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ASSESSING CORRELATION OF ENDOTRACHEAL TUBE CUFF PRESSURE BETWEEN ESTIMATION TECHNIQUES AND DIRECT CUFF PRESSURE MEASUREMENT BY ANAEROID MANOMETER-A PROSPECTIVE OBSERVATIONAL STUDY

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KEYWORDS :

6. AIM AND OBJECTIVES OF STUDY:

AIM:

To correlate the endotracheal tube cuff pressures attained by estimation techniques and direct cuff pressure measurement.

OBJECTIVES OF THE STUDY:

PRIMARY OBJECTIVE:

Is to assess the cuff pressure attained by estimation techniques with the help of anaeroid manometer.

SECONDARY OBJECTIVE:

To assess correlation between endotracheal tube cuff pressure and cuff volume.

7. MATERIAL AND METHODS:

7.1) STUDY DESIGN:

This is human based, clinical, observational and longitudinal, single center, open, Institutional based prospective study.

7.2) STUDY AREA:

Study was conducted in Kokilaben Dhirubhai Ambani Hospital and Research Centre, Mumbai in Anaesthesiology department which is a the only hospital in Mumbai to function with a full time specialist system, that ensures the availability and access to the best medical talent around-the-clock. The 750-bed hospital has over 103 full-time doctors, 520 nurses and about 200 paramedics, and growing.

7.3) STUDY POPULATION:

All consecutive subjects satisfying inclusion and exclusion criteria posted for elective surgeries under general anaesthesia at Kokilaben Dhirubhai Ambani Hospital & Medical Research Institute from JULY 2016 - AUGUST 2017 (13 MONTHS). Ethical approval was obtained from the Local Ethical Committee (ISEB).

7.4) SAMPLE SIZE & TECHNIQUE:

Based on literatures Stewart et al[12] & Sengupta et al[5], it was found that the mean pressure obtained by estimation techniques was 44.50 with standard deviation of 13.07. Expected mean pressure difference obtained by estimation techniques in our study was 2.8 with standard deviation 12. With 80% power and 5% level of significance, we required 144 patients for this study.

FORMULA:

$$n = \frac{[Z_{(\alpha/2)} + Z_{\beta}]^2 * \sigma^2}{d^2}$$

STEPWISE CALCULATION:

$Z(\alpha 2/)$ = 1.96 (Type-I error at 5% level of significance)

$Z\beta$= 0.842 (Type-II error 20% i.e. 80% of power) d= 2.8 (Expected difference between reported mean pressure and expected mean pressure)

= 12 (Expected standard deviation)

n = ((1.96 +0.842) ^2)*(12^2)/ (2.8^2)

n = (7.85*144)/ (7.84)

n= 144.20

n= 144 patients were required for this study.

7.5) METHODOLOGY:

Standard anaesthesia protocol was followed. Patients were induced with Fentanyl-Propofol- Atracurium sequence. Endotracheal intubation was performed with high volume, low pressure cuffed Portex endotracheal tube no. 6.5, 7, 7.5, 8, 8.5 mm ID accordingly to patients. At intubation the endotracheal tube cuff was inflated with some amount of air with 10ml leur lock syringe to create an intra-cuff pressure for proper seal by the anaesthesia provider. Endotracheal tube cuff is inflated accordingly by anaesthesia provider by using their estimation techniques such as direct cuff pressure measurement (Group A), minimal leak technique (Group B), minimal occlusive volume technique (Group C), palpation of pilot balloon (Group D), and predetermined volume technique (Group E).

Endotracheal tube intra-cuff pressure was measured with an aneroid manometer immediately after intubation and then recorded and the volume used to inflate the endotracheal tube cuff is asked to anaesthesia provider and then recorded. Endotracheal tube intra-cuff pressure was measured are informed to anaesthesia provider and changes which they made later are not included in the study.

7.6) DATA COLLECTION TECHNIQUE:

All data were collected in study proforma, meeting the objectives of the study for each patient.

All data collected were entered in master chart in excel sheet and analysed with help of statistician.

7.7) DATA ANALYSIS:

Data were analyzed using the Statistical package for social science (SPSS version 21).

The numeric data was summarized by descriptive statistics like; N, mean ± SD, median, minimum, maximum (e.g. Age, Height, weight, BMI, Tube size, volume of air and cuff pressure).

The categorical data was summarized by frequency count and percentage (e.g. Gender distribution, Age distribution, cuff pressure distribution and volume of air distribution etc.). Mean, median and Quartile range was reported for all estimation techniques. Normality of data was checked before applied to any statistical test and based on distribution of data, statistical test were applied to find out statistical significant results.

The Pearson correlation analysis was done for numeric data between Measured Cuff Pressure & Volume of air used and measured cuff pressure with demographics of patients (i.e. Age, Height, weight and BMI).

ANOVA was used for comparison of all techniques. Paired comparison was done between two techniques using Mann-Whitney test for cuff pressure and volume of air.

Graphical presentation done by using pie-chart, Regression plot and bar chart. A p-value less than 0.05 was considered statistically significant.

8. SALIENT FINDINGS:

Correlation between demographic data of patients and measured cuff pressure are statistically non-significant (p->0.05).Data is statistically comparable. In the study 64 patients of ASA I, 79 patients of ASA II, 1 patient of ASA III patients are involved. Endotracheal tube size from 6.5-8.5 were included in this study.

The manometric pressure (cm H2O) measured at the endotracheal tube cuff was 29.9±4.33, 37.32±16.40, 37.86±16.13 ,46.21±16.94, 45.19±16.61 cmH2O for group A, Group B and Group C, Group D, Group E, respectively. This difference was statistically significant amongst all the five groups with a p value <0.05 using Fisher's exact test. Direct cuff pressure measurement (Group A) shows cuff pressures of 29.9±4 (mean ± SD) which is in normal range (25-40cmH2O). Whereas other estimation techniques like Minimal leak test(Group B), Minimal occlusive volume test (Group C), Palpation of pilot balloon (Group D), Predetermined volume test (Group E), the pressures recorded are 37.32±16.40, 37.86±16.13 ,46.21±16.94, 45.19±16.61 respectively, which are either too low pressures or too high pressures when compared to normal range pressures(25-45cmH2O).

A positive correlation was seen between measured cuff pressure and Volume of air used and it was statistically significant. Increase the volume of air will lead to increase in cuff pressure also. Direct cuff measured technique required lesser volume of air when compared with Palpitation of pilot balloon and Pre-determine volume test which is statistically significant (p<0.05).

9. CONCLUSIONS:

From our study we conclude that the direct cuff pressure measurement method of cuff inflation technique resulted in adequate manometric cuff pressure (25-40 cmH20) and hence may be associated with lesser postoperative airway morbidity. Increase in the volume of air will lead to increase in cuff pressure also. There is no particular volume to attain normal cuff pressure (25-40cmH2O) pertaining to tube size. Thus direct cuff pressure measurement technique should be used to inflate the endotracheal tube cuff and cuff pressure monitoring should be practiced routinely in regular anaesthesia practice.

10. RECOMMONDATIONS:

1. Direct cuff measurement technique with anaeroid manometer should be used to inflate the endotracheal tube cuff.
2. Cuff pressure monitoring should be practiced routinely in regular anaesthesia practice as a standard of care.
3. Further studies can be conducted to evaluate cuff pressure changes intraoperatively and peri-operative laryngotracheal morbidities as this study was limited to the accuracy of measurement technology only.
4. A randomized double blinded study with larger study sample can be conducted to support results of this study.
5. Further studies are also recommended for monitoring cuff pressure changes and related laryngotracheal morbidities in airway devices other than endotracheal tube in perioperative and critical care setting.

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