Section: Anaesthesiology

Research

COMPARISON OF ENDOTRACHEAL TUBE CUFF PRESSURES USING THREE INDIRECT EVALUATION TECHNIQUES: A RANDOMISED CONTROL STUDY

Received : 19/11/2022
Received in revised form : 22/12/2022
Accepted : 05/01/2023

Keywords:
Endotracheal tube cuff, Cuff pressure, fixed volume injection, pilot balloon palpation, minimal occlusive volume.

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DOI: 10.47009/jamp.2023.5.1.64

Source of Support: Nil,
Conflict of Interest: Nonedeclared

Int J AcadMedPharm
2023; 5 (1); 308-312

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Abstract

Background: The endotracheal tube's (ETT) inflatable cuff is a necessary evil which prevents aspiration on one end, while damage the tracheal mucosa if the cuff pressures are increased. This study was conducted to evaluate the accuracy of ETT cuff pressure when inflated with different indirect techniques like fixed volume injection, minimal occlusive volume and pilot balloon palpation method, by using standard cuff pressure (CP) manometer. Settings and Design- This is a double blind, randomised, prospective study. **Materials and Methods:** One hundred ninety-eight patients belonging to ASA physical status I and II, aged 18-65 years, with body mass index (BMI) < 30kg/m2 undergoing elective surgeries under general anaesthesia were included in this study. Patients were randomly allocated to three groups, with group F, M and P representing fixed volume injection, minimal occlusive volume and pilot balloon palpation method, respectively. Patients were followed up to 24 hours for complications.Analysis of Variance (ANOVA) test was used to compare the means among groups and non-parametric tests were used to compare the means within the group. Chi-square test was applied to compare the qualitative variables. SPSS and Microsoft excel were used to analyse the data. **Result:** Endotracheal tube cuff pressures in group M were significantly lower than group F and group P, at the beginning ($p<0.05$). Group P has the highest incidence of complications as compared to other groups ($p<0.05$). **Conclusion:** The conventional methods of inflating ETT cuff have a high failure rate, with ETT cuff pressure exceeding the optimum range in 69.70%, 60.61% and 72.73% patients in group F,M and P, respectively. Hence, it is recommended to use cuff pressure manometer mandatorily to regulate the ETT cuff pressure in intubated patients under general anaesthesia.

INTRODUCTION

The endotracheal tube's cuff (ETTc) seals the airway to prevent aspiration of pharyngeal contents into the trachea, while simultaneously avoiding any air leak during positive pressure ventilation. The pressure exerted by the inflated ETTc on the trachea should be optimized to effectively seal the airway without hampering the capillary circulation. An ETTc pressure greater than 40 cm H2O for fifteen minutes is sufficient to induce histological evidence of tracheal mucosal lesions, which may progress to tracheal rupture.[1] Excessive ETTc pressure has been implicated as a cause of tracheal damage after intubation with cuffed tubes, despite being an avoidable factor. Various methods are used to inflate the ETT cuff i.e. fixed volume injection, minimal occlusive volume and pilot balloon palpation method, depending on the experience of the anaesthesiologist.

Hence, this study was conducted by us to evaluate the accuracy of ETTc pressure when inflated by different techniques (i.e. fixed volume injection, minimal occlusive volume and pilot balloon palpation method) by using standard cuff pressure (CP) manometer.

MATERIALS AND METHODS

This randomised, double blinded, prospective study was conducted after approval from the institution's ethics committee. After explaining the procedure and taking informed consent, 198 patients belonging to ASA physical status I and II, aged 18-65 years, with body mass index (BMI) < 30kg/m2 undergoing elective surgery under general anaesthesia were included in the study. Patients refusing to participate in the study, younger than 16 years of age, with anticipated difficult airway, with any anatomical abnormality of the airway, undergoing high risk or emergency surgery and with life threatening complications like sepsis were excluded from the study. Standard ASA monitoring and protocols were followed throughout the perioperative period with continuous monitoring of electrocardiogram and oxygen saturation and continual monitoring of non-invasive blood pressure at every five minutes. The patient was intubated with cuffed ETT (high-volume, low-pressure cuff) under direct laryngoscopy, which was inflated by a designated anaesthesiologist. Patients were randomly allocated to three groups. A predetermined fixed volume of 7ml of air was used to inflate the ETTc in group F. In group M, ETTc was inflated slowly at an approximate rate of no more than 0.3 ml/s, with the end point being fixed at the absence of an air leak, which was determined by placing the finger over the trachea. The anaesthesiologist inflating the cuff relied solely on the air leak to determine the inflating volume and avoided the cuff palpation. In Group P, the same anaesthesiologist inflated the ETTc by palpating the pilot balloon, till he was satisfied with the palpation pressure of the pilot balloon. After inflation, ETTc pressure was measured using standard CP manometer with pilot tubing (Initial ETTc pressure). Excessive or inadequate ETTc pressure was corrected to a standard range of 20-30 cm H_2O (adjusted ETTc pressure) by a designated anaesthesiologist who was blinded to the procedure. ETTc pressure at the end of surgery was labelled final ETTc pressure. Post-operatively, patients were followed till 24 hours and any upper airway complication pertaining to endotracheal intubation was observed, namely postoperative sore throat (POST), hoarseness, cough and blood-streaked expectoration; adequate treatment was administered, if required.

The primary aim of this study was to evaluate the accuracy of ETTc pressure when inflated with different techniques i.e. fixed volume injection, minimal occlusive volume and pilot balloon palpation method, by using standard CP manometer. The secondary objective was to evaluate the incidence of complications in the postoperative period in three groups.

Statistical analysis: Based on previously conducted study by Sanaie et al, sample size was calculated assuming 10% difference in the ETTc pressures between the groups.[2] With 80% power of the study, 95% confidence interval and allowable error of 10 %, sample size was calculated to be 66 in each group. Data were collected in MS excel format and analysed with SPSS 16 software. Data were represented as mean ± standard deviation. Analysis of Variance (ANOVA) test was used to compare the means among three groups. Non parametric tests were used to compare means within each group. Chi-square test was applied to compare the qualitative variables in the groups.

RESULTS

This study included data from 198 patients who were randomly divided into three groups of 66 each. Demographic data of the patient in all three groups was comparable [Table 1].

Initial ETTc pressure was significantly lower in group M as compared to group F and group P ($p<0.05$) (Table 2). Significant difference was observed in mean ETTc pressure of group F vs group M ($p<0.006$) and Group M vs group P ($p<0.001$) as compared to group F vs group P, at the beginning [Figure 1]. Adjusted ETTc pressure (p=0. 656), final ETTc pressure ($p=0.174$) and duration of surgery ($p=0.245$) were comparable in all the groups [Table 2].

There was a significant difference observed between initial ETTc pressure and the adjusted ETTc pressure in all three groups [Table 3]. Similarly, there was a significant difference observed between adjusted ETTc pressure and final ETTc pressure but no significant correlation could be established between the two (Pearson correlation coefficient, $R=0.125$, $p=0.80$). Furthermore, there was no significant correlation observed between the change in ETTc pressure and duration of surgery (for time < 2 hours), with Pearson correlation coefficient, R being 0.116 and p =0.104.

Group P had an overall high incidence of complications as compared to other groups especially postoperative sore throat (POST) ($p<0.05$) [Table 4].

Table 1: Demographic characteristics of study population

Parameter	Group F(n=66)	Group M(n=66)	Group P(n=66)	p value
Age (years)	34.62 ± 11.27	38.39 ± 13.85	36.92 ± 13.90	0.249
Weight (Kg)	71.83 ± 10.61	69.82 ± 10.49	72.88 ± 9.64	0.207
Height(cm)	163.00 ± 9.23	163.68 ±10.38	166.18 ± 10.05	0.222
Body Mass Index (Kg/m2)	27.11 ± 3.96	26.01 ± 2.76	26.36 ± 2.57	0.128
ASA PS I (%)	62.12 (41)	66.67 (44)	69.70(46)	
ASA PSII (%)	37.88(25)	33.33(22)	30.30(20)	

ISSN (O): 2687-5365; ISSN (P): 2753-6556

Female (%)	54.55(36)	46.97(31)	43.94(29)	
Male (%)	45.45(30)	53.03(31)	46.06(37)	

Mean ± Standard deviation

Table 2: Comparison of study groups

Parameters	Group F (n=66)	Group M (n=66)	Group P (n=66)	p value
InitialETTcpressure (cm H_2O)	43.61 ± 15.55	35.83 ± 11.07	45.36 ± 15.73	0.000
Adjusted ETTc pressure (cm H_2O)	25.42±2.82	25.85±2.70	25.73±2.67	0. 656
Final ETTcpressure (cm H_2O)	41.68±3.40	42.85±4.39	41.77 ± 4.04	0.174
Change in ETTc pressure (Final ETTc-Adjusted ETTc)(cm H_2O)	16.26 ± 4.25	17.00 ± 4.93	16.05 ±4.43	0.450
Total duration of surgery (minute)	87.88 ± 16.22	90.05 ± 16.32	85.15± 17.61	0.245

Mean ± Standard deviation

Table 3: Intragroup comparison of initial vs adjusted ETTc pressure

Variables	InitialETTcpressure (cm H2O)	Adjusted ETTc pressure (cm H2O)	p value
Group F	43.61 ± 15.55	25.42±2.82	0.000
Group M	35.83 ± 11.07	25.85±2.70	0.000
Group P	45.36 ± 15.73	25.73±2.67	0.000

Mean ± Standard deviation

Table 4: Incidence of complications

Complication	Group F (n=66)	Group M (n=66)	Group P (n=66)	p value
Post-operative Sore Throat	20	16	30	.029
Cough	8	6	9	0.709
Hoarseness	8	6	11	.419
BloodStreakedExpectoration	1	0	0	0.366

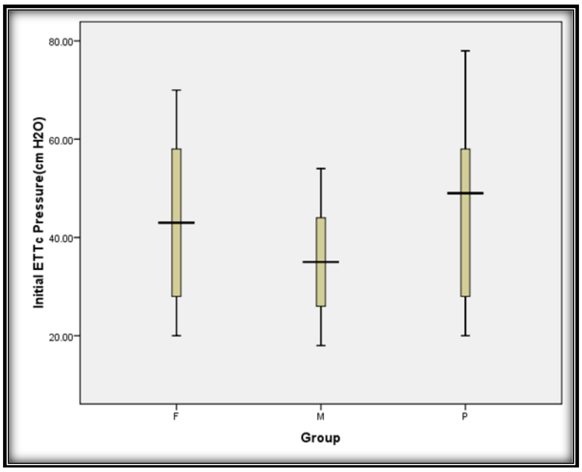

Figure 1: Stem and leaf plot of Initial ETTc pressure of three groups

DISCUSSION

This prospective randomised study was conducted to compare the three commonly used ETT cuff inflating methods i.e. fixed volume injection, minimal occlusive volume and pilot balloon palpation method. Mean ETTc pressures in group P were significantly higher than group M (p=0.001). Results of this study are in concordance with the previous studies which show that pilot balloon palpation is a crude method leading to significantly higher ETTc pressures and complications that follow.[3-5] Study conducted by Stewart et al demonstrated that pilot balloon palpation technique was not an appropriate way to control ETTc pressure, with ETTc pressure exceeding the normal range in 70% of the cases.6 Al-Metwalli et al performed a similar study to compare three methods of inflating the ETTc i.e. precise standard pressure, sealing pressure and finger estimation, and also concluded that cuff pressure was significantly higher in finger estimation(i.e. pilot balloon palpation) method as compared to other groups.[7] Various studies have previously observed that anaesthesiologist experience has little to do with success of conventional methods for inflation of ETT cuff.[8,9]

Group F also had high initial ETTc pressure of 43.61 ± 15.55 cm H2O which was found to be statistically significant against the mean ETTc pressure of group M (35.83 ± 11.07)(p=0.006). Previously conducted studies with fixed volume inflation of ETT cuff have resulted in highly variable ETTc pressures, owing primarily to use of higher inflating volume.[10] Despite use of seven ml volume air for ETTc inflation, as per recommendations of Carhart et al, ETTc pressure was still exceeded in majority of cases(69.70%) in group F.[11]

Group M had the highest number of successful inflation as defined by inflating pressures within the normal range of 20-30cm H2O i.e. 39.39% as compared to group F and P. But, overall percentage of ETTc pressure still exceeded normal range i.e. 69.70%, 60.61% and 72.73% cases in group F, M and P, respectively. Similar findings were observed by Soleimani et al who observed that minimal occlusive volume resulted in the most appropriate cuff pressures (20.78±1.4 cmH2O).12 Though Sanaie et al had observed in their study that ETTc pressure was normal in 70% of the cases, but results of this study aligned more with Saleh et al who had observed only 20% success rate with conventional methods.[2,13]

Final ETTc pressure had no significant correlation with the adjusted ETTc pressure in this study. ETTc pressure is affected by various factors including the volume injected into the ETT cuff but this was not observed in this study in contrast to the claims made by Khalil et al,[14] Increase in ETTc pressure was expected, owing to fresh gas composition of 60% Nitrous oxide (N2O) and 40% Oxygen (O2) as this has already been observed in previous studies.15 This could have been ameliorated with the use of similar gas composition for ETTc inflation instead of use of air. Though Sole et al have observed that there is loss of cuff volume over time in intubated patients but no such relation was observed in this study, rather an increase in ETTc pressure was observed which may again be attributed to use of Nitrous oxide in fresh gas flow.[16]

Various complications arising due to high ETTc pressure were observed in three groups, with incidence of POST upto 45.45% in group P, while one patient in group F experienced blood-streaked expectoration. Incidence of complication was comparable to previously conducted studies which showed that conventional methods fail to achieve optimum range of ETT cuff pressure and result in higher postoperative complications.[17] Liu et al have also observed similar findings where ETTc pressure was 43±23.3 mm Hg with the pilot balloon palpation method, before adjustment. Adjusting the cuff pressures with the manometer decreased complications like POST, hoarseness of voice, cough and bloody sputum.[18]Galinski et al have also observed that in the absence of manometer, ETTc pressure are seldom in normal range which justifies the need of CP manometer in all the intubated patients.[19]

Determination of appropriate size ETT as per tracheal diameter, body temperature, and various other factors affecting the ETT cuff were not measured in our study and need to be addressed in future studies. It would be prudent to use the gas mixture of similar composition for ETT cuff insufflation as being used for ventilation. Visual signs of tracheal mucosal injury could not be identified due to lack of fibreoptic bronchoscopy.

CONCLUSION

Though minimal occlusive volume has maximum success rate in achieving the optimum ETTc pressure and is associated with minimal complications of the three conventional methods, it can be concluded from this study that all the conventional methods of inflating ETT cuff fail to achieve optimum ETTc pressure (20-30cm H2O). The current study observed that both fixed volume injection and pilot balloon palpation methods are unreliable methods to inflate ETT cuff with pilot balloon palpation method resulting in the highest number of complications. Hence, it is recommended that cuff pressure manometer should be mandatorily used to regulate the ETTc pressure in intubated patients to optimize the cuff pressures and reduce associated complications.

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