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Effects of delayed suprapubic port removal on post-laparoscopic shoulder pain: a randomized controlled trial



Amphan Chalermchockcharoenkit, Pattaya Hengrasmee * D, Paiboon Sophontanarak, Korakot Sirimai, Pavit Sutchritpongsa and Pisutt Srichaikul

Abstract

Background: One of the major drawbacks of gynecologic laparoscopy is post-laparoscopic shoulder pain (PLSP) that is believed to result from intra-abdominal CO₂ retention leading to peritoneal and diaphragmatic stretching and causing referred pain in C4 dermatome. Several interventions have been applied to prevent and reduce its incidence and severity, with contradictory results. Only pulmonary recruitment maneuver, extended assisted ventilation, and active intra-abdominal gas aspiration have been mentioned to be effective interventions for CO₂ evacuation. However, in our experience, an alternative technique of delayed suprapubic port removal (DSPR) was found to be an effective method in CO₂ expulsion. Therefore, we conducted this randomized trial to determine the effectiveness of the DSPR technique in reducing the incidence and severity of PLSP. The trial was conducted at a single, tertiary hospital between May 2015 and May 2016. Having complied with the criteria, 220 patients scheduled for elective gynecological laparoscopy were randomly allocated into 2 groups after giving informed consent. Laparoscopic procedures were performed through 10-mm umbilical port and at least 2 ancillary, including suprapubic, ports. In conventional group, ancillary ports were removed at the end of surgery leaving only opened umbilical cannula for pneumoperitoneum deflation. Abdominal compression from periphery towards umbilicus was performed to further expel CO₂ before removing the umbilical cannula. In DSPR group, both umbilical and suprapubic cannulas were retained. Two-step abdominal compression was undertaken, primarily towards umbilicus and secondarily towards pelvic cavity, before sequentially removing the umbilical and the suprapubic cannulas. Postoperatively, each patient was asked to rate PLSP level on 100-mm VAS during 0-6, 6-12, 12-24, and 24-48 h, respectively. Statistical analysis was performed to determine both incidence and severity of PLSP during 24- and 48h post-laparoscopy.

Results: Patients in DSPR group demonstrated significantly lower incidence of PLSP within 24 h (43.8% vs 59.0%; p = 0.027) and 48 h (43.8% vs 60.0%; p = 0.019), and expressed apparently lower pain scores (0 (0–0) vs 0 (0–8); p = 0.020) during 24–48 h post-surgery.

Conclusion: DSPR is an effective CO₂ expulsion technique, resulting in significant reduction of both incidence and severity of PLSP within 24–48 h post-laparoscopy.

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registered; http://www.thaiclinicaltrials.org/

Keywords: Delayed suprapubic port removal, Post-laparoscopic shoulder pain, Incidence, Severity

Background

Laparoscopic surgery has been widely accepted as a surgical procedure for benign gynecologic diseases due to several advantages including less postoperative pain, shorter hospital stay, earlier recovery, less wound complications, and better cosmetic outcome [1–3]. Although the degree of postoperative pain can be expected to be diminished when compared to open procedures, it is still a significant factor during the post-laparoscopy recovery period, especially the post-laparoscopic shoulder pain (PLSP). Without active management, this ongoing pain may delay recovery, prolong hospitalization, and thereby increase the healthcare cost [4].

With the varying incidence of 35-63% [5], the mechanism of PLSP is somehow multifactorial and has been poorly understood. However, the most commonly believed etiology is carbon dioxide (CO2) retention within the abdominal cavity that causes peritoneal and diaphragmatic stretching, subsequently irritating the phrenic nerve, and causing referred pain in the C4 dermatome [5, 6]. Several interventions have been applied to prevent and reduce the incidence and the severity of PLSP, with contradictory results [7–9]. According to the Cochrane Database, there is low to moderate-quality evidence that a specific technique for pneumoperitoneum evacuation, intraperitoneal fluid instillation, intraperitoneal drainage, and intraperitoneal application of local anesthetic are associated with a reduction in the incidence and/or severity of PLSP [10]. However, only the techniques pulmonary recruitment maneuver, assisted ventilation and active intra-abdominal gas aspiration were mentioned to be effective interventions for evacuation of pneumoperitoneum. Laparoendoscopic single-site surgery (LESS) also has a potential role in minimizing postoperative pain when compared to the multiport laparoscopy. A study by Kliethermes et al. [11] reported a decreased level of overall postoperative pain throughout the recovery process with significant outcomes after postoperative day 3. Nevertheless, the results may not be applicable for the PLSP since shoulder pain is transient and usually persists for only 3 days postoperatively [12].

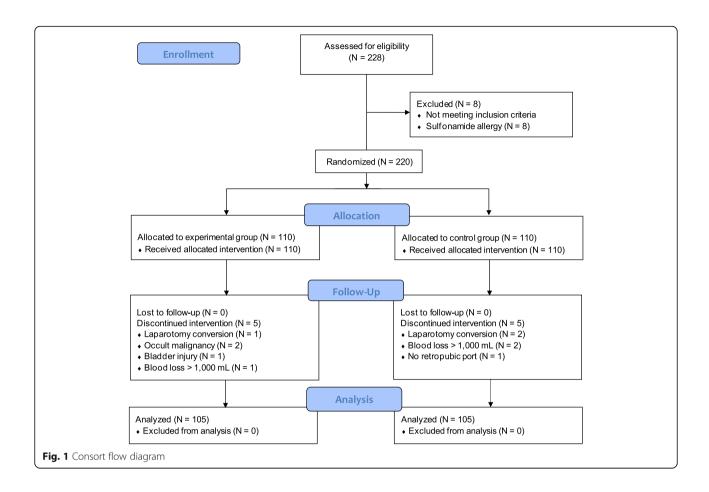
In our experience, there is an alternative technique of delayed suprapubic port removal (DSPR) which was initiated by Amphan Chalermchockcharoenkit (AC), the director of the Thai-German Multidisciplinary Endoscopic Training Center, and has been adopted into our routine practice since 2012. The DSPR was performed together with abdominal compression after peritoneal deflation at the end of each laparoscopic procedure and was found to be an effective method in reducing both incidence and severity of PLSP in most of our cases. The rationale for this is that evacuation of pneumoperitoneum through a single umbilical cannula at the end of each laparoscopic procedure while the patient is still in Trendelenburg position can cause entrapped $\rm CO_2$ in the pelvic cavity leading to subsequent diaphragmatic irritation and PLSP. Therefore, we conducted this randomized controlled trial to determine the outcomes and to prove the effectiveness of this delayed suprapubic port removal technique.

Methods

This randomized controlled study was conducted at the Thai-German Multidisciplinary Endoscopic Training Center, Department of Obstetrics and Gynaecology, Faculty of Medicine Siriraj Hospital, between 8 May 2015 and 7 May 2016, in accordance with the ethical principles stated in the most recent version of the Declaration of Helsinki. The study protocol was ethically approved (COA number Si 245/2015) and financially supported (grant number R015831072) by the Faculty of Medicine, Siriraj Hospital, Mahidol University. The trial was also registered in the Thai Clinical Trials Registry with the identification number of TCTR20160208003.

Sample size calculation

We initially performed a pilot study on patients undergoing elective laparoscopic surgeries for benign gynecologic diseases to find out the incidence of moderate to severe PLSP and had discovered noticeably lower incidence of shoulder pain in the DSPR group (20%) when compared with the conventional group (37.5%). With the assumed type I error of 0.05 and the study power of 80%, the sample size for each group was calculated to be at least 104 patients. Following the CONSORT 2010 flow diagram (Fig. 1), a total of 228 patients scheduled for elective gynecological laparoscopic surgeries were recruited. Only those aged 18 years old and above, with the American Society of Anesthesiologists (ASA) physical status classes I or II, who had given consent to participate in the study were eligible. Those with the



following criteria including pregnancy, poorer ASA scores, drug or alcohol abuse, preoperative shoulder pain or other chronic pain syndrome, prolonged use of analgesics, allergy to sulfonamides, contraindication to nonsteroidal anti-inflammatory drugs (NSAIDs) or any other drugs used in the study, intellectual or psychological disability affecting pain threshold evaluation, gynecologic malignancies, and/or uncontrolled cardiopulmonary-hepatorenal diseases were excluded from the study.

Of 228 enrolled patients, 8 were excluded due to the past history of sulfonamide allergy. After obtaining written informed consent, the remaining 220 patients were equally categorized into 2 groups including control group (n=110) and experimental group (n=110) using computerized randomization method. The randomization code was specified into numbers and concealed in the opaque envelopes. Each envelope was opened by the surgeon in the operating theater prior to commencing the laparoscopic surgery. All of the participants were blinded to their group allocation. During the study period, participants were further excluded from the trial if there was/were (1) unwillingness to participate; (2) no suprapubic port placement; (3) major complications such as bowel,

bladder, and/or ureteric injuries; (4) massive hemorrhage (blood loss \geq 1000 ml) and/or the need for intra- or post-operative blood transfusion; (5) conversion to laparotomy; and/or (6) occult gynecologic malignancy.

Steps of the delayed suprapubic port removal

Both conventional and DSPR techniques were implemented at the end of each elective laparoscopic surgery utilizing one primary (10-mm umbilical) port and at least two (5-mm) ancillary, including suprapubic, ports. All laparoscopic procedures were performed under 12mmHg carbon dioxide (CO₂) insufflation pressure with a flow rate of 20 l/min. All patients were positioned in a Trendelenburg position without the use of shoulder rest. CO₂ insufflation was discontinued at the end of the surgery. In the control (conventional) group, all ancillary ports were removed under vision, leaving only the opened umbilical cannula for passive abdominal deflation while the patient was still in Trendelenburg position. Gentle abdominal compression from periphery (360°) towards the umbilicus was undertaken to actively expel CO₂ gas, followed by removal of the umbilical cannula. In the experimental (DSPR) group, all ancillary ports were also removed under vision except the suprapubic cannula, thus leaving both the opened umbilical cannula and the opened suprapubic cannula for passive pneumoperitoneum deflation while the patient was still in Trendelenburg position. The two-step abdominal compression was performed, primarily from periphery (360°) towards the umbilicus to actively evacuate CO_2 prior to removal of the umbilical cannula, and secondarily from xiphoid and lateral abdominal aspects towards the pelvic cavity to further facilitate CO_2 expulsion prior to removal of the suprapubic cannula (Fig. 2).

Parecoxib and acetaminophen were routinely prescribed for postoperative pain control. All participants were provided with two separate doses of 40 mg intravenous parecoxib immediately at the end of the surgery and at 12 h after the surgery. An additional 500 mg acetaminophen tablet was given every 6 h postoperatively for 48 h. The 2 mg intravenous morphine was also administered on request every 2 h during the first 24 h for breakthrough postoperative pain control.

The incidence and the severity of PLSP were evaluated during the first 24- and 48-h post-surgery at different intervals including 0 to 6 h, 6 to 12 h, 12 to 24 h, and 24 to 48 h respectively, using the self-rating visual analogue scales (VAS). Each participant was asked to rate the level of PLSP on a 100-mm-long horizontal line VAS, from 0 (no pain) to 100 (worst imaginary pain), by placing a perpendicular mark at the point that corresponded to the perceived pain level. The level of PLSP was further classified into 4 pain categories, including no pain (0–4 mm), mild pain (5–44 mm), moderate pain (45–74 mm), and severe pain (75–100 mm) [13]. In case of early hospital discharge within 48 h postoperatively, the participants were assigned to continue rating their PLSP level at home.

Apart from PLSP assessment, other information regarding the participants' baseline characteristics and perioperative outcomes such as ASA physical status,

number of port placement, operative time, estimated blood loss, and length of hospital stay, as well as number of the participants requiring additional morphine injection, were also evaluated. All statistical analyses were performed using the Statistical Packages for the Social Sciences version 18 for Windows (SPSS Inc., Chicago, IL, USA). Continuous variables were expressed in terms of mean ± standard deviation or median (IOR), whereas categorical data were presented as number and percentage. Pearson Chi-square test or Fisher's exact test was used to compare the differences of categorical data between the control and the experimental groups, whereas independent Student's t-test or Mann-Whitney U-test was used to compare the differences of continuous variables. The p-value of less than 0.05 was used to determine statistical significance. With the design of randomized controlled study, the authors assumed that all confounding factors and biases were already minimized with no data variability. Hence, we omitted the use of regression analysis in this study.

Results

Of 220 participants undergoing elective laparoscopic surgeries between May 2015 and May 2016, 5 in the control group were further excluded from the study as the result of laparotomy conversion (2), no suprapubic port placement (1), and massive blood loss (2), whereas 5 in the experimental group were excluded due to laparotomy conversion (1), occult malignancy (2), bladder injury (1), and massive hemorrhage (1). Finally, there were 210 participants eligible for data recruitment and analysis.

Table 1 demonstrates the participants' baseline characteristics including mean age, mean body mass index (BMI), parity, and previous abdominal surgeries. No statistically significant differences were found when compared between the experimental and the control groups. When evaluating in terms of perioperative outcomes, no

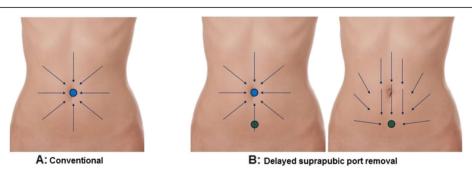


Fig. 2 Conventional versus delayed suprapubic port removal technique. **a** Abdominal compression from periphery towards umbilicus prior to removal of umbilical cannula. **b** (Left) Abdominal compression from periphery towards umbilicus prior to removal of umbilical cannula. **b** (Right) Abdominal compression from xiphoid and lateral abdominal aspects towards pelvic cavity prior to removal of suprapubic cannula

Table 1 Baseline characteristics

	Experimental ($N = 105$)	Control (<i>N</i> = 105)	<i>p</i> -value
Age (years)	43 ± 10.66	43 ± 7.71	0.252
Nulliparity	61 (58.10)	66 (62.90)	0.480
BMI ^a (kg/m2)	22.74 ± 4.69	22.05 ± 3.26	0.216
Previous abdominal surgery	26 (25.70)	32 (32.40)	0.354

Data presented as mean \pm standard deviation (SD) or number (%)

^aBMI Body mass index

considerable discrepancies were detected between the two groups, except the length of hospital stay (16.2% vs 6.7%; p=0.025). Regarding the 24-h postoperative morphine use, only a small, inappreciably different, number of participants from both experimental, and control groups requested additional intravenous morphine injection for breakthrough pain (2.9% vs 6.7%; p=0.166) (Table 2).

The comparative outcomes in terms of PLSP incidence are displayed in Table 3. Participants in the experimental group demonstrated significantly lower incidence of overall PLSP within 24 h (43.8% vs 59.0%; p = 0.027) and 48 h (43.8% vs 60.0%; p = 0.019) after surgery when compared to those in the control group. When specifically looking at the different postoperative intervals, the incidence of overall PLSP in the experimental group substantially decreased after 24 h (24–48 h) postoperatively when compared to the finding in the control group (14.3% vs 30.5%; p = 0.005). However, inconclusive results were obtained during each postoperative

interval when comparing the level of PLSP, either mild or moderate to severe, between the two groups.

With regard to the magnitude of PLSP, participants in the experimental group expressed apparently, though not significantly, lower median (IQR) pain scores during 0–6, 6–12, and 12–24 h post-laparoscopy when compared to those in the control group. The significant difference between the two groups was finally observed during 24–48 h after surgery (experimental 0 (0–0) vs control 0 (0–8); p = 0.020) (Table 4).

Discussion

Results from our randomized controlled trial have confirmed the effectiveness of the delayed suprapubic port removal (DSPR) in reducing both the incidence and the severity of shoulder pain within 24–48 h following elective laparoscopic surgeries without any potential morbidity. With the conventional port removal technique, only the opened umbilical cannula was retained for active evacuation of pneumoperitoneum during abdominal

Table 2 Perioperative outcomes

	Experimental (N = 105)	Control (N = 105)	<i>p</i> -value
ASA ^a physical status			
Class I	77 (73.30)	75 (71.40)	0.758
Class II	28 (26.70)	30 (28.60)	
Number of ports			
3 ports	11 (10)	19 (18)	0.167
4 ports	94 (90)	86 (82)	
Major laparoscopic procedure			
Hysterectomy	67 (63.80)	55 (53.38)	0.093
Adnexal surgery	26 (24.76)	35 (33.33)	
Myomectomy	17 (16.19)	15 (14.29)	
Others	7 (6.67)	4 (3.80)	
Operative time (min)	124.52 ± 51.15	125.56 ± 45.07	0.886
Estimated blood loss (ml) (median)	20 (12.50–50)	20 (10–50)	0.900
Postoperative hospital stay > 2 days	7 (6.70)	17 (16.20)	0.025*
Postoperative 24-h morphine use	3 (2.9)	7 (6.7)	0.166

Data presented as mean + standard deviation (SD) or number (%) or median (IQR)

^aASA American Society of Anesthesiologists

^{*}Statistical significance

Table 3 Incidence of post-laparoscopic shoulder pain

Postoperative interval	Experimental $(N = 105)$	Control (<i>N</i> = 105)	<i>p</i> -value
0–6 h			
Overall PLSP ^a	30 (28.6)	40 (38.1)	0.143
Mild PLSP	22 (21.0)	29 (27.6)	0.260
Moderate to severe PLSP	8 (7.6)	11 (10.5)	0.470
6–12 h			
Overall PLSP	24 (22.8)	37 (35.2)	37 (35.2)
Mild PLSP	16 (15.2)	25 (23.8)	25 (23.8)
Moderate to severe PLSP	8 (7.6)	12 (11.4)	12 (11.4)
12–24 h			
Overall PLSP	29 (27.6)	39 (37.1)	0.140
Mild PLSP	25 (23.8)	26 (24.8)	0.872
Moderate to severe PLSP	4 (3.8)	13 (12.4)	0.023*
24-48 h			
Overall PLSP	15 (14.3)	32 (30.5)	0.005*
Mild PLSP	14 (13.3)	29 (27.6)	0.010*
Moderate to severe PLSP	1 (1.0)	3 (2.9)	0.311
Within 24 h			
Overall PLSP	46 (43.8)	62 (59.0)	0.027*
Mild PLSP	32 (30.5)	33 (31.4)	0.881
Moderate to severe PLSP	14 (13.3)	29 (27.6)	0.010*
Within 48 h			
Overall PLSP	46 (43.8)	63 (60.0)	0.019*
Mild PLSP	31 (29.5)	32 (30.5)	0.880
Moderate to severe PLSP	15 (14.3)	31 (29.5)	0.008*

Data presented as number (%)

compression after passive peritoneal deflation. However, as a result of Trendelenburg position, a small amount of CO_2 could possibly be collected and trapped in the pelvic cavity leading to subsequent diaphragmatic irritation and PLSP after readjusting the patient in the neutral position. With the DSPR intervention, the suprapubic cannula was maintained and kept open after removal of the umbilical cannula at the end of the primary abdominal compression. The secondary abdominal compression from xiphoid and

lateral abdominal aspects towards the pelvic cavity while removing the suprapubic cannula could undoubtedly facilitate further expulsion of the residual CO₂, therefore, resulting in decreased incidence and severity of PLSP.

When focusing on each postoperative interval, the effectiveness of the DSPR became apparently noticeable after 24 h postoperatively, yielding a significant reduction in the incidence and the severity of PLSP during the 24–48-h postoperative interval. According to Joris et al.

Table 4 Maximum level of post-laparoscopic shoulder pain according to VAS

Postoperative interval	Experimental (N = 105)	Control (<i>N</i> = 105)	<i>p</i> -value
0–6 h	0 (0–8.5)	0 (0–23)	0.176
6–12 h	0 (0–3)	0 (0–24.5)	0.080
12-24 h	0 (0–5.5)	0 (0–18)	0.116
24–48 h	0 (0–0)	0 (0–8)	0.020*

Data presented as median (IQR)

^aPLSP post-laparoscopic shoulder pain

^{*}Statistical significance

^{*}Statistical significance

[14], the visceral pain predominates during the first 24 h and subsides soon after surgery, whereas the shoulder pain which appears minimal on the first day becomes more pronounced on the consecutive day. Another explanation is that early ambulation following operative laparoscopy in our study usually started after 6 h, gradually increased during 6-12 and 12-24 h, and became fully enabled after 24 h post-surgery. With the upright position, the residual CO2 could exert mechanical pressure on the diaphragm [15], thus provoking persistent PLSP and prolonged hospitalization (exceeding 48 h) in the control group. In previous literatures, most investigators studying PLSP often chose pain scores as their primary outcome measure. However, with the use of 0-100 self-rating visual analogue scales (VAS), a great deal of variability in pain scores was observed. As a result, the pain scores were subsequently categorized into 4 levels of pain, including no pain (0-4 mm), mild pain (5–44 mm), moderate pain (45–74 mm), and severe pain (75-100 mm) for uncomplicated data interpretation and analysis. Furthermore, due to non-normal distribution of VAS pain scores found in this study, the data regarding the maximum level of PLSP were presented as median (IOR) in Table 4.

In general, the length of hospitalization required after laparoscopic surgery is approximately 1 to 2 days. Based on the authors' experience, PLSP was found to be one of the common causes contributing to an extended duration of inpatient admission beyond postoperative day 2, we then aimed to compare between the two groups regarding the number of participants requiring longer hospitalization (exceeding 48 h) and eventually found that the participants in the control group remarkably outnumbered those in the experimental group.

Information regarding PLSP level during each postoperative interval was rather ambiguous when compared between the experimental and the control groups, especially when looking at the incidence of moderate to severe PLSP. This could possibly result from too small sample size to empower significant differences between the two groups. Regardless of these inconclusive outcomes, most of the participants from both groups (> 90% experimental and > 80% control) reported none or only mild PLSP during the first 24 h post-laparoscopy. This could somehow reflect the potency of intravenous parecoxib and oral acetaminophen in providing adequate pain control. In addition, it could be the reason for the minimal requirement of postoperative rescue morphine injection, leading to an inconsiderably different finding when compared between the two groups.

With the application of the per protocol analysis, 5 participants from the control group and 5 participants from the experimental group were further excluded from the study as the result of laparotomy conversion, no

suprapubic port placement, occult malignancy, bladder injury, and massive hemorrhage to eliminate the possible confounders that might interfere with the study outcomes. However, this may be considered one of the limitations since the intention to treat analysis is more preferable.

Conclusion

The delayed suprapubic port removal technique is a practical and effective non-pharmacologic intervention to reduce both incidence and severity of postoperative shoulder pain within 24–48 h post-laparoscopy.

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Authors' contributions

AC substantially contributed to the conception and the design of the study, data analysis, data interpretation, and revision of manuscript. PH contributed to data analysis and data interpretation and was a major contributor in writing the manuscript. PS contributed to data collection and analysis. KS was involved in data collection. PS was involved in data collection. PS was involved in data collection. The authors read and approved the final manuscript.

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Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declaration

Ethics approval and consent to participate

The study protocol was officially approved by the Ethics Committees of the Faculty of Medicine Siriraj Hospital, Mahidol University (COA number Si 245/2015). The trial was also registered in the Thai Clinical Trials Registry with the identification number of TCTR20160208003. All participants had given the written informed consent to participate in the study.

Consent for publication

Not applicable

Competing interests

The authors declare that they have no competing interests

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