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Original Article

Low-pressure Pulmonary Recruitment Maneuver to Decrease Post-laparoscopic Shoulder Pain in Gynecologic Surgery: A Double-blind Randomized Placebo Controlled Trial

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Pulmonary recruitment maneuver, post-laparoscopic shoulder pain, gynecologic laparoscopic surgery

Abstract

Objective: *To evaluate the efficacy of minimum optimal pressure (30 and 40 cmH_2O) of pulmonary recruitment maneuver (PRM) for reducing post-laparoscopic shoulder pain (PLSP).*

Methods: *Women who were scheduled for laparoscopic gynecologic surgery during October 2020 to June 2021 were enrolled and randomly assigned to three groups: PRM 30 cmH_2O (30-PRM) group, PRM 40 cmH_2O (40-PRM) group and control group. All participants were placed in the Trendelenburg position and compressed abdomen to eradicate gas. PLSP scores were assessed by using a visual analog scale (VAS).*

Results: *Total of 80 women were included and randomized to 30-PRM group (N = 28), 40-PRM group (N = 26) and control group (N = 26).The PLSP scores at 12-hour after surgery in 40-PRM group were significantly lower than the control group (VAS 0 = 57.7%, VAS 1-3 = 19.2% and VAS ≥ 4 = 23.1% in 40-PRM group vs VAS 0 =19.2%, VAS 1-3 = 26.9% and VAS ≥ 4 = 53.9% in control group, P = 0.018), while no significant difference of PLSP between 30-PRM and control groups (P = 0.256). Other variables, such as PLSP at 24 and 48 hrs., post-operative surgical pain, nausea and vomiting, vital signs and residual gas in abdominal cavity at 24-hour were similar among three groups.*

Conclusions: *PRM with pressure 40 cmH_2O significantly decreases PLSP at 12 hours. This procedure is feasible and safe. Using the PRM with pressure 40 cmH_2O may be applied at the end of laparoscopic procedure.*

Introduction

Laparoscopic surgery is a modern minimal invasive technique and commonly used for surgical practice. In gynecologic procedure, we use it for myomectomy, cystectomy, tubal resection, hysterectomy or diagnosis, etc. The advantages include earlier recovery, lower morbidity, decrease blood loss during procedure, decrease wound size and analgesic requirements, shorter admitted time or better cosmetic result [1–4]. However, more than half of people who underwent this procedure have experience of post-operative shoulder pain which causes more discomfort and often does not relieve by analgesic drug [5].

Postoperative laparoscopic shoulder pain is caused by insufflated or remnant carbon dioxide gas, changes to carbonic acid [6,7], that induces an irritation of the phrenic nerve at diaphragm and caused referred pain to the dermatome of shoulder (C4 nerve) [8–10]. In the literatures, to decrease this side effect, there are many ways to get rid of the post-laparoscopic shoulder pain (PLSP) by using fluid instillation, intraperitoneal drainage, subdiaphragmatic intraperitoneal local anesthesia, local anesthetic into peritoneal cavity, gasless laparoscopy or using warmed and humidified carbon dioxide (CO_2) gas [11–14]. One of the ways that easy to perform is using the pulmonary recruitment maneuver (PRM).

The PRM is used to open alveoli by positive inspiratory pressure. Increasing of the intrapulmonary pressure result in an increase of the intraperitoneal pressure and consequently release of CO_2 gas from abdominal cavity. However, using of higher inspiratory pressure of PRM can make more complications; hemodynamic deterioration or pulmonary barotrauma [15–17].

Recent study has compared using PRM with maximum inspiratory pressure 40 cm H_2O and 60 cm H_2O which could decrease PLSP significantly than in the control group, but there were no statistically significant different of PLSP between two intervention group [18]. In the earlier study, the PRM was performed

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using pressure at 30 cm H_2O [19] to reduce PLSP, but in control group was not set in the Trendelenburg position which effects for removing residual CO_2 gas.

Therefore, this randomized controlled trial was designed to assess the efficacy of minimum optimal pressure (30 and 40 cm H2O) of using PRM to reduce PLSP after surgery.

Material and methods

We performed the randomized controlled trial (RCT) study at Rajavithi Hospital, Bangkok, Thailand, between October 2020 and June 2021. The present study was approved by the Ethics Committee, Rajavithi Hospital and was registered to ClinicalTrials.gov (NCT04642118).

Women who were scheduled for laparoscopic gynecologic surgery were asked to be the participants in the study. The inclusion criteria were composed of age between 18 and 65 years, American Society of Anesthesiologists physical status (ASAPS) classification I-II and informed consent. The exclusion criteria were as follows: psychiatric disorder, inability to accurately express their pain, present of pregnancy, drug allergy (naproxen, paracetamol), currently of corticosteroid drug used, past history of shoulder or lung surgery, chronic shoulder problem or epigastric pain, and lung disease such as chronic obstructive pulmonary disease (COPD), pneumothorax, pleural effusion or emphysema.

All participants were counselled for the study about information from clinician and informed consent was written. Subjects were classified by procedure; the laparoscopic hysterectomy group and another surgical (non-hysterectomy) group. Then they were assigned to 3 groups, PRM with pressure 30 cm H_2O (group A), PRM with pressure 40 cm H_2O group (group B) and the control group (group C) at 1:1:1 ratio by using a random-permuted block randomization via web-based system (www.randomization.com). All patients, surgeons and outcome assessors (in-patient department (IPD) nurses) were blinded except anesthesiologist who would open the concealment allocated paper to do the intervention follow with protocol (PRM 30 cm H_2O group, PRM 40 cm H_2O group, and the control group).

All participants received the same anesthetic protocol. Intravascular fentanyl 1 mcg/kg and propofol 2 mg/kg were administered. Then, cisatracurium 0.15 mg/kg was injected and maintained with cisatracurium 0.03 mg/kg for neuromuscular block (or atracurium 0.5 mg/kg was used instead and maintained with atracurium 0.1-0.2 mg/kg). After that, endotracheal tube with cuff was intubated and sevoflurane 1.5-2 vol% was used to achieve state entropy. Intravascular fentanyl 1- 2 mcg/kg could be used to maintain anesthesia during laparoscopic surgery and total dosages of fentanyl would be recorded. The gas pressure was set at 12-15 mmHg during the procedure. After the surgery, patients in all groups would be set into Trendelenburg position 2 minutes for abdominal compression by surgeon to eradicate residual gas and PRM procedure by anesthesiologist. Patients in PRM group would be receive positive inspiratory pressure 5 times and maintained at an end plateau pressure at 30 or 40 cm H_2O for 5 second per time (that can be control pressure at machine). Post-operative pain would be care with paracetamol 500 mg. oral every 4-6 hours if patient felt pain and naproxen 250 mg oral post-meal 3 times per day. For break-through pain, morphine and parecoxib could be given and would be recorded.

Shoulder and surgical pain would be followed and recorded by using the visual analogue scale (VAS) from score 1 to 10 at 12, 24 and 48 hours by IPD nurses whom did not know group of intervention. The residual gas in abdomen will be followed by chest x-ray (CXR) upright position at 24 hours after surgery. Primary outcome was comparing intensity of shoulder pain among three groups at 12, 24 and 48 hours. The secondary outcomes included the post-operative surgical pain score at 12, 24 and 48 hours, the height of residual pneumoperitoneum at first day, gastrointestinal discomfort symptom, duration of hospital staying, administered additional analgesics, and lung complication such as pneumothorax, lung atelectasis, pleural effusion or subcutaneous emphysema.

From Lee J et al [19], we used the result on pain intensity of PLSP more than wound pain at 24 hours after surgery to calculated the sample size. With an alpha value of 5% and a power of 80%, we estimated that 26 women would be need per each group. We anticipated a dropout rate of 15%, the total sample size per each arm was 30 women.

Statistical analyses were performed using STATA 15 (STATA Corporation). All data were analyzed according to the basis of intention-to-treat principle. The categorical data was presented as frequencies (percentage) and continuous data was presented as median (interquartile range, IQR) or mean ± standard deviation (SD). For the inferential statistics, the categorical data were compared by using the Chi-square test or Fisher's exact test and continuous data were compared by using one-way ANOVA or Kruskal-Wallis test. We also used generalized linear mixed model of ordinal logistic and quantile regression for analysis.

Result

In the study periods, there was COVID-19 outbreak. In total, 106 women who were scheduled for laparoscopic gynecologic surgery, 26 women were excluded. Thus, 80 women were randomized by block of three to PRM 30 cm H_2O (group A, N=28), PRM 40 cmH_2O (group B, N=26) and control group (group C, N=26) as show in Figure 1.

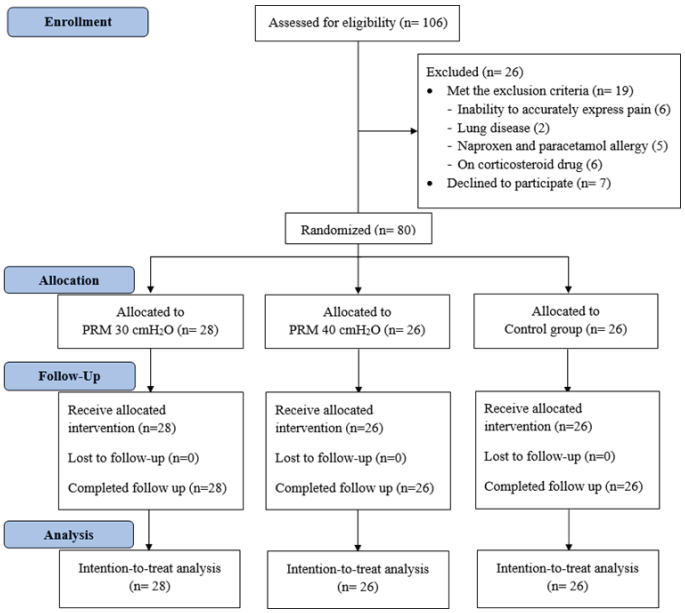


Figure 1. *Flow diagram of the participants*

Table 1. *Baseline characteristics of woman who received laparoscopic gynecologic surgery*

Variables	Woman who received laparoscopic gynecologic surgery (N=80)			P – value
	Group A (N=28)	Group B (N=26)	Group C (N=26)	
Age (yrs.), median (Range)	40.5 (31)	40.0 (38)	37.5 (28)	0.37
Hight (cm.), mean (SD)	158.50(5.62)	157.42 (5.65)	157.73 (5.01)	0.75
Weight (kg.), mean (SD)	60.25 (12.37)	60.80 (9.18)	60.59 (9.80)	0.98
BMI (kg/m^2)				
< 25 kg/m^2, N (%)	18 (64.3%)	18 (69.2%)	16 (61.5%)	0.84
≥ 25 kg/m^2, N (%)	10 (35.7%)	8 (30.8%)	10 (38.5%)	
Underlying disease, N (%)	7 (25.0%)	3 (11.5%)	7 (26.9%)	0.33
Hypertension, N (%)	2 (7.1%)	1 (3.8%)	3 (11.5%)	0.57
Diabetes Mellitus, N (%)	1 (3.6%)	1 (3.8%)	0 (0%)	0.61
Dyslipidemia, N (%)	1 (3.6%)	0 (%)	1 (3.8%)	0.61
ASA physical status				
I, N (%)	22 (78.6%)	18 (69.2%)	18 (69.2%)	0.67
II, N (%)	6 (21.4%)	8 (30.8%)	8 (30.8%)	
Smoking (%)	0 (0%)	1 (3.8%)	1 (3.8%)	0.58
Alcohol drinking (%)	0 (0%)	1 (3.8%)	1 (3.8%)	0.58
Abdominal surgery history, N (%)	11 (39.3%)	12 (46.2%)	11 (42.3%)	0.88
Type of surgery				
Hysterectomy (%)	12 (42.9%)	12 (46.2%)	9 (34.6%)	0.68
Myomectomy or Adnexal surgery (%)	16 (57.1%)	14 (53.8%)	17 (65.4%)	

Abbreviations: SD, standard deviation; N, number; BMI, body mass index; ASA, the American Society of Anesthesiologists; m, meter; kg, kilogram; yrs., years Group A, PRM 30 cmH_2O; Group B, PRM 40 cmH_2O; Group C, control

Table 2. *Operative details*

Variables	Woman who received laparoscopic gynecologic surgery (N=80)			P – value
	Group A (N=28)	Group B (N=26)	Group C (N=26)	
CO2 volume (L), median (Range)	40.5 (31)	40.0 (38)	37.5 (28)	0.37
Operative time (min), mean (SD)	167.68 (64.34)	163.46 (55.11)	167.31 (66.77)	0.96
Gas pressure (cmH_2O), mean (SD)	14.82 (0.95)	14.85 (0.61)	14.65 (0.98)	0.68
Estimated blood loss (ml), median (Range)	50.0 (495.0)	65.0 (1,095.0)	50.0 (795.0)	0.80
Amount of fentanyl used in OR[a] (mcg), mean (SD)	179.11 (51.21)	175.19 (61.83)	169.42 (50.48)	0.81

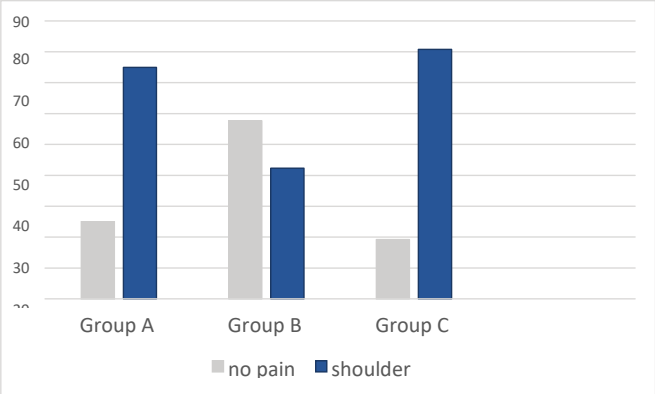
Abbreviations: L, Liters; ml, milliliter; SD, standard deviation; mcg, micrograms, N, number; min, minutes; OR, operating room; a, Timing during operating room until 2 hours in recovery room; Group A, PRM 30 cmH_2O; Group B, PRM 40 cmH_2O; Group C, control

Demographic baseline characteristics are presented in Table 1. The factors including age, body mass index (BMI), underling disease, history of surgery or type of surgery were similar among 3 groups. For the operative details were the same, CO_2 gas volume, gas pressure, operative time, fentanyl used in operative room (OR), or estimated blood loss were not statistically significant difference in all groups as show in Table 2.

For primary outcome, we found that there was statistically significant difference in post- laparoscopic shoulder pain at 12 hours among 3 groups with median pain score 3, 0 and 4.5 (P = 0.016) in group A, group B and group C respectively. The graph in Figure 2 shown that the incidences of PLSP for group A, B and C were 75%, 42.3% and 80.8% respectively. Another variable, the secondary outcomes, such as surgical pain, postoperative nausea vomiting, length of hospital stay or residual gas in abdominal cavity at 24 hrs. were similar in all groups as show in Table 3. Almost of patient in group B had no pain or had an incidence of mild pain, which can see in Table 3 and Figure 3.

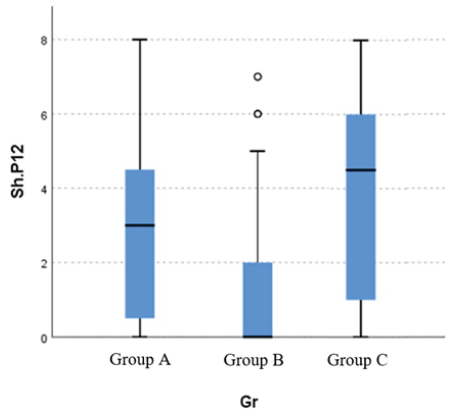
Then, we had classified patient in to 3 groups, pain score 0 is no pain, pain score 1 – 3 is mild pain, and pain score more than 4 is moderate to severe pain as present in Table 4. The range of VAS scores of PLSP at 12 hrs. in the group B were significantly lower than the group C (VAS 0=57.7%, VAS 1-3=19.2% and VAS ≥4=23.1% in the group B vs VAS 0=19.2%, VAS 1-3=26.9% and VAS ≥4=53.8% in the group C) (P = 0.018), while no significant difference of PLSP between the group A and the group C (P = 0.256).

Generalized estimating equations for ordinal outcome was used and shown that using of PRM with pressure 40 cm water could reduce PLSP significantly with odd ration 0.375 (95%CI: 0.166-0.845) or around 62.5% (P-value 0.018) when compared with the control group (Table 5).



Group A, PRM 30 cmH_2O; Group B, PRM 40 cmH_2O; Group C, control

Table 2. *Incidence of shoulder pain in 12 hrs. after surgery (%)*



Group A, PRM 30 cmH_2O; Group B, PRM 40 cmH_2O; Group C, control

Table 2. *Distribution of shoulder pain in 12 hrs. after surgery*

Table 3. *Operative details*

Variables	Woman who received laparoscopic gynecologic surgery (N)			P - value
	Group A (N=28)	Group B (N=26)	Group C (N=26)	
Shoulder pain (VAS), median (IQR)				
12 hrs. post-surgery	3.0 (5.0)	0.0 (3.0)	4.5 (5.0)	0.016*
24 hrs. post-surgery	1.5 (3.0)	1.0 (3.0)	2.0 (4.0)	0.548
48 hrs. post-surgery	0.0 (0.0)	0.0 (0.0)	0.0 (1.0)	0.124
Surgical pain (VAS), median (IQR)	6.0 (4.0)	4.5 (2.0)	5.0 (2.0)	0.475
12 hrs. post-surgery	4.0 (4.0)	2.5 (2.0)	3.0 (2.0)	0.393
24 hrs. post-surgery	1.5 (3.0)	1.0 (2.0)	1.0 (2.0)	0.299
48 hrs. post-surgery				
Administered additional analgesics	2.57 (2.673)	2.31 (3.427)	1.85 (2.412)	0.646
Morphine 2-24 hr. after surgery (mg), mean (SD)	1 (3.6)	1 (3.8)	3 (11.5)	0.398
Parecoxib 2-24 hr. after surgery (mg.), N (%)				
Postoperative nausea and vomiting, N (%)	8 (28.6%)	5 (19.2%)	3 (11.5%)	0.292
Plasil, N (%)	8 (28.6%)	4 (15.4%)	2 (7.7%)	0.123
Length of hospital stay (days), mean (SD)	2.46 (0.64)	2.62 (1.36)	2.46 (0.76)	0.804
Residual gas in abdominal cavity (mm.)	3.77 (5.69)	3.80 (5.62)	5.97 (7.30)	0.346

Abbreviations: VAS, Visual analogue scale; SD, standard deviation; N, number; mm., millimeter; IQR, interquartile range
Group A, PRM 30 cmH_2O; Group B, PRM 40 cmH_2O; Group C, control
*Significant difference at $p < 0.05$

There was just only 1 case per each group who had subcutaneous emphysema which could occur after the laparoscopic surgery. During the study, there was no adverse event from using the PRM with low pressure at 30 and 40 cm H_2O as show in Table 6 and 7.

Discussion

Shoulder pain is the common symptom after laparoscopic procedure. In the present study, 21 from 29 participants who were underwent laparoscopic surgery in group C (no intervention group) had experience of shoulder pain at 12 hours (80.8%). This incidence is similar to prior study from Dong-Hee L et al [20]. They reported that 84 form 105 patients (80%) had experienced of shoulder pain which was less responsive to analgesic drugs. In group A and B, the incidences of PLSP at 12 hours were 75% and 42% respectively which were lower than in group C. The result is correlate to previous systemic review about using PRM significantly decreased PLSP that reported by Pergialiotis V et al [21].

The present RCT study is compare using PRM with two difference inspiratory pressure at 30 and 40 cm H_2O to reduce PLSP. We agree with study of Ryu K et al [18]. that using PRM with pressure 40 cm H_2O could reduce PLSP significantly when compared with control group. This pressure was safe and no adverse effected from using PRM with pressure 40 cm H_2O. However, our finding is consistent with previous study of Lee J et al [19]. Their study performed RCT of 84 women which randomized into PRM 30 cm H_2O group (N=42) and control group (N=42). They reported that patient in 30-PRM group had no shoulder pain in 24 hours (VAS=0) while in the control group, median VAS was 1.5 (P<0.001). But, in the control group, patients did not set into the Trendelenburg position

Table 4. *Post operative pain outcome*

	Woman who received laparoscopic gynecologic surgery (N)									
Variables	**Group A (N=28)**			**Group B (N=26)**			**Group C (N=26)**			**P- value**
VAS.	0	1-3	≥4	0	1-3	≥4	0	1-3	≥4	
Shoulder pain, N (%)										
12 hrs.	7 (25)	8 (28.6)	13 (46.4)	15 (57.7)	5 (19.2)	6 (23.1)	5 (19.2)	7 (26.9)	14 (53.9)	0.033*
24 hrs.	11 (39.3)	11 (39.3)	6 (21.4)	11 (42.3)	10 (38.5)	5 (19.2)	8 (30.8)	11 (42.3)	7 (26.9)	0.922
48 hrs.	24 (85.7)	3 (10.7)	1 (3.6)	21 (80.8)	5 (19.2)	0	16 (61.5)	10 (38.5)	0	0.1
Surgical pain, N (%)										
12 hrs.	2 (7.1)	5 (17.9)	21 (75.0)	0	6 (23.1)	20 (76.9)	0	3 (11.5)	23 (88.5)	0.281
24 hrs.	5 (17.9)	7 (25.0)	16 (57.1)	3 (11.5)	16 (61.5)	7 (26.9)	2 (7.7)	15 (57.7)	9 (34.6)	0.058
48 hrs.	7 (25.0)	19 (67.9)	2 (7.1)	10 (38.5)	15 (57.7)	1 (3.8)	9 (34.6)	16 (61.5)	1 (3.8)	0.839

Abbreviations: VAS, Visual analogue scale; SD, standard deviation; N, number; 0, no pain; 1-3, mild pain; ≥4, moderate to severe pain
Group A, PRM 30 cmH2O; Group B, PRM 40 cmH2O; Group C, control
*Significant difference at $p < 0.05$

Table 5. *Generalized estimating equations for ordinal outcome*

Intervention	**Shoulder pain at 12 hrs.**			**OR**	**95% CI**	**P -value**
	VAS. 0	VAS. 1-3	VAS. ≥4	0	1-3	≥4
Control, N (%)	5 (19.2)	7 (26.9)	14 (53.8)	-	-	-
PRM 30 cm. H_2O, N (%)	7 (25.0)	8 (28.6)	13 (46.4)	0.670	0.335-1.337	0.256
PRM 40 cm. H_2O, N (%)	15 (57.7)	5 (19.2)	6 (23.1)	0.375	0.166-0.845	0.018*

Abbreviations: VAS, Visual analogue scale; SD, standard deviation; N, number; cm., centimeter; 0, no pain; 1-3, mild pain
*Significant difference at $p < 0.05$

Table 6. *Hemodynamic status during receive procedure.*

Variables		**Group**			**P - value**
Hemodynamic	**Time**	**Group A (N=28)**	**Group B (N=26)**	**Group C[a] (N=26)**	
MAP (mmHg), mean (SD)	Before PRM	90.36 (12.65)	90.35(10.06)	88.14 (8.80)	0.69
	PRM stat	86.45 (9.40)	87.69 (12.22)	85.81 (9.42)	0.80
	After PRM 2 minutes	86.33 (9.37)	85.46 (13.62)	88.17 (9.74)	0.67
HR (beats/min), mean (SD)	Before PRM	74.39 (11.26)	74.54(11.61)	75.04 (9.41)	0.97
	PRM stat	75.00 (11.60)	76.77 (13.38)	74.46 (9.31)	0.75
	After PRM 2 minutes	74.46 (12.56)	76.12 (12.71)	75.84 (10.07)	0.86
RR (time/min), mean (SD)	Before PRM	15.82 (1.89)	15.54 (1.98)	15.50 (1.96)	0.86
	PRM stat	15.89 (2.08)	15.54 (1.98)	15.50 (1.82)	0.72
	After PRM 2 minutes	15.61 (1.81)	15.31 (2.04)	15.23(1.80)	0.74

Abbreviations: min, minutes; mmHg, millimeter of mercury; SD, standard deviation; MAP, mean arterial blood pressure; HR, heart rate; RR, respiratory rate; PRM, pulmonary recruitment maneuver
a, PRM stat in control group was measured when patient had been in Trendelenburg position and after PRM 2 minutes was measured after Trendelenburg position 2 minutes
Group A, PRM 30 cmH_2O; Group B, PRM 40 cmH_2O; Group C, control

Table 7. *Lung complication*

Lung complication	Group			P - value
	Group A (N=28)	Group B (N=26)	Group C (N=26)	
Pneumothorax (%)	-	-	-	-
Pleural effusion (%)	-	-	-	-
Lung atelectasis (%)	-	-	-	-
Subcutaneous emphysema, N (%)	1 (3.6)	1 (3.8)	1 (3.8)	0.998

Abbreviations: N, number

Group A, PRM 30 cmH_2O; Group B, PRM 40 cmH_2O; Group C, control

that might be the confounding factor. Therefore, when we set patients in all groups into the Trendelenburg position, there was no significantly difference of PLSP between PRM 30 cm H_2O and control group.

The ex-vivo animal model, the study of Javier G et al [22], reported that using PRM with higher pressure associated with pulmonary barotrauma. However, there is no side effect from using PRM at pressure 30 cm H_2O and 40 cm H_2O. Correlated with recent study from Ryu K et al [18], no incidence of the pulmonary barotrauma was reported like present RCT study.

Radiologic study demonstrated that the height of the postoperative residual gas among 3 groups was no statistically significant difference, which is consistent with previous studies [16,18], but it seemed to be higher in group C. This phenomenon could be explained due to gas was absorbed. The intensity of PLSP was highest in first 12 hours, so it might be late if patients were taken CXR upright position at 24 hours. Moreover, using height of residual gas might not be interpret due to irritation of CO2 gas at diaphragm should use surface of diaphragm and volume of residual gas more than height of residual gas alone.

The present study tried to get rid of the confounding factors follow as; RCT intervention with random allocated concealment, all surgeons, patients, outcome assessors were blinded, and intervention among 3 groups were similar. So, it had less of confounding bias.

The further study should evaluate about effect of Trendelenburg position or comparing Effect of PRM with another mode.

Conclusion

Using of PRM with pressure 40 cm H_2O significantly decreases postoperative shoulder pain at 12 hours. This procedure is feasible and safe. Therefore, using the PRM with pressure 40 cm H_2O may be routinely applied after laparoscopic surgery.

Conflict of interest

There was no conflict of interest in this study.

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