Comparison of effects of volume-controlled and pressure-controlled mode of ventilation on endotracheal cuff pressure and respiratory mechanics in laparoscopic cholecystectomies: A randomised controlled trial

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ABSTRACT

Background and Aims: One of the pathophysiological consequences of pneumoperitoneum is variations in endotracheal cuff pressure (ETTc). Volume-controlled mode and pressure-controlled mode of ventilation being two modes of ventilatory strategies; we intended to find out variations in ETTc governed by respiratory mechanics between these two modes during laparoscopic cholecystectomies. Methods: After obtaining ethics committee approval, this randomised (1:1), active-controlled, parallel-assigned study was done on 60 patients undergoing laparoscopic cholecystectomies. These patients were allocated into two groups by computer-generated randomisation: Volume-controlled mode (V) and pressure-controlled mode (P). We observed for variations in ETTc which was the primary aim and haemodynamic parameters; respiratory mechanics at baseline (T1), at pneumoperitoneum (T2), after 10 min (T3), 20 min (T4) of pneumoperitoneum and at desufflation (T5). Post-operative laryngotracheal co-morbidities were also observed. Analysis was done using Statistical Package for the Social Sciences version 16.0 (IBM SPSS Statistics, Somers NY, USA). Results: No statistically significant difference was found in both groups either concerning ETTc, haemodynamic parameters or complications. In both groups, ETTc variation was statistically significant when compared from baseline to desufflation (T1 versus T5) and in group V additionally from baseline to time of pneumoperitoneum (T1 versus T2). Group P showed lower peak airway pressure at desufflation and higher mean airway pressure throughout at all the time intervals. **Conclusions:** There is no variation in ETTc between the two modes. Group P appears to be better in terms of lower Ppeak and better Pmean.

Key words: Endotracheal tube cuff pressure, laparoscopic surgery, respiratory mechanics

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INTRODUCTION

During laparoscopic surgeries, different ventilatory modes are being used incorporated with various lung-protective strategies to mitigate various physiologic alterations induced by pneumoperitoneum and positioning. There is no consensus regarding the superiority of the modes.^[1-3]

Secondary to pneumoperitoneum, endotracheal tube cuff pressure (ETTc) increases, which is a less explored concept. Previous studies have noted changes in ETTc due to pneumoperitoneum and complications due to endotracheal cuff over-inflation in volume-controlled mode (VCV). $^{[4,5]}$ This effect on ETTc is secondary to

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increased intrathoracic pressure and peak airway pressure (Ppeak). $^{[5,6]}$

As pressure-controlled mode (PCV) has lower Ppeak when compared to VCV,^[3] we intended to find out variations in ETTc between these two different modes which was our primary objective and secondary objective being changes in respiratory mechanics.

METHODS

After approval from the institutional ethical committee with protocol number BMCRI/PS/66/2018-19, this single-blinded, prospective randomised, interventional, active-controlled, parallel-assigned clinical trial was registered in the clinical trial registry (CTRI REF/2018/07/020991). Our study was conducted from August to November 2018 and followed the principles of the Declaration of Helsinki.

The sample size was estimated based on the study by Yildirim et al.^[5] We hypothesised that pressure-controlled ventilation would result in less endotracheal cuff pressure compared to volume-controlled ventilation governed by its effect on peak airway pressure. Assuming an effect size of 10% and a standard deviation of 3.5, at 20 min after insufflation, between the two groups, a minimum of 24 patients per group would be necessary to achieve 80% power at an alpha error of 0.05. To compensate for possible dropouts, 30 patients per group were enrolled constituting a total of 60 physical status. A total of 63 patients undergoing laparoscopic cholecystectomy under general anaesthesia belonging to the American Society of Anesthesiologists I and II physical status, of both genders aged 20 to 50 years were screened for eligibility and enrolled for the study. Written informed consent was obtained. Patients with a preoperative history of sore throat, cough or hoarseness, anticipated difficult intubation or in whom intubation took two or more attempts, unstable ventilator settings for more than 30 min or those who required mechanical ventilation in post-operative period, difficult nasogastric tube insertion and any major obstructive or restrictive lung disease as ruled out by bedside pulmonary function tests, prolonged duration of surgery (>60 min) and conversion to laparotomy were excluded. All patients underwent detailed pre-anaesthetic check-up a day before surgery. A thorough airway examination was done. Predicted body weight was calculated for all patients. All patients were kept fasted for 8 h before surgery. An automatic leak test was performed on the

anaesthesia machine, Datex Ohmeda Avance S5TM anaesthesia workstation ventilator (GE Healthcare, Finland) to detect any leak. Intravenous (IV) access was secured with 18-gauge cannula and patients preloaded with 6–8 mL/kg normal saline. Inj. pantoprazole 40 mg and ondansetron 0.15 mg/kg were administered IV before induction of anaesthesia. Patients were randomised to either group V (volume-controlled mode) or group P (pressure-controlled mode) by computer-generated randomisation (www.random.org).

electrocardiography, Continuous non-invasive blood pressure and pulse oximetry were attached and baseline vitals were recorded. All patients were intravenously premedicated with Inj. glycopyrrolate 0.2 mg and fentanyl 2 µg/kg. After pre-oxygenation for 3 min with 100% oxygen, the patient was induced with 1.5-2 mg/kg propofol. After confirming mask ventilation, intubation was facilitated with vecuronium 0.1 mg/kg. An appropriate sized low pressure and high volume cuffed endotracheal tube (Rusch portex endotracheal tube, Dublin) was used. Proper positioning of the endotracheal tube was confirmed. The cuff was inflated using the cuff pressure manometer (Cufflator endotracheal tube inflator, Posey Company, United States). Spirometry was connected and the head was fixed in a neutral position.

Anaesthesia was maintained with 50% oxygen in air mixture and isoflurane at one minimum alveolar concentration. Fresh gas flow initially kept at 4 L/min and then reduced to 2 L/min after 10 min. Neuromuscular blockade was maintained with intermittent doses of vecuronium 0.02 mg/kg to maintain train-of-four (TOF) count of 2. Nitrous oxide was avoided. Group allocation was done using the opaque sealed envelope method. Mechanical ventilation was continued throughout with a preset tidal volume of 7 mL/kg predicted body weight in group V whereas, in group P, the ventilator was adjusted so that the set pressure attained the desired tidal volume of 7 mL/kg even after insufflation and desufflation. A variation of 5% in tidal volume was accepted and respiratory rate between 12 to 20/min to maintain normocapnia (end-tidal carbon-dioxide within 30 and 35 mmHg) and oxygen saturation >95% with positive end-expiratory pressure of $+ 5 \text{ cm of H}_{2}\text{O}$ and inspiratory expiratory ratio (I: E) of 1:2. When these parameters could not be achieved for 30 min, they were not to be considered part of the study. Endotracheal cuff pressure was adjusted at 26 cm H₂O by the manometer and noted as baseline just before skin incision and any leak confirmed again from pressure-volume loop

closure from the monitor of the ventilator display. In this study, all cuff pressure measurements were made with the same manometer. Table tilt was uniform during all surgeries. Baseline measurements of haemodynamic parameters, oxygen saturation, peak airway pressure (Ppeak in a centimetre of water-cm of H₂O), mean airway pressure (Pmean in a centimetre of water-cm of H₂O), dynamic compliance (in millilitres per centimetre of water-mL/cm of H₂O) and resistance (in centimetre of water per litre per second-cm of H₂O/L/ sec) were noted. All respiratory parameters were recorded from the ventilator display. After abdominal CO₂ insufflation, intra-abdominal pressure (IAP) was set to automatically maintain at 14 mmHg using Storz electronic laparoflator. All respiratory parameters and corresponding cuff pressures were recorded soon after abdominal insufflation till 20 min after pneumoperitoneum and at complete desufflation. On completion of the surgery, residual muscle relaxation was reversed with IV neostigmine 0.05 mg/kg and glycopyrrolate 0.04 mg when TOF count was 4 and extubation was performed after gentle oropharyngeal suctioning under vision after complete recovery by clinical assessment. Haemodynamic parameters and oxygen saturation monitored up to 2 h post-operatively. In the recovery room and again after 24 h, an anaesthesiologist blinded to the intervention asked the patients for specific symptoms like sore throat, hoarseness and cough.

Student's 't-test was used to compare the difference in the means of ETTc, respiratory parameters and haemodynamic parameters between the two groups. Repeated measures of analysis of variance (ANOVA) was used to compare the difference in means of the parameters at baseline, after pneumoperitoneum, at regular intervals till desufflation within the groups. Post hoc analysis with Bonferroni correction was applied for intergroup comparison of continuous variables. Categorical variables were compared using Chi-square or Fisher's test as applicable. All variables followed normal distribution. For all statistical tests, P' < 0.05 was considered as statistically significant and 'P' < 0.001 as highly statistically significant. The final analysis was performed using Statistical Package for Social Sciences for Windows, version 16.0 (IBM SPSS Statistics, Somers NY, USA).

RESULTS

We enrolled in a total number of 63 patients for the study as shown in consort diagram [Figure 1]. Two patients out of these had multiple attempts at intubation and another patient underwent open cholecystectomy due to surgical factors.

Both groups were comparable in terms of age, sex and weight. Mean operative time also was comparable between the two groups [Table 1].

Haemodynamic variables were comparable between both groups. Among the two groups, during all the study intervals (baseline, at the creation of pneumoperitoneum, after 10 min, after 20 min and at desufflation), the mean values of ETTc and compliance were comparable and did not differ significantly (P > 0.05). Ppeak although not significantly different between both groups was on the higher side in group V and was statistically significant only at desufflation (P = 0.03). The mean values of Pmean were significantly higher in group P compared to group V at baseline and other intervals of the study (P < 0.05). The mean values of resistance were significantly higher in group P compared to group V only at the creation of pneumoperitoneum (P = 0.03) [Table 2].

In group P, only one out of 30 patients (3.34%) had sore throat in the immediate post-operative period [Figure 2].

In group V, two out of 30 patients (6.67%) had sore throat, one in the immediate post-operative period and the other one after 8 h after surgery. On comparing the occurrence of sore throat among the two groups, there was no significant difference (Z = -0.58, P = 0.56). One patient had cough in the immediate post-operative period (3.34%) [Figure 2].

No incidence of hoarseness or desaturation in either of the groups was noted.

DISCUSSION

Our findings are lower peak airway pressures only at desufflation and higher mean airway pressure in group P. There is no difference concerning endotracheal cuff

Table 1: Demographic parameters and mean operative ti								
Participants	Group P (<i>n</i> =30)	Group V (<i>n</i> =30)	Ρ					
Age in years, mean (SD)	43.33 (14.0)	36.87 (13.04)	0.06					
Sex (Male:Female)	10:20	13:17	0.28					
Weight in kg, mean (SD)	63.60 (11.86)	62.73 (10.90)	0.77					
Operative time in min, mean (SD)	53.00 (16.00)	59.33 (14.36)	0.11					
SD – Standard Deviation								

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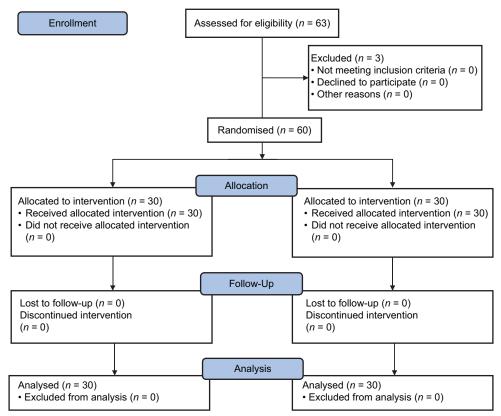


Figure 1: CONSORT flow diagram

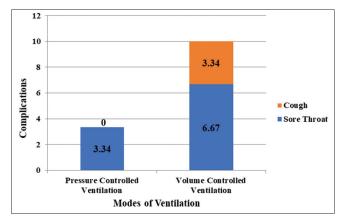


Figure 2: Complications (in proportions and percentages)

pressure and post-operative complications between the two groups.

Parametric data were collected intraoperatively for the first 20 min following pneumoperitoneum as we assumed that respiratory parameters and hence endotracheal cuff pressure would stabilise completely after 20 min of CO_2 insufflation and at complete desufflation.

We have not used N_2O as it diffuses rapidly into the endotracheal tube cuff as shown in a few previous studies.^[7,8] We have eliminated other confounding

factors that can alter ETTc by using an unlubricated endotracheal tube and intubated without a stylet. Intraoperatively, the head was fixed in a neutral position and table tilt was uniform in all subjects. IAP was maintained at 14 mmHg. Cuff pressure manometer was continuously kept attached to endotracheal cuff and monitored intraoperatively because detaching it frequently causes some degree of intracuff volume loss.

In our study, within group P, ETTc showed statistical significance on comparing baseline and at desufflation (T1 versus T5, P = 0.008) suggesting a significant fall in ETTc at this time interval. Within group V, a similar decrease was noted between baseline with the creation of pneumoperitoneum as well as desufflation (T1 versus T2, P = 0.02 and T1 versus T5, P = 0.01) which is undesirable. Previous studies show significant changes in endotracheal pressure in laparoscopic surgeries over time.^[5,7-9] We noticed lower Ppeak in group P and corresponding lower endotracheal pressures as assumed but statistically not significant. Changes might be observed in surgeries requiring long duration of mechanical ventilation.

In our study, Ppeak although not significantly different between the two groups was on the higher

Table 2: Endotra	cheal cuf	f pressure	s and resp	piratory m	echanics I	between g	roups in te	erms of m	iean (SD)	
	ETTc [†]		Ppeak [‡]		Pmean [§]		Compliance		Resistance [¶]	
	Р	V	Р	V	Р	V	Ρ	V	Р	V
Baseline (T1)	26.00 (0.0)	26.00 (0.0)	16.20 (1.71)	16.36 (2.65)	9.50 (1.88)	8.07 (1.04)	40.20 (13.81)	39.30 (8.78)	9.43 (1.97)	9.57 (5.67)
Р	1.00		0.78		0.001*		0.76		0.90	
At creation of pneumo (T2)	28.27 (5.57)	28.07 (3.67)	21.33 (2.42)	23.26 (4.55)	10.57 (1.00)	9.30 (0.98)	28.13 (9.32)	26.87 (7.66)	12.53 (3.47)	10.47 (3.98)
Р	0.87		0.44		0.001*		0.56		0.03*	
After 10 mins (T3)	27.27 (7.45)	26.90 (4.27)	21.50 (3.18)	24.53 (5.43)	10.67 (1.39)	9.60 (1.38)	26.97 (8.37)	25.20 (4.95)	12.37 (3.61)	10.63 (3.42)
Р	0.81		0.10		0.004*		0.32		0.06	
After 20 mins (T4)	25.13 (7.29)	25.83 (4.39)	21.45 (2.16)	24.60 (5.64)	10.83 (1.05)	9.37 (1.09)	27.10 (8.29)	25.67 (6.54)	12.47 (3.60)	10.87 (3.50)
Р	0.65		0.33		0.001*		0.46		0.08	
At desufflation (T5)	21.77 (6.19)	22.93 (4.94)	17.83 (2.19)	20.76 (4.12)	9.53 (1.07)	8.23 (1.43)	38.90 (13.41)	36.97 (9.28)	9.87 (2.36)	9.33 (5.95)
Р	0.	42	0.0)3*	0.0	01*	0.	51	0.	65

P - Group P, V-Group V. †ETTc in terms of cm of H₂O. [‡]Ppeak in terms of cm of H₂O. [§]Pmean in terms of cm of H₂O. ^{II}Compliance in mL/cm of H₂O. ¹Resistance in cm of H₂O/litre/second. *statistically significant

side in group V and statistically significant only at desufflation (P = 0.03). Similar findings have been observed by Sen and Wang *et al.*^[3,10]

We observed that Pmean was significantly higher in group P at all intervals in our study, increasing in both groups after pneumoperitoneum. Mean airway pressure reflects an average airway pressure over the entire respiratory cycle and is also directly concerned with gas distribution and gas exchange in alveoli with non-homogeneous constants. An increase in mean airway pressure is due to initial rapid flow leading to early alveolar inflation and suggests better oxygenation.^[10] A meta-analysis by Wang *et al.* compiled that group P caused higher mean airway pressure after pneumoperitoneum suggesting better alveolar ventilation.^[10]

In our study, compliance was on a slightly higher side in group P although not statistically significant (P > 0.05). Compliance was higher in group P and with lower airway resistance as concluded by the meta-analysis.^[10]

Resistance was significantly higher in group P at the creation of pneumoperitoneum in concurrence with Sen and Wang *et al.*^[3,10] In both groups, corresponding Ppeak has increased from baseline values in both groups [Tables 3 and 4].

Rosero *et al.* in their study hypothesised that an increase in airway pressures cause an increase in ETTc.^[6] Ppeak reflects pressure in larger airways. During positive pressure ventilation, changes in Ppeak might affect

Table 3: Endotracheal cuff pressures and respiratory mechanics within Group P						
Variables	ANOVA	$T_1 vs T_2$	$T_1 vs T_3$	$T_1 vs T_4$	T ₁ vs T ₅	
ETTc	<0.0001*	0.34	1.01	1.01	0.008*	
Ppeak	<0.0001*	<0.0001*	<0.0001*	<0.0001*	0.74	
Pmean	<0.0001*	0.02*	0.02*	0.004*	1.01	
Compliance	<0.0001*	<0.0001*	<0.0001*	<0.0001*	1.01	
Resistance	<0.0001*	<0.0001*	<0.0001*	<0.0001*	1.01	
*Statistically significant						

Table 4: Endotracheal cuff pressures and respiratory mechanics within Group V						
Variables	ANOVA	T ₁ vs T ₂	T ₁ vs T ₃	T ₁ vs T ₄	T ₁ vs T ₅	
ETTc	<0.0001*	0.02*	1.01	1.01	0.01*	
Ppeak	<0.0001*	<0.0001*	<0.0001*	<0.0001*	0.58	
Pmean	<0.0001*	<0.0001*	<0.0001*	<0.0001*	1.01	
Compliance	<0.0001*	<0.0001*	<0.0001*	<0.0001*	1.01	
Resistance	0.02*	0.91	1.01	0.44	1.01	

*Statistically significant

ETTc when the cuff is not compliant enough to resist changes in larger airway pressures as the trachea and endotracheal tube cuff are part of the same pneumatic system. These changes in cuff pressure hamper tracheal mucosal microcirculation. We observed that ETTc was comparable between the two groups although slightly on the lower side in group P.

Haemodynamic variables were comparable in our study. Similar results have been observed in other studies.^[1-3,10] They have attributed it to a smaller magnitude of changes in mean airway pressure. There was a possibility of haemodynamic instability in group P due to the effect of increased mean airway pressure on pleural pressure.^[2] We have not noticed such changes.

We did not notice any difference in sore throat, hoarseness and cough between the two groups. This is because cuff pressure has not exceeded a safe limit at any point of time. Impact of controlling and measuring endotracheal cuff pressure with and without nitrous oxide on the spectrum of complications such as cough, sore throat, hoarseness and blood-streaked expectoration has been investigated by Mogal and Kosar *et al.*^[7,8]

Kwon *et al.* conducted a trial to correlate BMI, pneumoperitoneum time and ETTc in laparoscopic surgeries in head-up position and could correlate the only duration of pneumoperitoneum with ETTc changes.^[9]

Jaju *et al.* in their study concluded that pressure-controlled ventilation is a safer alternative to volume-controlled ventilation in patients undergoing robot-assisted pelvic surgeries as it offers advantages.^[11] Moningi *et al.* on evaluating in patients undergoing single-level anterior cervical discectomy and fusion surgery found either mode to be equally efficacious clinically.^[12] Movassagi *et al.* also suggested usage of dual modes for better lung and oxygenation parameters resulting in a decrease in ventilator-induced lung injury in obese patients.^[2]

The limitations of our study were that various baseline endotracheal cuff pressures were not evaluated. Cuff pressure manometer does not measure small variations in ETTc. Intracuff pressure can increase due to a cephalad displacement of the diaphragm and decreased intrathoracic volume, so evaluation of this issue in a setting of steep Trendelenburg position (e.g. prostatectomy or colectomy) or obese patients or surgeries of longer durations would be better. Arterial blood gas analysis was not done to assess oxygenation as these were short duration surgeries and significant blood gas changes were not expected. Oxygen saturation was monitored intraoperatively and in the recovery room. Sample size may be small and is not powered to consider outcomes in terms of respiratory mechanics or to detect pharyngeal co-morbidities. Fibre-optic bronchoscopy was not used to assess the tracheal mucosal injury. Our study can serve as a potential pilot study for future research projects and similar studies can be done with other modes of ventilation and subjects with poor cardiopulmonary reserve to assess the effect of respiratory parameters on endotracheal cuff pressure. Although pressure time

scalar is different in the two modes of ventilation, we have compared respiratory mechanics between them as tidal volume was maintained at 7 ml/kg in both groups.

In conclusion, group P and group V appear to be equally efficacious and did not cause significant variation of ETTc by respiratory mechanics. Endotracheal cuff pressure may not vary with these two modes of ventilation but can vary at various time intervals due to pneumoperitoneum. However, in terms of respiratory parameters, group P appears to be better as it shows lower Ppeak and higher Pmean.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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