

Effects of Delayed Suprapubic Port Removal on Post-laparoscopic Shoulder Pain: A Randomized Controlled Trial

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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 hours respectively. Statistical analysis was performed to determine both incidence and severity of PLSP during 24- and 48-hours post-laparoscopy.

Results: Patients in DSPR group demonstrated significantly lower incidence of PLSP within 24 hours (43.8% vs 59.0%; p=0.027) and 48 hours (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 hours post-surgery.

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

Trial registration: Thai Clinical Trials Registry; TCTR20160208003; Registered 8 February 2016 - Retrospectively registered; <http://www.clinicaltrials.in.th/index.php?tp=regtrials&menu=trialssearch&smenu=fulltext&task=search&task2=view1&id=1715>

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% 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, 8, 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 or severity, or both of PLSP [10]. However, only the techniques of pulmonary recruitment maneuver, extended assisted ventilation and active intra-abdominal gas aspiration were mentioned to be effective interventions for evacuation of pneumoperitoneum. In our experience, there is an alternative technique of delayed suprapubic port removal (DSPR) which was initiated by Amphan Chalermchokcharoenkit (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 CO₂ 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 (Figure 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 non-steroidal 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 $\geq 1,000$ milliliters) 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 12-mmHg carbon dioxide (CO₂) insufflation pressure with a flow rate of 20 liters per minute. 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 degree) 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 degree) towards the umbilicus to

actively evacuate CO₂ prior to removal of the umbilical cannula, and secondarily from xiphoid and lateral abdominal aspects towards the pelvic cavity to further facilitate CO₂ expulsion prior to removal of the suprapubic cannula (Figure 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 hours after the surgery. An additional 500 mg acetaminophen tablet was given every 6 hours postoperatively for 48 hours. The 2 mg intravenous morphine was also administered on request every 2 hours during the first 24 hours for breakthrough postoperative pain control.

The incidence and the severity of PLSP were evaluated during the first 24- and 48-hours post-surgery at different intervals including 0 to 6 hours, 6 to 12 hours, 12 to 24 hours, and 24 to 48 hours 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) [11]. In case of early hospital discharge within 48 hours postoperatively, the participants were assigned to continue rating their PLSP level at home.

Apart from PLSP assessment, other information regarding the participants' baseline characteristics, 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 \pm standard deviation or median (IQR) 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 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-hour 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).

Table 1
Baseline characteristics

	Experimental (N = 105)	Control (N = 105)	p-value
Age (years)	43 ± 10.66	43 ± 7.71	0.252
Nulliparity	61 (58.10)	66 (62.90)	0.480
BMI ^a (kg/m ²)	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 ± standard deviation (SD) or number (%)			
a) BMI body mass index			

Table 2
Perioperative outcomes

	Experimental (N = 105)	Control (N = 105)	p-value
ASA ^a physical status			0.758
class I	77 (73.30)	75 (71.40)	
class II	28 (26.70)	30 (28.60)	
Number of ports			0.167
3 ports	11 (10)	19 (18)	
4 ports	94 (90)	86 (82)	
Major laparoscopic procedure			0.093
Hysterectomy	67 (63.80)	55 (53.38)	
Adnexal surgery	26 (24.76)	35 (33.33)	
Myomectomy	17 (16.19)	15 (14.29)	
Others	7 (6.67)	4 (3.80)	
Operative time (minutes)	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-hour morphine use	3 (2.9)	7 (6.7)	0.166
Data presented as mean + standard deviation (SD) or number (%) or median (IQR)			
a) ASA American Society of Anesthesiologists			
* statistical significance			

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 hours (43.8% vs 59.0%; p = 0.027) and 48 hours (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 hours (24–48 hours) 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.

Table 3
Incidence of post-laparoscopic shoulder pain

Postoperative interval	Experimental (N = 105)	Control (N = 105)	p-value
0 – 6 hours			
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 hours			
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 hours			
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 hours			
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 hours			
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 hours			
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 (%)			
a) PLSP post-laparoscopic shoulder pain			

* statistical significance

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 hours post-laparoscopy when compared to those in the control group. The significant difference between the two groups was finally observed during 24–48 hours after surgery (experimental 0(0–0) vs control 0(0–8); $p = 0.020$) (Table 4).

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

Postoperative interval	Experimental (N = 105)	Control (N = 105)	p-value
0 – 6 hours	0 (0 – 8.5)	0 (0 – 23)	0.176
6 – 12 hours	0 (0 – 3)	0 (0 – 24.5)	0.080
12 – 24 hours	0 (0 – 5.5)	0 (0 – 18)	0.116
24 – 48 hours	0 (0 – 0)	0 (0 – 8)	0.020*
Data presented as median (IQR)			
* statistical significance			

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 hours 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 compression after passive peritoneal deflation. However, as a result of Trendelenburg position, a small amount of CO₂ 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 hours postoperatively, yielding a significant reduction in the incidence and the severity of PLSP during the 24-48-hour postoperative interval. According to Joris et al [12], the visceral pain predominates during the first 24 hours 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 hours, gradually increased during 6–12 and 12–24 hours, and became fully enabled after 24 hours post-surgery. With the upright position, the residual CO₂ could exert mechanical pressure on the diaphragm [13], thus provoking persistent PLSP and prolonged hospitalization (exceeding 48 hours) 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 (IQR) 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 hours), 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 were 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 hours 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 the study outcomes. However, this may be considered as 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 hours post-laparoscopy.

Declarations

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

Availability of data and materials

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

Competing interests

The authors declare that they have no competing interests

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The study protocol was financially supported (grant number R015831072) by the Faculty of Medicine Siriraj Hospital, Mahidol University. However, the funding body was not involved in the design of the study, data collection, data analysis, data interpretation, and in writing the manuscript.

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, 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.

All authors read and approved the final manuscript.

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Not applicable

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Figures

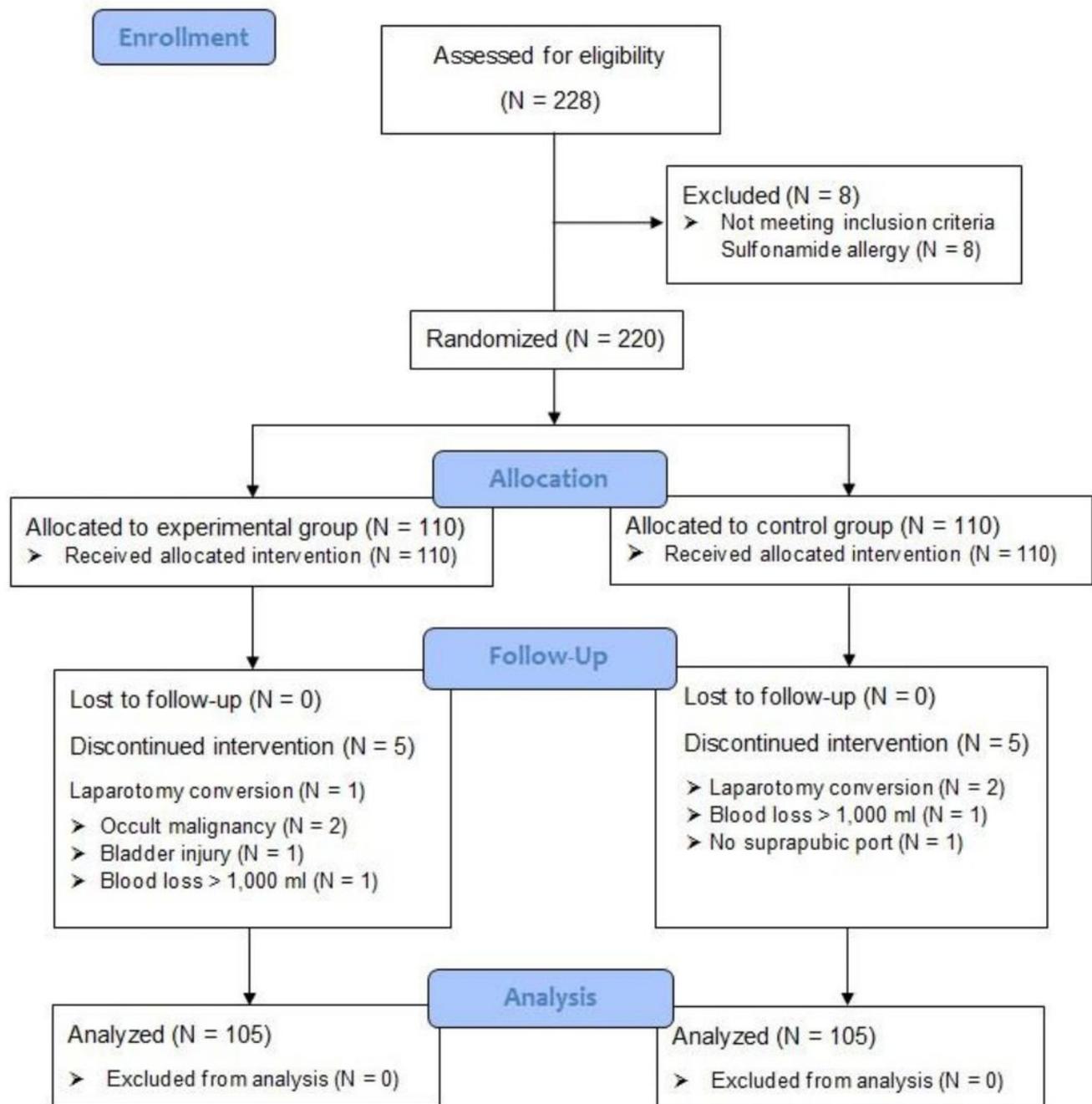


Figure 1

Consort flow diagram

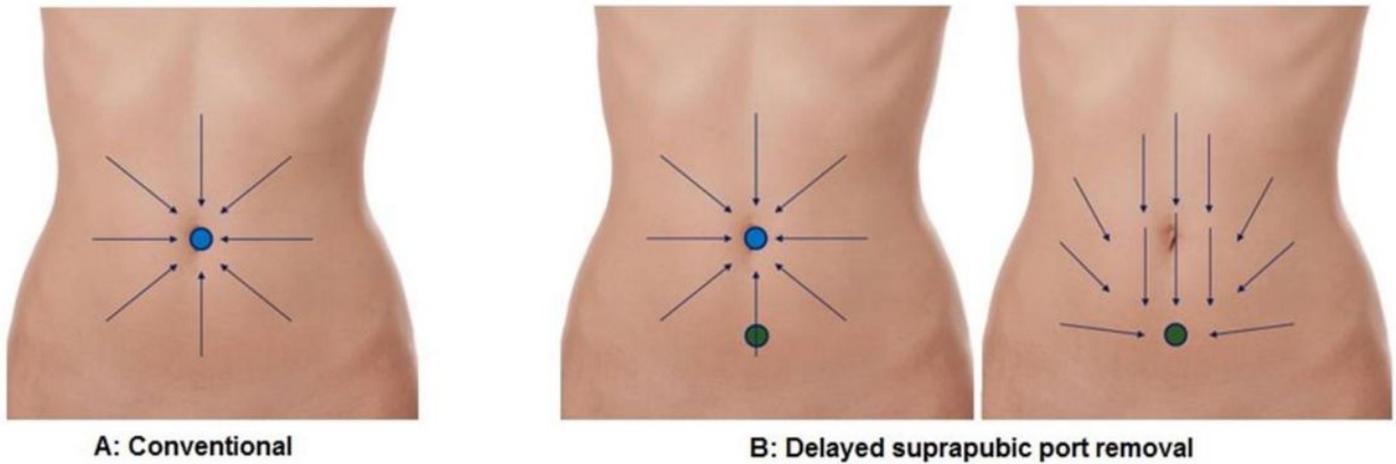


Figure 2

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