

Effect of Fixed Tracheal Cuff Volume vs Fixed Tracheal Cuff Pressure on Hemodynamic Parameters and Postoperative Airway Complications, A Prospective Randomized Control Trial in a Tertiary Care Hospital

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ABSTRACT

Background: The current study is aimed to compare the effect of fixed cuff volume and fixed cuff pressure technique on hemodynamic parameters and on postoperative complications.

Methods: The prospective, randomised, controlled study was conducted in a tertiary care hospital with 100 patients aged between 18 to 60 yrs. The patients who are undergoing for elective surgeries under general anaesthesia were enrolled after obtaining ethical committee approval. Patients were randomized based on computer generated random numbers into two groups, fixed volume (7ml) group (group V, n-50) and fixed cuff pressure group (group P, n-50). The ETT cuff was filled with 7 ml of air in the fixed volume technique, and in the fixed cuff pressure group -cuff pressure was maintained at 20 cmH₂O, after intubation. Tracheal tube cuff pressures were measured by AMBU cuff pressure gauge manometer. Hemodynamic parameters SBP, DBP, MAP and PR were noted at the time of cuff inflation, after extubation in the both the groups. Post-operative sore throat, hoarseness and cough was assessed at the time of extubation in the both the groups.

Results: Mean age in both the groups was 41 years. Statistical significance (P< 0.0001) was observed in Group P in systolic blood pressure (SBP), diastolic blood pressure (DBP), MAP, HR whereas no significance was seen in group V. The percentage of post-operative complications like hoarseness, cough, sore throat, and dysphagia were seen to be less in group P when compared to group V.

Conclusion: With present data we could conclude that the fixed minimal cuff pressure (20 mm H₂O) is an ideal and reliable technique in reducing the post-operative complications along with maintenance of hemodynamic parameters.

The use of a cuffed endotracheal tube (ETT) is essential for a patient who needs protected airway. High volume low pressure cuffed endotracheal tubes are standard of airway protection. ETT cuff pressure management is an important step in the management of airway after endotracheal intubation in patients undergoing surgeries under general anaesthesia [1-2]. Insufficient cuff pressure causes pulmonary aspiration of oropharyngeal content and excessive

amounts of cuff pressure leads to decreased tracheal capillary perfusion [3-4]. There is a correlation between cuff pressure and airway complications. An ideal pressure range is defined to be 20-30 cmH₂O and both under and overinflation of the ETT cuff can cause various complications [5]. The gold standard technique of measuring the cuff pressure is using calibrated manometer. More often, patients complain of symptoms like sore throat, hoarseness and dysphagia in the

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immediate postextubation period [6]. In fact, sore throat and hoarseness have been reported up to 50% of patients in the first few hours after extubation. Coughing induced by an ETT cuff can complicate emergence from general anaesthesia, thus resulting in potentially dangerous hyperdynamic responses after extubation and in the postoperative period [7]. Such responses include hypertension, tachycardia, dysrhythmia, increased intraocular pressure, increased intracranial pressure, wound dehiscence, and bronchospasm. Based on the different methods and various results, we designed a trial to compare the fixed cuff volume vs fixed tracheal cuff pressure on hemodynamic parameters and on postoperative complications like sore throat and cough. The main aim of the study is to compare the effect of fixed cuff volume and fixed cuff pressure technique on hemodynamic parameters and on postoperative complications. Primary objective is to compare the hemodynamic parameters in both the groups and secondary objective is estimation of incidence of postoperative complications.

Methods

The prospective, randomised, controlled study was conducted to compare the fixed minimal tracheal cuff pressure VS fixed cuff volume in a tertiary care hospital, India after obtaining ethical committee approval (ESICMC/SNR/IEC-F0243/12-2020). 100 patients between 18-60 years of age, both genders who are undergoing elective surgeries under general anaesthesia were included in the study over a period of one year from December 2020 to December 2021. The sample size was calculated based on confidence interval, odds ratio, previous studies reference using G*power software. Inclusion criteria for the study is ASA grade 1 & 2 patients were taken and the exclusion criteria were patient refusal, age less than 18 and more than 60, patients with difficult airway. For the enrolled patients demographic characteristics, type of surgery, duration of surgery were noted. All subjects were randomized based on computer generated random numbers into two groups, fixed volume (7ml) group (group V, n=50) and fixed cuff pressure group (group P, n=50). After a thorough preanesthetic check-up and after taking written informed consent, all patients were subjected to standard monitoring of Electrocardiography (ECG), pulse oximetry (SpO₂), blood pressure (SBP, DBP, MAP) and heart rate and baseline values recorded. All patients were administered general anaesthesia as per institutional protocol. After adequate preoxygenation, patients were premedicated with inj.midazolam 0.1mg/kg, inj.ondansetron (0.1mg/kg), inj fentanyl (1-2mcg/kg) intravenously.

Patients were induced with propofol (1.5-2mg/kg) intravenously and inj.atracurium (0.5mg/kg) was used as muscle relaxant for endotracheal intubation. Under direct laryngoscopic vision, patients were intubated with

appropriate size cuffed endotracheal tube. The ETT cuff was filled with 7 ml of air in the fixed volume technique, and in the fixed cuff pressure group cuff pressure maintained at 20 cmH₂O, after intubation. All cases were checked using the standard pressure control method with manometer. Both techniques were applied by single anesthesiologist and study anesthesiologist was blinded. Tracheal tube cuff pressures were measured by AMBU cuff pressure gauge manometer. Hemodynamic parameters SBP, DBP, MAP and PR are noted at the time of cuff inflation, after extubation in the both the groups. At the end of surgery extubation was performed following gentle oro-pharyngeal suctioning. Post-operative sore throat, hoarseness and cough was assessed at the time of extubation in the both the groups.

Data was analysed by using Graphpad InStat version 3.0. Demographic characteristics, ASA status, Hemodynamic parameters (Mean \pm SD) were analysed by using independent sample t-test. Incidence of post-operative sore throat, hoarseness and cough were assessed by using Chi-square test. P value < 0.05 was considered as statistically significant in all the tables.

Results

Demographic data age, gender, and ASA grading of the patients was described in (Table 1). Mean age in both the groups was 41 years and male patients were more in group P whereas female patients are higher in group V. ASA grading percentage was observed to be similar in both the groups.

In (Table 2), after intubation and extubation an observed statistical significance (P < 0.0001) was seen in Group P whereas no significance was seen in group V in systolic blood pressure of both groups. There is no statistical significance seen in systolic blood pressure (SBP) at Baseline, and before induction parameters in both the groups. When it comes to diastolic blood pressure (DBP), MAP, HR, a statistically significant difference was seen in Group P after extubation when compared to group V. There is no statistically significant difference was seen in baseline and before intubation for all the hemodynamic parameters in both the groups.

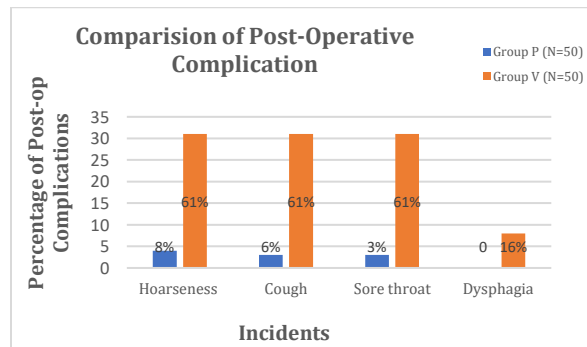
All the post-operative complications like hoarseness, cough, sore throat, and dysphagia (Table 3) were significantly lower in group P (P<0.0001) when compared to group V. Comparative incidents of post-operative complications after extubation are shown in (Figure 1).

Table 1- Demographic characteristics of the patients.

Parameter	Group P (N=50)	Group V (N=50)
Mean age (years \pm SD)	41.5 \pm 11.4	41.7 \pm 9.4
Gender (M/F)	29/21	20/30
ASA grading		
Grade 1	26 (52.0 %)	25 (50.0 %)
Grade 2	24 (48.0 %)	25 (50.0 %)

Table 2- Hemodynamic parameters in both groups.

Parameter	Group P (N=50)	Group V (N=50)	P value
SBP (mean \pm SD)			
Baseline	120.9 \pm 14.8	121.4 \pm 15.0	0.867
Before induction	118.9 \pm 14.2	114.9 \pm 16.5	0.197
After intubation	111.5 \pm 12.9	142.8 \pm 13.1	<0.0001*
After extubation	111.5 \pm 12.9	142.8 \pm 13.1	<0.0001*
DBP (mean \pm SD)			
Baseline	76.6 \pm 12.6	77.6 \pm 10.8	0.671
Before induction	76.1 \pm 11.2	74.2 \pm 11.0	0.394
After intubation	72.2 \pm 8.9	73.5 \pm 11.0	0.517
After extubation	68.9 \pm 6.1	83.5 \pm 10.3	<0.0001*
MAP (mean \pm SD)			
Baseline	89.6 \pm 10.2	86.5 \pm 11.5	0.157
Before induction	86.6 \pm 10.5	87.7 \pm 10.2	0.596
After intubation	84.3 \pm 9.2	87.3 \pm 13.2	0.190
After extubation	79.9 \pm 8.5	99.9 \pm 6.6	<0.0001*
PR (mean \pm SD)			
Baseline	81.5 \pm 11.9	82.5 \pm 10.4	0.656
Before induction	87.7 \pm 12.3	83.2 \pm 12.0	0.067
After intubation	82.2 \pm 10.6	81.8 \pm 11.4	0.856
After extubation	84.8 \pm 11.9	94.7 \pm 10.3	<0.0001*

Figure 1- Incidence of post-operative complications in both groups.

Discussion

The data from the current study indicates that fixed minimal cuff pressure technique reduces post-operative airway complications along with post extubation hemodynamic parameters over fixed cuff volume technique. ETT cuff pressure maintenance between 20 and 30 cm H₂O is an important aspect under general anaesthesia and is proved to be safest method [8]. Inadequate maintenance of ETT cuff pressure led to many complications like aspiration pneumonitis and pneumonia, bronchitis at cuff pressure <20cmH₂O and at cuff pressure > 30 cmH₂O hampered local tissue blood flow, damage to the tracheal mucosal wall [2,9].

A study done by Sen Gupta, et al [10] says that the 2-4ml of injected volume range gives a cuff pressure of 20 and 30 cm H₂O and present study had demonstrated that irrespective of cuff volume in group P, a minimal amount of 20 cm H₂O cuff pressure was maintained and achieved less postoperative complications and less hemodynamic (P<0.0001) after extubation. This indicates a routine cuff pressure monitoring would decrease postoperative complications to a major extent

A randomised control study done by Bulamba et al, [11] concluded that even after optimising a safe cuff pressure resulted in post-operative complications like sore throat, continuous throat pain, dysphagia, uncoordinated swallowing, dysphonia, hoarseness in voice, and cough after extubation. However, in the present study post-operative complications were successfully overcome by using fixed minimal cuff pressure technique at 20 cmH₂O (P<0.0001) and has stable hemodynamic parameters at extubation.

In a study done by Lakhe G, et al [12], they have measured ETT cuff pressure throughout the intraoperative period and concluded that maintaining ETT cuff pressure between 20-30 cmH₂O will decrease post-operative sore throat and other complications and our study results also emphasizes the importance of monitoring ETT cuff pressure.

In a study conducted by Rahmani F, et al [13], where they have compared fixed cuff volume versus pilot balloon palpation and concluded that both the techniques are not appropriate techniques to assess cuff pressure and recommended to monitor cuff pressure and present study also concludes that fixed cuff volume is not appropriate technique when compared to fixed minimal cuff pressure.

Along with the positive side of this research, there are few limitations, cuff pressure was not monitored at different time points. Further studies with a greater number of patient population in different ethnic regions will be an added advantage for fixed minimal cuff pressure technique.

Conclusion

Based on our study results we conclude that the fixed minimal cuff pressure (20 mm H₂O) is an ideal and reliable technique in reducing the post-operative complications along with maintenance of hemodynamic parameters. We recommend to anaesthetic personnel to follow this simple viable method for all the surgeries to see a cherished results post operatively.

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