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A COMPARATIVE STUDY BETWEEN MANUAL VERSUS MONITOR GUIDED INSUFFLATION OF ENDOTRACHEAL TUBE CUFF IN PROLONGED SURGERY –A PROSPECTIVE RANDOMIZED SINGLE BLIND STUDY

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ABSTRACT

Introduction: By using CETT, the objective is to create a seal between the trachea and the cuff that is both sufficiently strong to avoid aspiration and not so strong as to obstruct tracheal blood flow. According to several studies, the optimal ETT cuff pressure should be in the range of 25 to 40 cm of H2O.

Aims: Comparing the pressure of an endotracheal tube cuff that is manually inflated with any amount of air to one that is insufflated by a specialized monitor that is aiming for a preset level of pressure.

Materials & Methods: This investigation was prospective, single-blind, randomized, and prospective. This study was carried out at the Different OT Complex, Medical College & Hospital, Kolkata, from November 1, 2014, to October 31, 2015. This research covered 45 patients in total.

Result: The two groups were statistically similar in terms ofdistribution of ASA physical status grading($p>0.05$). The two groups were statistically similar in terms of Mallampati Score distribution ($p>0.05$). Graph 11B shows post operative complication in 2nd24 hours was not statistically significant[$p>0.05$].

Conclusion: In order to prevent tracheal damage, the ETTc pressure assessed by clinical judgement is frequently substantially higher than the suggested levels. This study also showed that using a manometer to properly manage ETTc pressure can help lower the risk of problems linked to postprocedural endotracheal intubation, especially in short operations.

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Keywords: Manual vs. monitor-guided endotracheal tube cuff insufflation, Endotracheal cuff pressure management prolonged surgery, Cuff insufflation techniques in prolonged surgeries and Cuff pressure monitoring in anesthesia.

INTRODUCTION

Anaesthetists often manage CETA in their practice. Despite the use of a variety of cuff inflation procedures, no accepted standard for cuff inflation or intracuff pressure management in anesthetic practice has been found in the literature.

By using cETT, the objective is to create a seal between the trachea and the cuff that is both sufficiently strong to avoid aspiration and not so strong as to obstruct tracheal blood flow. According to several studies, the optimal ETT cuff pressure should be in the range of 25 to 40 cm of H2O.Although there isn't a set amount, experts agree that a maximum cuff pressure of 25 to 40 cm of H2O is appropriate [1].This pressure limit is determined in part by the capillary blood pressure supplying the trachea, which is approximately 48 cm of H2O [1]. When pressure from the hyperinflated cuff presses on the tracheal wall more than the pressure in the capillary blood supply, ischemia and stenosis of the tracheal mucosa result. Diminished perfusion to the trachea may occur from an intracuff pressure higher than 34 cm of H2O. [2] whereas total obstruction of the tracheal blood flow occurs at approximately 50 cm of H2O [3]. Using a large volume, low pressure cuff 3 is linked to a lower incidence and severity of tracheal damage when the pressure is less than 34 cm of H2O.At the cuff location, tracheal blood flow is decreased by 75% even at 27 cm of H20.

At the point where the cuff and trachea meet, pathological alterations brought on by overinflation of the cuff include ischemia, inflammation, ulceration, granulation, and stenosis1.Furthermore, when the ETT cuff pressure is raised, there is a correlation with postoperative sore throat [4].

With the widespread use of low pressure, high volume cuffs, the catastrophic effects of overinflating an ETT cuff—such as tracheal rupture, tracheal carotid artery erosion, and tracheal innominate artery fistulas—are becoming less common. Nonetheless, ischemia of the oropharyngeal and tracheal mucosa can contribute to post-intubation sore throat, a typical side effect of general anesthesia, and cuff-related tracheal damage continues to be the most prevalent cause of non-malignant tracheoesophageal fistula [5].

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MATERIALS AND METHODS

Study area

Different OT complex, Medical college & Hospital, Kolkata.

Study period

1st NOV 2014 to 31st OCT 2015

Definition of problem

Endotracheal tube cuff pressure comparison between manual versus monitor guided insufflation and their consequences.

Study Population

Patients aged between 18-65 yrs ,ASA status I-III, scheduled for primary elective and emergency surgery under general anaesthesia would be included in the study and all would given written consent to participate in this prospective randomised trial.

Study Variables

- Baseline Endotracheal tube cuff pressure
- Endotracheal tube cuff pressure changes with duration of surgery.
- Post operative complication like cough, sore throat, horseness, blood streaked expectoration

Inclusion Criteria

- Patients with ASA physical status I to III
- Age between 18 to 65 years of either sex
- Patients who are eligible and give consent to perform in the study for elective or emergency surgery under general anaesthesia lasting more than 2 hrs.

Exclusion Criteria

- Patients refusal\

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- Suspected difficult airway
- Risk factors for perioperative aspiration
- Pregnancy and lactation
- Morbid obesity
- Chronic coughing
- Uncontrolled hypertension
- Uncontrolled diabetes mellitus
- Recent history of respiratory tract infection
- Chronic obstructive pulmonary disease
- Surgery less than 2 hrs

Sample Size

One hundred(100) patients, randomly devided into two groups each consisting of fifty(50) patients by computer generated random number.

Sample Size Calculation

Sample size chosen for the study was based on a pilot study of 10 cases done in the preliminary stage following which the result showed that 45 patients would be required in each group assuming a drop out of 10%(recruited 50 patients in each group)to find a significant differences [20%] of cuff pressure measured in two groups with a power of 80% and alpha(a) error of 0.05.

Sample Design

A prospective, randomised, single-blind study

Randomization And Single Blinding

100 Consecutive patients scheduled for elective and emergency surgery under GA will be included in this study, the patients will be randomly assigned to receive either manual inflation of cuff as judged by anaesthesiologist or inflation of pilot balloon with air at a cuff pressure upto 25 cm of H2O .Randomization would be done by a computer generated random number.

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Ideally a double blind study would demand that both the person inflating the ET tube cuff and the person monitoring the cuff pressure would be blinded to the group in which patient would be allotted. However in this case, person who would be inflating ET tube cuff with the help of a cuff pressure monitor would automatically know the patient in which group he/she belongs. Therefore this study would be single blind as the person who would monitor subsequent cuff pressure would not know the group allocation of individual patients.

Procedure

After obtaining institutional ethics committee approval and written informed consent from total 100 patients, aged between 18 to 65 years of either sex, belonging to American Society Of Anaesthesiologists (ASA) physical status I to III undergoing elective or emergency surgery under general anaesthesia lasting more than 2 hrs were considered for this study. Patients refusal, suspected difficult intubation, risk factors for perioperative aspiration, pregnancy, morbid obesity, chronic coughing, uncontrolled hypertension, uncontrolled diabetes mellitus, recent history of respiratory tract infections were excluded from this study. The patients were randomly allocated into two groups comprising of 50 patients each.

In group M:50 Patients would have their ETT Cuff manually inflated by injecting air with a syring by an anaesthesiologist and pressure of the cuff would be checked initially & half hourly till the completion of surgery by a separate anaesthesiologist who does not know the study group. Volume of air that will be required to inflate the ET cuff by palpation of pilot ballon will be solely at the discretion of attending anaesthesiologist. Cuff pressure of those cases ,above 50 cm of H20 & below 20 cm of H20 would be excluded from this study for ethical reason but percentage of cases would be calculated.

In group C:50 patients would have their ETT cuff inflated by cuff pressure monitor at a cuff pressure upto 25 cm of H20 and it would be maintained at that pressure level throughout surgery. Cuff pressure would also be monitored in this group half houry and if changes make it to the base line pressure.

High volume, low pressure cuff single use oral ETT [paramount surgimed, new delhi, India]with internal diameter 7.0-8.5 mm would be used in all patients. This ETT cuff pressure would be measured by highly sensitive and accurate cuff pressure aneroid manometer [portex medical ;Germany]

Techniques Of Anaesthesia

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After induction of anaesthesia with inj. propofol and administration of Inj. vecuronium , oral endotracheal intubation would be done with appropriate sized high volume low pressure endotracheal tube in all patients . Maintainance of anaesthesia is done by N2O :02 and fluorinated volatile agent [sevoflurane] and intermittent dose of Inj. vecuronium. Volume of air to inflate the cuff would be recorded in manual cases .

Outcome Measure

- Primary outcome measure would be comparison of cuff pressure when ETT cuff is inflated manually versus monitor guided method.
- Secondary outcome measure would be whether these changes in cuff pressure monitoring make any differences in post operative complication like sore throat, cough, horseness, or other upper airway complication.

Peri Operative Monitoring

- Preoperative: Age, Sex, Weight, Height, ASA grade of the patient, MPS of the patients, Clinical examination, Airway examination of the patients.
- Intraoperative: Air volume required to inflate the cuff,pressure changes at half hour interval ,duration of surgery, maintainance of anaesthesia.
- Postoperative: Any complication such as cough, sore throat. Horseness, blood streaked expectoration.

Statistical Analysis

The analysis was performed using SPSS 14.0(Tongji university ,Shanghai, China).The data obtained were entered into the data bank and checked for use. To test the normality of the distribution of the continuous variables, the Shapiro-wilk statistic would be performed. Normally distributed data ,at each time ,would be analyzed with two tailed unpaired students t test and expressed as means and standard deviation. Non normally distributed variables would be evaluated with the Mann-Whitney U test, and expressed as medians and 25^{th} to 75^{th} percentiles. Catagorical data would be analyzed with chi-square test or fishers test, as appropriate. A p value less than 0.05 would be considered significant.

Patients Consent

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Apart from hospital consent form applicable for all anaesthetic procedures, a separate study consent form will also be used for this study.

RESULTS

Table 1: distribution of ASA physical status of patients in both the groups

ASA grade		
Group	**I**	**II**
Group C	31	19
Group M	34	16

Table 2: distribution of mallampati score of patients in both the groups

MPS			
Group	**I**	**II**	**III**
Group C	37	13	0
Group M	32	16	2

Table no 3:Post operative complication[>24 -<48hours]in concern to pt's no.

>24-<48 hours	Group C	Group M	P Value
Cough	0	2	>0.05
Sore throat	4	6	>0.05
Horseness	0	3	>0.05
BSE	0	1	>0.05

The two groups were statistically similar in terms of distribution of ASA physical status grading($p>0.05$). The two groups were statistically similar in terms of Mallampati Score distribution ($p>0.05$). Graph 11B shows post operative complication in 2nd24 hours was not statistically significant[$p>0.05$]

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DISCUSSION

Previous research indicates that when the ETT cuff is inflated with an arbitrary volume of air and the efficacy of an appropriate seal is evaluated using a manual palpation approach, the cuff pressure is either overestimated or underestimated. For example, . Sole et al.[6] revealed from firsthand experience that only 54% of patients had their ETTc pressure maintained within the advised range of 20 to 30 cm of H20. Svenson et al.[7] reported that ETTc pressure was by far higher than 30 cm of H20 in 58% of patients Braz*et al*. [5] 91% of PACU patients after nitrous oxide anesthesia, 55% of ICU patients, and 45% of PACU patients following anesthesia without nitrous oxide had cuff pressures more than 40 cm H2O. In a research project that was experimental, Fernandez *et al*. [8] noticed that participating physicians and ICU nurses were able to identify the group in 69% of the high-pressure instances, 58% of the normal pressure cases, and 73% of the low pressure cases when the cuff was randomly inflated to 10, 20, or 30 cmH2O.

According to our findings, 62% of the patients had recorded cuff pressures that were higher than the suggested cuff pressure of 30 cm of H20. When the cuff is manually inflated with an arbitrary volume of air, an additional 18% of the patients recorded a baseline cuff pressure of greater than 70 cm of H20. Even so, it was reassuring that we found very few exceptionally high values—at least a lot less than those found in earlier research [5]. This finding implies that medical professionals are now trying their best to refrain from indulging in unduly high cuff inflation.

None of our patients had a baseline cuff pressure reading of less than 20 cm of water, which is necessary to create a sufficient seal around the trachea. As a result, we think that manually inflating an ETT cuff with an arbitrary volume of air will always cause the cuff to become overinflated.

Because symptoms are usually subjective, it is unclear if there is a strong association between the extent of mucosal injury and the severity of patient symptomatology. Our hypothesis was that morbidity associated to endotracheal intubation would be decreased by using an acceptable ETTc pressure, even during brief operations (120–150 minutes). Preferably, the cuff inflation volume shouldn't be fixed. In this study, we adjusted the ETTc pressure to not more than 25 cm of H20 in the Control group without observable air leakage. This was done because, in order to ensure adequate ventilation, the cuff should be inflated only until it prevents an air leak. Most hospitals do not routinely monitor ETTc pressure during endotracheal intubation, despite the recommendation that this be done [9] Rather, the anesthesiologist often uses the pilot balloon

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palpation approach to estimate the pressure based on personal experience. According to the pilot balloon palpation, the mean ETTc pressure in the Manual group was 50.16±19.14 cm of H20 (with a maximum of 90 cm of H20) prior to correction. This confirms that, based on personal experience, cuff inflation is much greater than the typical restriction. Following the Manual group's adjustment, the ETTc pressure was 40.32±7.64 cm of H20.

Following endotracheal intubation under general anesthesia, cough and painful throat are frequent side effects. In fact, the prevalence of sore throat can range from 30% to 55%. Within 24 hours following extubation, the study found that the Control group experienced 32%, 6%, and 2% of the cases of sore throat, horseness, and blood-streaked expectoration, respectively, whereas the Manual group experienced 46%, 16%, and 12% of these cases.Therefore, when the cuff is manually inflated, sore throats and horseness are just as likely to occur.

Within 24 hours of extubation, the Control group (surgery lasting longer than 180 minutes) experienced significantly lower rates of sore throat, hoarseness, and blood-streaked expectoration (41%, 7%, and 4%, respectively) than the manual group (19%, 16%, and 55%). This suggests that routine monitoring of ETTc pressure following endotracheal intubation, even during short surgical procedures, can help prevent respiratory complications related to postoperative intubation.

The study's findings also indicate that the Manual group experienced an increase in the incidence of sore throat and blood-stained expectoration within 24 or more hours of removing the ETT as the duration of endotracheal intubation increased. The Control group also experienced an increase in sore throat, particularly when the duration of endotracheal intubation exceeded 180 minutes. This data suggests that for airway-related complications, the duration and amplitude of pressure are equally significant. This is most likely caused by the trachea being compressed for an extended period of time and the local ischemia getting worse. It would appear wise to utilize a manometer to set and maintain ETTc pressure in light of the study's findings.

There are several restrictions on this study. Nonetheless, we observed that 20% of patients in our research had cuff pressures between 50 and 70 cm of H2O, and 18% of patients had cuff pressures more than 70 cm.However, we have reduced the cuff pressure in the manual arm to 50 cm of H2O for ethical reasons. This is because, in our opinion, it is not acceptable to permit a cuff pressure of more than 50 cm of H2O for an extended length of time during a research, as this might put a patient at danger of serious morbidity. When the control group's baseline cuff pressure was truly measured using a manometer. As a result, it was impossible to determine the

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full impact of such a high cuff pressure on patients who had undergone lengthy surgery. For example, if a patient with a baseline cuff pressure of 100 cm of H2O underwent a 6-hour procedure, the results would likely be disastrous.

Second For ethical reasons, no histology investigation including patients with tracheal mucosal damage was carried out. Fibre optic bronchoscopy should ideally be used to evaluate the relationship between the cough, horseiness, and laryngeal mucosal edema following endotracheal intubation; however, we think that not all patients will consent to this procedure as it is a routine one following endotracheal intubation.

Due to the lack of an estimation mechanism in our manometer system, we were unable to determine the volume of air needed to inflate the ETT cuff to achieve a sealing pressure of 20–30 cm of H20. Similarly, we were unable to determine the volume of air needed to deflate the cuff to achieve the recommended sealing pressure of 20–30 cm of H2O during the course of surgery.

We were aware that the administration of N2O would cause the cuff pressure to rise gradually, but since our operating room lacks a compressed air delivery system for the anesthetic machine, we are forced to accept the possibility that N2O administration may cause the ETTc pressure in both groups to rise excessively.

We therefore think that continuous measurement of ETTc pressure should be included as part of basic monitoring and should be integrated in multichannel monitor systems. It would have been more appropriate if the cuff pressure could have been monitored on a continuous basis, just like pulseoximetry, ECG, and ETCO2.

In addition, these patients were followed up for only 48 hours without a longer follow-up plan to observe their full recovery time and long-term complications.

In summary, clinical judgment-based ETTc pressure estimates are frequently significantly higher than the values advised to avoid tracheal damage. This study also showed that, even in operations lasting only a few hours, appropriate regulation of ETTc pressure with a manometer helps to minimize difficulties associated to post-procedural endotracheal intubation.

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CONCLUSION

In order to prevent tracheal damage, the ETTc pressure assessed by clinical judgement is frequently substantially higher than the suggested levels. This study also showed that using a manometer to properly manage ETTc pressure can help lower the risk of problems linked to postprocedural endotracheal intubation, especially in short operations.

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