml)					
	3.0 ML		3.5 ML		4.0 ML	
	Frequency	%	Frequency	%	Frequency	%
MM	9	18	25	50	16	32
CSP	17	34	12	24	21	42

Table 5 A: Table for incidence of cough

	MM				CSP			
Cough	PACU		24 HRS		PACU		24 HRS	
	NO. OF PTS	%	NO. OF PTS	%	NO. OF PTS	%	NO. OF PTS	%
Absent	37	74	47	94	38	76	47	94
Mild	11	22	3	6	10	20	3	6
Moderate	2	4	0	0	2	4	0	0
Severe	0	0	0	0	0	0	0	0

Table 5 b: Table for incidence of sore throat

	MM				CSP			
Sore Throat	PACU		24 HRS		PACU		24 HRS	
	NO. OF PTS	%	NO. OF PTS	%	NO. OF PTS	%	NO. OF PTS	%
Absent	43	86	47	94	44	88	46	92
Mild	7	14	3	6	6	12	4	8
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

Table 5c Table for incidence of hoarseness

	MM				CSP			
Hoarseness	PACU		24 HRS		PACU		24 HRS	
	NO. OF PTS	%	NO. OF PTS	%	NO. OF PTS	%	NO. OF PTS	%
Absent	49	98	49	98	47	94	48	96
Mild	0	0	1	2	2	4	2	4
Moderate	1	2	0	0	1	2	0	0
Severe	0	0	0	0	0	0	0	0

Table 5 d: Table for incidence of post operative bloody secretions

	MM				CSP			
Bloody Secretions	PACU		24 HRS		PACU		24 HRS	
	NO. OF PTS	%	NO. OF PTS	%	NO. OF PTS	%	NO. OF PTS	%
Absent	49	98	50	100	49	98	50	100
Mild	1	2	0	0	1	2	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

Results

Both the groups were statistically similar regarding the demographic profile of the patients and the duration of anesthesia. The intra operative course and recovery was uncomplicated in all the patients. The duration of anesthesia was statistically similar in both the groups and ranged from 90 minutes to 300 minutes. The mean intubation time was 129.60±58.92 minutes in MM Group and 127.80±46.79 minutes in CSP Group. The mean duration of surgeries was comparable in both and there was no statistically significant difference between the two groups. There was no significant difference between the 2 groups with respect to mean Systolic Blood Pressure (SBP) Mean Diastolic Blood Pressure (DBP), Mean Blood Pressure (MBP) & Mean Heart Rate (HR) preoperatively.

The endotracheal tube cuff pressure was noted in both the groups at end of each hour. The difference in the mean cuff pressure values in both the groups was statistically insignificant .3.0 ml of gas mixture was required in 18% and 34 % in MM and CSP group respectively. Comparing the two groups, more number of patients(42 %) required injection of 4 ml of gas mixture to achieve cuff seal whereas only 32 % required injection of 4 ml of gas mixture in MM group. Maximum number of patients(50%) achieved cuff seal with injection of 3.5 ml of gas mixture in the MM Group as compared to 24 % in CSP group.

Volume of gas mixture injected at the time of intubation – In the MM group,3.5 ± 0.18 ml was injected during the first hour while in the CSP Group 3.52±0.36 ml of gas mixture was injected at the time of intubation. The P value is found out out to be 1.00. Thus the difference in volume of gas mixture injected was statistically insignificant in both the groups.

74 % patients had no cough in MM Group as compared to 76 % in CSP Group.22% had mild cough in MM Group and 20 % complained of mild cough in CSP Group. Incidence of moderate cough was 4 % in both the groups. No patient had severe cough as a complication in PACU.94 % patients did not complain of cough in both the groups whereas 6 % had mild cough at that time. None of the patients complained of moderate or severe cough. From the above observations.it is obvious that there was no significant difference in the incidence of cough between the two groups.

In MM Group, 7 patients(14 % of the patients) complained of mild sore throat in PACU which reduced to 3 patients(6 %) 24 hrs post op.In CSP Group, 6 patients(12 %) had mild sore throat in PACU and 4 patients(8 %) 24 hrs post op.2 patients(4 %) had complains of moderate sore throat in PACU. Moderate and severe sore throat was not complained in both the groups. From the above observations, it is clear that there is no significant difference in the incidence of sore throat between the two groups.

In CSP Group, 3 patients(6%) had hoarseness in PACU out of which 4 % had mild hoarseness and 1 patient(2 %) had moderate hoarseness . 2 patients (4 %) had hoarseness in 24 hrs post op and it was mild in nature.No patient had severe hoarseness in our study.From the above observations, it is clear that there is no significant difference in incidence of hoarseness between the two groups.

98 % patients had no bloody secretions in both the groups in PACU. 2 % of the patients had mild bloody secretions in both the groups. Moderate and severe bloody secretions was not complained. None of the patients complained of bloody secretions 24 hour post operatively. From the above observations, it is clear that the incidence of bloody secretions has no significant difference between the two groups.

Statistical Analysis:

Statistical testing will be conducted with the statistical package for the social science system version SPSS 17.0. Continuous variables will be presented as mean±SD or median if the data is unevenly distributed. Categorical variables will be expressed as frequencies and percentages. The comparison of continuous variables between the groups will be performed using Student's t test. Nominal categorical data between the groups will be compared using Chi-squared test or Fisher's exact test as appropriate. Non-normal distribution continuous variables will be compared using Mann Whitney U test. For all statistical tests, a p value less than 0.05 will be taken to indicate a significant difference.

Discussion

Inflation and measurement of endotracheal (ET) tube cuff pressure is often not seen as a critical aspect of care in surgical patients. [5] The morbidity associated by an overinflated cuff has been regularly highlighted in literature, for example mucosal ulceration and vocal cord paralysis Grant T et al did a review on current methods for endotracheal tube cuff inflation and whether they create pressures above the recommended range .Their article outlines techniques for the methods of inflation based on the latest scientific evidence. The author will seek to examine if intra-operative cuff assessment and monitoring should become routine for the anaesthetic practitioner and if current practice for inflating cuffs creates pressures outside the safe range. [6]

Al-Metwalli RR et al did a comparative study on sealing cuff pressure & sought an

easy, reliable and safe technique for endotracheal tube cuff inflation. They compared the three common methods of endotracheal tube cuff inflation (sealing pressure, precise standard pressure or finger estimation) regarding the effective tracheal seal and the incidence of post-intubation airway complications. Tracheal leaks, incidence of sore throat, hoarseness and dysphagia were tested. Cuff pressure was significantly low in the sealing group compared to the control group ($P<0.001$), the incidence of sore throat was similar in both groups. On the other hand, cuff pressure as well as the incidence of sore throat were significantly higher in the finger group compared to both the control and the sealing group ($P<0.001$ and $P=0.008$). The incidence of dysphagia and hoarseness were similar in the three groups. None of the patients in the three groups developed air leak around the endotracheal tube cuff. In N_2O, free anesthesia sealing cuff pressure is an easy, undemanding and safe alternative to the standard technique, regarding effective sealing and low incidence of sore throat. [7]

The Endotracheal Tube (ETT) cuff performs a critical function of sealing the airway during positive pressure ventilation. There is a narrow range of cuff pressure required to maintain a functionally safe seal without exceeding capillary blood pressure.Many of the complications related to prolonged ventilation are related to inappropriate handling of endotracheal tube (ETT) cuff. Das S et al did comparison of minimal leak test and manual cuff pressure measurement technique method for inflating the endotracheal tube cuff. [8] This article by Efrati S et al reviews the possible complications associated with the ETT cuff, and the landmark development made in that field. The article challenges the present paradigm of cuff use and reviews the current clinical practice in that area. Borhazowal R et al did similar study by comparing between two endotracheal tube cuff inflation methods; just-seal vs. stethoscope-guided. [9] Statistically significant difference (p-value of less than 0.05) was noted between the two methods based on the volume of air injected into the cuff .ETT cuff inflation guided by a stethoscope is an effective technique for ensuring appropriate cuff pressures thus accomplishing the objective of providing safe and superior quality care of the patient both during and after anaesthesia and reducing the likelihood of even minimal risk complications that may still have legal implications. [10]

Zanella A et al studied about the fluid leakage across tracheal tube cuff, effect of different cuff material, shape, and positive expiratory pressure [11]

we compared the effect of different cuff materials (PVC, polyurethane, and guayule latex), shapes (cylindrical, conical), and positive end expiratory pressures (PEEP) in reducing fluid leakage across the cuff. They compared fluid leakage across a cylindrical double-layer guayule latex prototype cuff, three cylindrical PVC cuffs .The guayule latex cuffs always prevented fluid leakage; the polyurethane and PVC cuffs required incremental levels of PEEP to prevent fluid leakage ever-present at zero PEEP.

Sole ML et al did a pilot study on assessment of endotracheal cuff pressure by continuous monitoring. Cuff pressure is measured and adjusted intermittently. Values obtained with the cufflator-manometer and the transducer were congruent. The cuff pressure was high in 16% of measurements and low in 30%. No statistically significant changes over time were noted. Endotracheal suctioning, coughing, and positioning affected cuff pressure. Continuous monitoring of cuff pressure is feasible, accurate, and safe. Cuff pressures vary widely among patients.

Overinflation into the bronchial cuff causes damage to the tracheobronchial mucosa, whereas underinflation leads to an incomplete collapse of the nonventilated lung or incomplete ventilation of the

ventilated lung. Yamada Y et al did a prospective randomized controlled study on comparison of the required bronchial cuff volume obtained by 2 cuff inflation methods, capnogram waveform-guided versus pressure-guided. The lowest cuff volume providing an air-tight bronchial seal was obtained by the capnogram waveform–guided bronchial cuff inflation method. Since the cuff volume required to achieve an air-tight seal decreases after opening the chest, readjustment of the bronchial cuff volume to prevent bronchial cuff damage to the tracheobronchial mucosa after opening the chest may be advisable.

There is a correlation between endotracheal cuff pressure and airway complication; therefore, cuff pressure measurement is of an essential importance. The gold standard technique is measuring the cuff pressure by a calibrated manometer. However, there are several methods that injects air into balloon pilot and measures the cuff pressure. Stewart SL et al did comparison of endotracheal tube cuff pressures using estimation techniques and direct intracuff measurement. Sanaie S et al did comparison of tracheal tube cuff pressure with two technique: fixed volume and minimal leak test techniques. Both techniques cause above normal intracuff pressure; however, MLT produces more acceptable pressure than fixed volume. It seems that the volume of 10 cc produces high pressures; therefore, fixed values may yield more appropriate results in lower volumes.

Conclusion

There is no standard found in the anesthesia literature that addresses endotracheal tube cuff inflation techniques, although various estimation techniques are in use. This study and the limited data in the literature suggest that estimation techniques are inadequate for determining cuff pressures. The literature clearly delineates the morbidity associated with overinflation or underinflation of cuffs. The use of manometers in practice is strongly recommended.The present study was conducted to compare the efficacy of a clinical method of estimating endotracheal tube cuff pressure with the manometer method and compare the incidence of post operative respiratory complications in the two groups.

Declarations:

Funding: None

Availability of data and material: Batra Hospital and Medical Research Centre, New Delhi

Code availability: Not applicable

Consent to participate: Consent taken

Ethical Consideration: There are no ethical conflicts related to this study.

Consent for publication: Consent taken

What this Study Add to Existing Knowledge

Complaints ranging from a minor throat irritation to debilitating pain, inability to swallow and temporary voice changes are a frequent observation on the postoperative visit. Whilst seldom delaying discharge, these complaints nevertheless affect patient satisfaction and may well effect their activities after leaving hospital. In a small number of cases, pharyngo-laryngeal injury may take months to recover and may even be permanent. For this reason, follow-up of minor complaints should be considered an essential component of the postoperative visit, as timely referral and intervention may prevent irreversible damage.

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