New Supraglottic Airway Device; I- Gel in Elective Laparoscopic Cholecystectomy Using Volume Controlled Ventilation versus Pressure Controlled Ventilation

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Abstract: Background: Now a dayes we have several types of supraglottic airways devices rather than classic laryngeal mask airway, such as the LMA ProSeal (LMA North America, Inc.), LMA Supreme (LMA North America, Inc.), i-gel (Intersurgical Inc.). Several publications have reported successful, safe use of supraglottic airway for general anesthesia with positive pressure controlled ventilation. In this study may aimed to compare how the VCV and PCV modes using I-gel affecting the hemodynamic, pulmonary mechanics and gas exchange. **Methods:** Fifty six patients ASA Ⅰ-Ⅱ, undergoing elective laparoscopic cholecystectomy were randomly allocated to the study. Standard anesthesia technique was used for all patients. The patients were divided into two equal groups, (the pressure controlled -PCV- and volume controlled -VCV-). Patients in both groups ventilated with constant tidal volume 7ml/kg (T_v), inspiratory time, inspiratory flow and respiratory rate.
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Key words: Supraglottic; LMA ProSeal; LMA Supreme , i-gel.

1. Introduction

The i-gel airway is a novel and innovative supraglottic airway management device, made of a medical grade thermoplastic elastomer, which is soft, gel-like and transparent. The i-gel was designed to create a non-inflating anatomical seal of the pharyngeal, laryngeal and perilaryngeal structures while avoiding the compression trauma that can occur with inflatable supraglottic airway devices[1, 2]. The i-gel is a truly anatomical device, achieving a mirrored impression of the pharyngeal, laryngeal and perilaryngeal structures, without causing compression or displacement trauma to the tissues and structures in the vicinity. The i-gel has evolved as device that accurately positions itself over the laryngeal framework providing a reliable perilaryngeal seal and therefore no cuff inflation is necessary[3]. Its advantages include easier insertion, minimal risk of tissue compression and stability after insertion. An integrated gastric channel can provide an early indication of regurgitation, facilitates venting of gas from the stomach and allows for the passing of a nasogastric tube to empty the stomach contents[4].

Several studies have reported the successful safe use the supraglottic airway devices in patients who are undergoing laparoscopic surgery[5-8]which have increasingly been used in many surgical procedures[9]. Cardiopulmonary physiology and pathophysiology of pneumoperitoneum is now well understood[10]. Besides cardiovascular effects, one of the most obvious ventilator consequences is the increased peak airway pressure (P_{peak}), and the other one is decrease in pulmonary dynamic compliance due to increases of intrathoracic pressure in relation to elevated intraabdomenal pressure and abdominal expansion shifts the diaphragm upward and the abdominal part of chest wall stiff[10, 11]. However, high airway pressure and decreased compliance

In order to limit this increase in the P_{peak}, the anesthesiologist can change the respiratory rate and $T_{v,}$ or they can change from VCV to PCV. PCV is now frequently used in the operating room in the management of patients with elevated P_{peak} despite on incomplete understanding of its ventilator and hemodynamic effects or its potential complication[10, 12-13]. The PCV is a time-cycled mode in which square waves of pressure are applied and released by means of a decelerating flow[14]. The decelerating flow often results in a higher mean inflation pressure when compared with constant flow[15,16]. Therefore, with the concomitant presence of pneumoperitoneum, complex cardiopulmonary responses can occur[17]. As for as we know, the effects of PCV on ventilator and hemodynamic parameter during laparoscopic procedures have not been assessed carefully by controlled studies. My study was aimed to evaluate how the PCV and VCV affect the pulmonary mechanics, the gas exchange and hemodynamic responses in patients who are undergoing laparoscopic cholecystectomy using i-gel.

2. Patients and Methods:

After approval by local ethics committee of King Abdulla Medical City, 56 male and female, 22-65 years old, ASA physical status Ⅰ - Ⅱ, Mallampati class Ⅰ or Ⅱ were selected for laparoscopic cholecystectomy

gave me their written informed consent to be included in this study, the patient with history of gastric reflux, hiatus hernia, history of allergy to any of study drugs and suspected difficulty with their airway passages were excluded.

The patients were randomly allocated to one of two groups (the PCV and VCV groups); all patients received premedication 1mg midazolam, 50mg ranitidine, 4mg ondansetron and 0.2mg glycopyrrolate 45min before induction of anesthesia. The anesthetic management and intraoperative care were standardized and same for all patients. Routine monitoring and ventilation was established by using Datex-Ohmesa aisys machine with (GE healthcare) standard monitor. After preoxygenation induction of anesthesia was done by propofol 2-2.5mg/kg, fentanyl 1-1.5mcg/kg and neuromuscular relaxation achieved by rocuronium 0.8-1mg/kg, after adequate depth of anesthesia and relaxation i-gel device was inserted after carefully selection according to manufacturer recommendation and proper preparation with water soluble lubricant. Correct placement of the device was confirmed by observation of proper chest expansion, square shape of end tidal CO_2 waveform and absence of audible leak sounds and leak pressure was obtained by closing the expiratory valve of the anesthesia circuit with a fixed gas flow rate of 3l/min and noting the airway pressure at which equilibrium was reached, it was not exceed 40cm H_2O. Device was then tapped over the chin and connected to anesthesia machine. Gastric tube is lubricated and inserted down via the gastric drainage channel. Monitoring included electrocardiography (ECG), noninvasive arterial pressure, pulsoexmetry, capnography, neuromuscular transmission, inspiratory and expiratory concentrations of oxygen, carbon dioxide, and sevoflurane. The P_{peak}, P_{mean}, airway resistance, leak pressure, compliance, inspiratory and expiratory tidal volume by spirometry. The P_{plat} calculated during inspiratory and expiratory hold. Depth of anesthesia monitored by approximate entropy of EEG, by M-Entropy Module S/S Datex-Ohmeda.

Anesthesia was maintained with propofol, sevoflurane and fentanyl in 40% oxygen/air and this was adjusted to keep the entropy values between 40 and 60 and neuromuscular block was assured with the administration of rocuronium as evidenced by the lack of a train of four responses to neuromuscular stimulation. After completion of surgery, the residual neuromuscular block was reversed with pyridostigmine and glycopyrrolate. During the study period, the mechanical ventilator was set to obtain, with both the ventilatory modalities, A tidal volume of 7ml/kg, a respiratory rate (R.R) of 12 breaths/min and an inspiratory/expiratory (I:E) ratio of 1:2, no end inspiratory pause or positive end-expiratory pressure were used.

My study consisted of four steps for both groups, first step was 5 minutes after i-gel insertion (T zero), the second step was 10 minutes after pneumoperitoneum (T1), the third step was 50 minutes after pneumoperitoneum (T2) and the last step was at the time of end of procedure (T3). Arterial blood sample was taken for blood gas analysis in all steps. In both groups, a carbon dioxide pneumoperitoneum was induced with a maximal intraabdomenal pressure of 15mmHg, and the maximal allowed head-down trendelenberg position was 15˚.

Statistical analysis:

Data were computerized and analyzed using Epi-info. Software, version6.04. A word processing, database and statistics program (WHO, 2001). The comparison between data obtained from VCV and PCV was performed by a χ mean, SD (standard deviation) test to measure the central tendency of data and the distribution of data around their mean value, Student 's t-test for testing statistical significant difference between mean values of two samples, χ^2 test (Chi square test) for statistical significant relation between different variable or grades in qualitative data, Paired t-test P^t for significant difference between two reading for the same person (before and after intervention or between his two left and right sides), Fisher 's exact test for comparing two independent proportions when the expected observation in any cell of the table is below 5. Significant result is considered if P <0.05.

3. Results:

The study included 56 patients randomized into two groups of 28 patients according to ventilation mode (VCV or PCV). No patient was excluded or withdrawn from the study. None of the study patients was noticed as positive for gastric distention or vomiting during the procedure. Demographic characteristics are shown in table (1). The hemodynamic response at each time is presented in table (2). The mean values gas exchange at each time is presented in table (3). The mean values of ventilation and lung mechanics are presented in table (4).

Pneumoperitoneum did not induce a significant increase in the heart rate, systolic arterial pressure and mean arterial pressure, (Table 2). Arterial oxygen tension show significant difference between pressure controlled and volume controlled ventilation groups at T0 and T2 as pressure controlled group show higher arterial oxygen tension. End tidal CO_2, arterial carbon dioxide tension increased and pH decreased after CO_2 insufflation with no significant difference between two groups at all times (Table 3).

The peak airway pressure increased in both groups after CO_2 insufflation but with high significant difference between pressure controlled and volume

controlled ventilation groups, plateau pressure was significantly higher during volume controlled than pressure controlled ventilation group at all time, mean airway pressure show significant decrease at T1 and T2 in pressure controlled than volume controlled ventilation group (Table4). Comparison of lung compliance in both groups of pressure and volume controlled ventilation modes revealed significant decrease in volume controlled ventilation group at all times of study, (Fig. 1, Table 4). As regarding to airway resistance it reveal significant increase in volume controlled ventilation group after pneumoperitoneum at T1 and T2, fig. (2) ; table (4).

None of the study patients was noticed as gastric distention or vomiting during the procedure and on removal of i-gel there was no spasm of upper airway or hoarseness of voice.

Values are means ± SD, $ETCO_2$: End tidal CO2, PAO_2 Arterial oxygen tension, $PACO_2$ arterial carbon dioxide tension, T0: 5 minutes after incretion of laryngeal airway, T1: 10 minutes after pneumoperitoneum, T2: 50 minutes after pneumoperitoneum, T3: at the end of procedure. There was significant difference between groups in PAO2 at T2. Pressure controlled group recorded higher readings.

Table (1): Demographic characteristics of cases in the studied groups:

Variables	Pressure controlled group No=28	Volume controlled group No=28	*P* value
Age /year	40.07±5.13	40 ± 3.95	0.9536
Sex: males no. (%) Females no.(%)	14 (50%) 14 (50%)	12 (42.9%) 16 (57.1%)	0.5920
Weight/kg	79 ± 5.58	75.54 ± 4.96	0.0173
Height /cm	169.89 ± 1.87	169.68 ± 1.96	0.6776
OT / minute	114.43 ±17.39	113.11 ± 19.86	0.7921
AT / minute	125.43 ±17.3	124.39 ± 18.58	0.8299

Values are means ± SD, OT: operation time, AT: anesthetic time

Table (2): Hemodynamic responses at different time for the studied groups:

Heart rate (bpm)	Pressure controlled group No=28	Volume controlled group No=28	*P* value
T0	74.39 ± 5.37	75.75 ± 5.52	0.3553
T1	73.29 ± 4.74	74.39 ± 5.59	0.3626
T2	72.07± 5.09	70.64 ± 3.72	0.2359
T3	72.5 ± 4.37	73.96 ± 4.58	0.2262
Systolic pressure (mmHg)			
T0	129.61 ± 7.34	131.46 ± 7.62	0.5389
T1	131.25 ± 6.4	132.82 ± 6.44	0.3637
T2	135.61± 6.56	136.54 ± 5.36	0.5641
T3	135.42 ± 6.32	136.21 ± 6.56	0.6497
Mean arterial pressure (mmHg)			
T0	75.25 ± 3.89	77.61 ± 6.62	0.4163
T1	86.54 ± 6.97	87.36 ± 7.39	0.6703
T2	89.82± 6.88	90.57 ± 8.63	0.5324
T3	88.89 ± 7.44	89.07 ± 7.57	0.9293

Values are means ± SD, T 0: 5 minutes after incretion of laryngeal airway, T1: 10 minutes after pneumoperitoneum, T2: 50 minutes after pneumoperitoneum, T3: at the end of procedure .There was no statistical significant difference between groups.

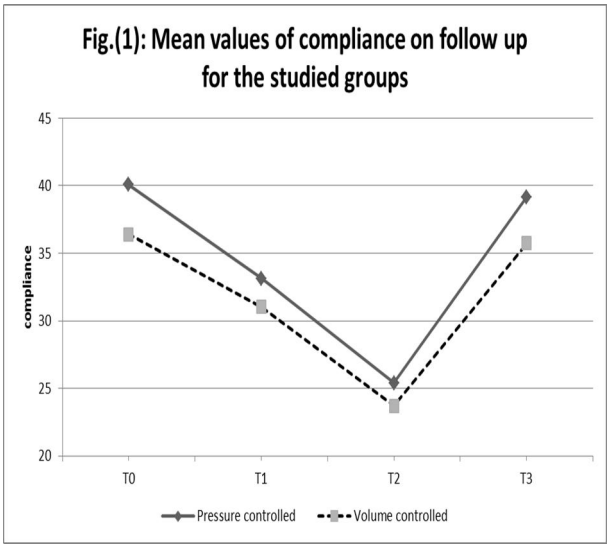
Table (3): Gas exchange at different time for the studied groups:

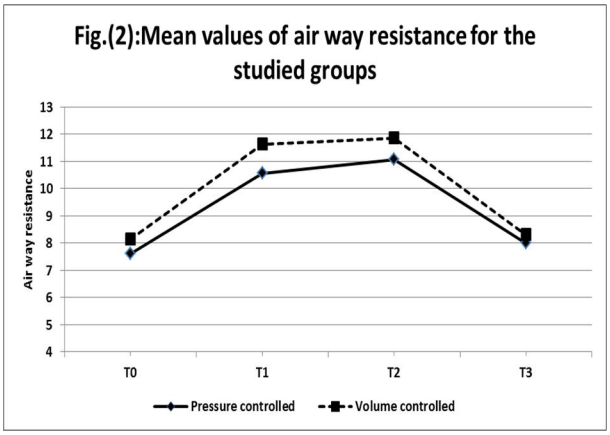
$ETCO_2$	Pressure controlled group No=28	Volume controlled group No=28	*P* value
T0	30.79 ± 1.59	31.32 ± 1.79	0.2416
T1	38.54 ± 1.79	38.75 ± 1.88	0.6642
T2	30.79± 1.59	31.32 ± 1.79	0.2416
T3	39.25 ± 1.89	38.86 ± 2.66	0.5276
PH			
T0	7.450 ± 0.051	7.457 ± 0.050	0.5999
T1	7.429 ± 0.07	7.439± 0.04	0.6642
T2	7.393± 0.047	7.379 ± 0.050	0.2728
T3	7.379 ± 0.042	7.386 ± 0.036	0.4942
PAO_2			
T0	258.4 ± 11.93	255.20 ± 9.02	0.1368
T1	236 ± 9.79	231.15 ± 10.88	0.0642
T2	258.4± 11.93	252.20 ± 9.02	0.0279
T3	254.36 ± 19.83	252.39 ± 16.59	0.2971
$PACO_2$			
T0	34.78 ± 2.51	33.88 ± 2.98	0.2266
T1	36.54 ± 1.79	37.81 ± 1.88	0.1652
T2	34.784± 2.51	33.88 ± 2.98	0.2266
T3	38.90 ± 1.84	39.59 ± 1.8	0.1601

Table (4): Mean values of ventilation and lung mechanics at different time for the studied groups:

T_v	Pressure controlled group No=28	Volume controlled group No=28	*P* value
T0	533 ± 39.09	528.75 ± 34.74	0.0173
T1	553 ± 39.09	528.75 ± 34.74	0.0173
T2	533 ± 39.09	528.75 ± 34.74	0.0173
T3	533 ± 39.09	528.75 ± 34.74	0.0173
P_{peak}			
T0	18.25 ± 1.53	19.07 ± 1.48	0.0753
T1	21.96 ± 1.32	23.32 ± 1.19	0.0001
T2	26.71± 1.46	27.89 ± 1.55	0.0049
T3	18.82 ± 1.28	19.54 ± 1.84	0.0968
P_{plat}			
T0	13.71 ± 1.15	14.79 ± 1.23	0.0013
T1	15.68 ± 1.39	17.14 ± 1.35	0.0001
T2	18.32± 1.42	19.25 ± 1.56	0.0231
T3	14.14 ± 1.01	15.5 ± 1.07	0.0001
P_{mean}			
T0	6.43 ± 0.88	6.82 ± 1.06	0.1361
T1	7.71 ± 0.85	8.68 ± 0.91	0.0001
T2	8.79± 1.17	9.54 ± 1.2	0.0213
T3	6.79 ± 1.17	7.04 ± 1.11	0.4138
Compliance			
T0	40.07 ± 1.61	36.39 ± 3.55	0.0001
T1	33.14 ± 2.01	31.04 ± 2.01	0.0001
T2	25.39± 1.77	23.71 ± 2.21	0.0027
T3	39.18 ± 1.31	35.75 ± 2.79	0.0001
Airway resistance			
T0	7.61 ± 1.03	8.14 ± 1.41	0.1089
T1	10.57± 1.62	11.64 ± 1.22	0.0072
T2	11.07± 1.36	11.86 ± 1.08	0.0200
T3	8 ± 0.86	8.32 ± 1.09	0.2261

Values are means ± SD, T_v: tidal volume (ml), P_{peak}: peak airway pressure (cmH_2O), P_{plat}: plateau pressure, P_{mean}: mean airway pressure, T0: 5 minutes after incretion of laryngeal airway, T1: 10 minutes after pneumoperitoneum, T2: 50 minutes after pneumoperitoneum, T3: at the end of procedure. There was significant difference between groups at: - P_{peak}, P_{mean} and air way resistance as pressure controlled group show low reads on T1 and T2.- P_{plat} and compliance as pressure controlled group show low reads on all times.





4. Discussion:

Volume controlled ventilation is the common mode of ventilation used in operating theater with endotracheal tube, now a day supraglottic airway devices used safely in laparoscopic surgery with more advantages including more hemodynamic stability during induction and maintenance of anesthesia, lower incidence of sore throat and less upper airway trauma.

This study demonstrated that, i-gel used safely during laparoscopic cholecystectomy with no hemodynamic changes after pneumoperitoneum comparing pressure controlled ventilation with volume controlled ventilation. This study also shows improving of arterial oxygen tension during pneumoperitoneum with pressure controlled ventilation. As regarding to ventilatory data and lung mechanics after pneumoperitoneum revealed more improvement with pressure controlled ventilation mode than with volume controlled ventilation mode in form of reduction of peak airway pressure, plateau pressure, mean airway pressure, improvement of lung compliance and airway resistance.

Earlier studies have shown that the LMA-Classic can be successfully used to ventilate with adequate pulmonary ventilation during laparoscopic surgical procedures[5, 6, and 18]. Galvin *et al.*[6] demonstrated that pressure controlled ventilation using LMA-Classic might be useful during pneumoperitoneum. However, they did not compare the effects of volume controlled and pressure controlled ventilation. The clinical utility of peak airway pressure limitation during mechanical ventilation is usually questionable while the plateau pressure, which is measured during the end-inspiratory pause, is considered the more reliable pressure limit because it avoids the main complication caused by positive-pressure ventilation (*i.e.*, pulmonary over inflation and barotrauma)[19]. During one lung anesthesia, Tuğrul *et al.*[20] concluded that pressure controlled ventilation appeared to be an alternative to volume controlled ventilation and it might be superior to volume controlled ventilation for patients with respiratory disease. However, Unzueta *et al.*[21] found that the use of pressure controlled ventilation during one-lung ventilation did not lead to improved oxygenation compared with that of volume controlled ventilation for patients with good preoperative pulmonary function, but pressure controlled ventilation did lead to a lower $P_{peak.}$ During laparoscopy, Balick-Weber *et al.*[9] found no advantage of pressure controlled ventilation over volume controlled ventilation regarding the respiratory mechanics, gas exchange or the cardiac function, and specifically the risk of barotrauma was not decreased by pressure controlled ventilation. However, Woo Jae *et al.*[22] concluded that pressure controlled ventilation using a LMA is a rational method of ventilation during gynecological laparoscopy, and it ensures oxygenation while minimizing the increases of P_{peak} after CO_2 insufflation. De Baerdemaeker *et al.*[23] demonstrated that volume controlled ventilation and pressure controlled ventilation appeared to be equally suited ventilator techniques for laparoscopic procedures in morbidly obese patients, and the CO_2 elimination was more efficient when using volume controlled ventilation. They also found that this observation must be because of differences of minute ventilation, physiologic dead space or CO_2 production. Endotracheal intubation was performed that previous study. Giuseppe *et al.*[24] found

that pressure controlled rather than volume controlled ventilation can improve the effectiveness of mechanical ventilation in patients with high airway pressure. Mustafa *et al.*[25] found that lower P_{peak}, P_{plat}, and airway resistance and higher compliance are observed with pressure controlled ventilation in laparoscopic gynecologic surgery. Cadi *et al.*[26] concluded during anesthesia for laparoscopic bariatric surgery comparing pressure controlled with volume controlled ventilation improves gas exchanges without increasing ventilation pressures or causing any hemodynamic side effects. A. Tyagi *et al.*[27] concluded that pressure controlled ventilation is a safe alternative and offers some advantages to volume controlled ventilation in form of lower P_{peak} and high compliance except P_{mean} was increased.

In conclusion, till now use of supraglottic airway in laparoscopic surgery is probably just a fragment of puzzle in anesthesia field, but I found i-gel can be used safely as alternative to endotracheal tube for lung ventilation during elective laparoscopic cholecystectomy without any complication and pressure controlled ventilation has no advantage over volume controlled ventilation regarding hemodynamic response. Regarding gas exchange and respiratory mechanics pressure controlled ventilation can improve the effectiveness of mechanical ventilation and oxygenation compared to volume controlled ventilation. Further studies are required to explore the effects of pressure controlled and volume controlled ventilation on hemodynamic response, gas exchange and ventilatory mechanics in variety of patient undergoing laparoscopic surgery.

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