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# Subphrenic Saline Irrigation for Reducing Postoperative Shoulder Pain after Gynecologic Laparoscopic Surgery: A Randomized Controlled Trial

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**ABSTRACT**

**Objective:** To determine the effectiveness of subphrenic saline irrigation for postoperative shoulder pain reduction in gynecologic laparoscopic surgery.

**Materials and Methods:** A randomized controlled trial comparing subphrenic saline irrigation and no irrigation for shoulder pain reduction was conducted at Khon Kaen Hospital between May 1st and August 20th, 2014. A total of 62 patients were randomly allocated into two groups: Group A: Subphrenic saline Irrigation (n=31) and Group B: No irrigation (n=31). The primary outcomes were postoperative shoulder pain at 12, 24, and 48 hours, evaluated by using visual analog scale. The secondary outcomes were data of additional analgesics drug use, abdominal discomfort, fever, wound infection and bradycardia.

**Results:** Postoperatively shoulder pain in subphrenic saline irrigation was significantly less than in no irrigation group at 12 hours [median (IQR) 2 (0-3) and 5 (0-6); P=0.01] and at 24 hours [median (IQR ) 0 (0) and 2 (0-4); P=0.004]. Abdominal discomfort was significantly higher in the control group [74.2% and 48.4%; P=0.03]. Mean additional analgesic drugs in intervention group was lower than in the control group [2.1±1.5 and 3.6±1.6; P=0.001]. There was no complication.

**Conclusions:** Subphrenic saline irrigation significantly reduced postoperative shoulder pain in gynecologic laparoscopic surgery without serious complications.

**Keywords:** Laparoscopic surgery, shoulder pain, subphrenic saline irrigation

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## Introduction

At present, open surgery in benign gynecologic diseases is gradually replaced by laparoscopic surgery. This procedure becomes an attractive surgical method because of its shorter hospital stay, faster recovery, low morbidity and pleasant cosmetic results[1-4]. Despite

this surgical method provided a satisfy results, it induces shoulder pain and causes abdominal discomfort. The incidence of shoulder pain varies from 35-80%[5,6]. Shoulder pain is hypothesized to occur by carbon dioxide insufflation, which was used to create pneumoperitoneum, stretched the peritoneum, irritated diaphragm and phrenic nerve resulting in referred pain to the shoulder[7]. Some studies mentioned that shoulder pain results from peritoneal irritation by carbonic acid, together with pneumoperitoneum creates space between liver and diaphragm, cause loss of suction support of the heavy liver[8]. After laparoscopy, carbon dioxide gas remains within the peritoneal cavity for few days, especially after ambulation[9] and could irritate phrenic nerve and leading to postlaparoscopic shoulder pain. Several techniques were initiated in order to reduce shoulder pain e.g. intraperitoneal local anesthesia, pulmonary recruitment maneuver, drainage, gasless laparoscopy, minilaparoscopy, and intraperitoneal saline. Subphrenic saline irrigation acts as physiological buffer whereby the residual carbon dioxide is dissolved. However, from the systematic review of Taş, et al[10] found that the current data of intraperitoneal saline or saline irrigation was too weak to make any definite conclusions. Therefore, we interested in conducting the randomized controlled trial to evaluate the effectiveness of subphrenic saline irrigation compared to no irrigation for reducing postoperative shoulder pain and we hypothesize that subphrenic saline irrigation was superior to no irrigation in shoulder pain reduction.

## Materials and Methods

The present study was a randomized controlled trial. Participants were recruited at Khon Kaen Hospital from May 1st and August 20th, 2014. This study was approved by Khon Kaen Hospital Institute Review Board in Human Research. The individual informed consent was obtained. Women at age of 15 to 65 years with benign gynecologic diseases were enrolled. Heart diseases, chronic lung diseases and denied to participate were excluded. We determined a required sample size of 28 women per group with 80% power and 5% level of significance based on the pilot study. Assuming a 10% drop-out rate, the trial protocol specified a sample size of 62 patients. The trial is reported and analyzed in accordance with the CONSORT criteria.

A total of 62 patients were randomly allocated into two groups: Group A: subphrenic saline irrigation and Group B: no irrigation. Computer-generated randomization was used. Allocation concealment was assigned by sequentially opaque, sealed envelopes. An envelope was picked up and opened by the surgeon in the operating room before the operation started. The patients and outcomes assessors were blinded to the intervention after assignment.

We used 3-4 ports to perform laparoscopic operations. One 5-mm port was inserted through the umbilicus, and the other 5-mm ports were inserted through the lateral lower abdominal wall and suprapubic area. Peritoneal access was performed by using direct primary trocar entry through umbilicus. The entry into peritoneum is confirmed with direct visualization through the laparoscope then warm $CO_2$ gas was insufflated at the pressure of 13 mmHg with insufflation rate of 3 L/min. After laparoscopic surgery finished, routine method of removing carbon dioxide by passive exsufflation through the port sites was performed without saline irrigation in the control group. In the intervention group, normal saline 15-20 ml/kg[15] was irrigated under right hemidiaphragm and then aspirated before exsufflated of carbon dioxide. Skin was closed by sterile strip or polyglactin 4-0. Postoperative pain control was provided for both groups with intravenous morphine 3 mg q 4 hours at first 24 hours. After 24 hours, postoperative pain was controlled by additional intravenous morphine and paracetamol as required.

After surgery, shoulder pain was assessed at 12, 24, 48 hours by nurse who did not involve in the operation using a 10-cm visual analog scale (0 = no pain and 10 = worst pain imaginable). Participants were asked about any occurrence of nausea and/or vomiting, abdominal discomfort. Additional analgesic drugs, fever, wound infection and bradycardia were also recorded.

Statistical analysis was performed with SPSS version 19.0.0 statistical software. Analysis by

chi-square test was done to evaluate categorical variables. For continuous variables, student t-test was used and in case of skewed data, Mann-Whitney U test was considered. Statistical significance was defined as $P \leq 0.05$.

## Results

Between 1st May - 20th August 2014, a total of 62 patients were recruited in this study. None had been excluded. Sixty-two patients were randomly assigned into two groups (31 each), the participant flow was shown in Figure 1. Demographic data were shown in Table 1. Surgical time and length of hospital stay were not different in both groups (Table 1).

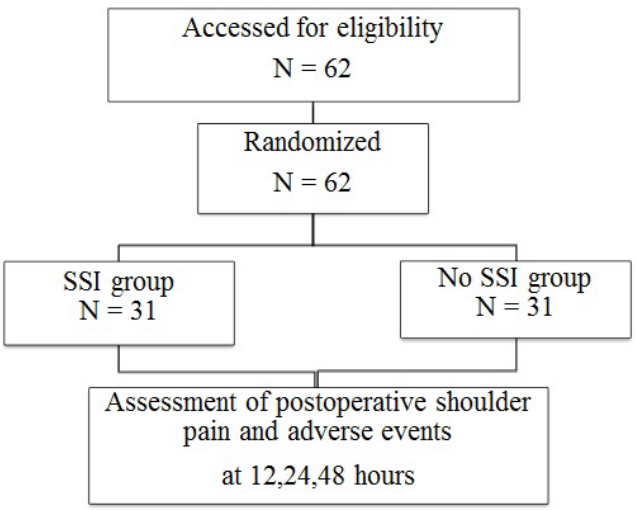


**Fig 1.** Participant Flow of randomization and group allocation

**Table 1.** Demographic Data.

| Characteristics | Saline irrigation (n=31) | No irrigation (n=31) |
|---|---|---|
| Age (yrs), mean±SD | 40.6±8.3 | 37.8±8.7 |
| Weight (kg), mean±SD | 59.0±7.9 | 56.9±10.5 |
| Height (cm), mean±SD | 157.9±5.5 | 157.3±6.7 |
| BMI (kg/m2), mean±SD | 23.6±2.9 | 22.9±4.4 |
| Parity , n (%) | | |
| Nulliparous | 14.0 (45.2%) | 12.0 (38.7%) |
| Multiparous | 17.0 (54.8%) | 19.0 (61.3%) |
| Underlying disease, n (%) | | |
| Yes | 5.0 (16.1%) | 8.0 (25.8%) |
| No | 26.0 (83.9%) | 23.0 (74.2%) |
| Type of operation, n (%) | | |
| LAVH | 0 (0%) | 1.0 (3.2%) |
| TLH | 20.0 (64.5%) | 18.0 (58.1%) |

**Table 1.** Demographic Data. (Cont.)

| Characteristics | Saline irrigation (n=31) | No irrigation (n=31) |
|---|---|---|
| LOC | 11.0 (35.5%) | 12.0 (38.7%) |
| Time (min), mean±SD | 127.5±40.8 | 110.7±29.3 |
| Estimated blood loss (ml), median (IQR) | 50 (10-100) | 50 (10-100) |
| Hospital stay (hours) | 48.7±4.3 | 49.0±5.7 |

SD, Standard deviation; BMI, Body mass index; LAVH, Laparoscopic assisted vaginal hysterectomy; TLH, Total laparoscopic hysterectomy; LOC, Laparoscopic ovarian cystectomy; ml, milliter; IQR, Interquatile range

**Table 2.** Postoperative shoulder pain at 12, 24, 48 hours.

| Characteristics | Saline irrigation (n=31) | No irrigation | P |
|---|---|---|---|
| Pain, median (IQR) | | | |
| 12 hours | 2 (0-3) | 5 (0-6) | 0.011 |
| 24 hours | 0 | 2 (0-4) | 0.004 |
| 48 hours | 0 | 0 | - |

IQR, Interquatile range

**Table 3.** Secondary outcomes.

| Characteristics | Saline irrigation (n=31) | No irrigation | P |
|---|---|---|---|
| Additional analgesics, mean (SD) | 2.1 (1.5) | 3.6 (1.6) | 0.001 |
| Nausea/vomiting | 5.0 (16.1%) | 1.0 (3.2%) | 0.195 |
| Abdominal discomfort | 15.0 (48.4%) | 23.0 (74.2%) | 0.037 |
| Fever | 9.0 (29%) | 8.0 (25.8%) | 0.776 |
| Surgical wound infection | 0 (0%) | 1.0 (3.2%) | 0.313 |

SD, Standard deviation

Postoperatively shoulder pain in subphrenic saline irrigation was significantly less than in no irrigation group at 12 hours [median (IQR) 2 (0-3) and 5 (0-6); P= 0.01] and at 24 hours [median (IQR) 0 and 2 (0-4); P= 0.004]. There was no shoulder pain at 48 hours after operation in both groups (Table 2).

The incidence of nausea and/or vomiting, bradycardia, fever and wound infection were not significant different in both groups. Abdominal discomfort was significantly higher in no irrigation group [74.2% and48.4%; P=0.03]. Mean additional analgesic drugs in subphrenic saline irrigation was lower than in no irrigation group [2.1±1.5 and 3.6±1.6; P=0.001] (Table 3).

## Discussion

This study supported that saline irrigation was significantly reduce postoperatively shoulder pain after

laparoscopic surgery better than no irrigation and this finding was similar to Tsai, et al[15]. They found that saline infusion was not only significant reduction of shoulder pain when compared to routine laparoscopic surgery (without saline infusion), but it also more effective than pulmonary recruitment maneuver technique[16]. There were two mechanisms of this method hypothesized to reduce shoulder pain. The first mechanism is that saline infusion displaced the residual carbon dioxide from the peritoneal cavity by increases intraperitoneal pressure. The second mechanism is that saline acts as physiologic buffer whereby the residual carbon dioxide is dissolved and forms carbonic acid[11,16]. Carbonic acid is then absorbed into the circulation and transformed into bicarbonate by carbonic anhydrase in the contacts red blood cells, after that bicarbonate is converted back into carbon dioxide again in the lungs and be expelled[16]. Despite the present study used saline infusion as in Tsai, et al[15] but the different point was that we aspirated saline from the peritoneal cavity after subphrenic saline irrigation was performed, whereas they left it in. The advantage of aspiration of saline after deflation of the pneumoperitoneum is it reduces the space between liver and diaphragm cause more contact of these two organs, therefore there is no residual carbon dioxide to induce pain[17]. Aspiration of the saline also makes better cleaning the peritoneal cavity which reduces the peritoneal irritation and pain[8]. The present study found that the peak of postoperative shoulder pain was at 24 hours. In subphrenic saline irrigation group, only mild postoperative shoulder pain was observed at first 24 hours. This finding was similar to Tsai, et al[16]. It is possible that early ambulation causes strong and severe pain[8]. The study of Suginami, et al[11] reported that one patient who had early ambulation experienced worse shoulder pain when she was in upright position. The other factors affected on shoulder pain after laparoscopic surgery were the residual gas volume and insufflation rate. Jackson, et al reported the association between the dimension of the gas bubbles in the peritoneal cavity and the severity of pain[12]. High flow insufflation rate makes rapid distension of the peritoneal cavity and causes tearing of blood vessels, traumatic traction of the nerves and release of inflammatory mediators leading to postoperative shoulder and abdominal pain[5]. However, we found low level of pain perception in both groups, although we used high insufflation rate. It is possible that the operative time in our study was not so long, the process of exsufflation of the residual carbon dioxide was adequate and postoperative pain control was provided in both groups.

Postoperative pain control in our study was intravenous morphine around the clock for first 24 hours. The addition analgesic drugs requirement was available when needed. We found that the requirement of addition analgesic drugs was significantly more in no irrigation group. This could indirectly reflect that subphrenic saline irrigation was more effective in shoulder pain reduction than no irrigation. In contrast, Tsai, et al reported no different of analgesic requirement between groups[15]. They explained that pain induced by carbon dioxide retention could not relief by analgesics. The individual pain threshold is also play an important role in pain perception. Adequate randomization and masking of participants from the intervention were the effective ways to minimize the bias on pain perception. The adverse events of the intervention in this study were also recorded. The majority of adverse event was abdominal discomfort. It is significantly greater in no irrigation group. It differed from previous studies[15,16]. It could directly explained by saline irrigation displaced the residual carbon dioxide from peritoneal cavity and acts as physiologic buffer as mentioned above. Additionally, while aspiration of saline was performed, the residual carbon dioxide was also aspirated at the same time, made the saline irrigation group had less incidence of abdominal discomfort. Postoperative fever and wound infection were not different in both groups. The standard pre- and postoperative care, including prophylactic antibiotic were similarly provided in both groups, the incidence of these adverse events in our study was therefore low. One of the serious adverse events during laparoscopic surgery is bradycardia. Based on physiological knowledge, pneumoperitoneum by carbon dioxide creating during laparoscopic surgery had risks of cardiovascular changes such as severe bradycardia, arrhythmia and cardiac arrest[18]. It is

known to be associated with vagal reflex initiated by rapid peritoneal distension due to insufflation or gas embolism[19]. Intra-abdominal pressure below 12-15 mmHg during insufflation is known to be effective to prevent pathophysiological changes of pneumoperitoneum[18]. There was no bradycardia found in our study. It might possible that most of our participants were young and had intact cardiovascular function and intra-abdominal pressure was not exceeded 15 mmHg.

The strengths of our study were, firstly, this study was a randomized controlled trial. Adequate randomization and allocation concealment were conducted to balance any possible confounding factors in the study. The second strong point of our study was double blinded trial. Patients and outcome assessors were blinded from the intervention, which could minimize the possible outcome biases. Thirdly, the operations were also performed by only one surgeon. Therefore, experience, surgical skills of surgeon which might affect the operative time, intraoperative blood loss, morbidity rate and pain assessment due to different in the length of surgery were reduced. Lastly, all of patients were remained in the hospital until 48 hours or more, allowed us to get the complete postoperative pain data.

However, we also had the limitationsin this study. First, the evaluation of additional analgesic drugs requirement. We evaluated the number of analgesic drugs requirement. It would be more clinical meaningful if the analgesics consumption were recorded in term of the total of milligrams of drugs requested. Although, shoulderpain score was significantly lower in subphrenic saline irrigation group, however, finer VAS should be suggested because VAS, when used in millimeters, would be more precise and accurate in evaluatingof pain level.

## Conclusion

Subphrenic saline irrigation significantly reduced postoperative shoulder pain in gynecologic laparoscopic surgery without serious complications.


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## *การล้างน้ำเกลือใต้กระบังลม เพื่อลดอาการปวดไหล่หลังการผ่าตัดส่องกล้องทางนรีเวช การวิจัยเชิงทดลองแบบสุ่ม*

***ธัญญารัตน์ วินิจธนา, สิทธิพงศ์ ถวิลการ, ทุมวดี ตั้งศิริวัฒนา***

***วัตถุประสงค์:*** *เพื่อศึกษาประสิทธิภาพของการล้างน้ำเกลือใต้กระบังลม เพื่อลดอาการปวดไหล่หลังการผ่าตัดส่องกล้องทางนรีเวช*
***วัสดุและวิธีการ:*** *การวิจัยเชิงทดลองแบบสุ่ม ศึกษาที่โรงพยาบาลขอนแก่น ตั้งแต่ 1 พฤษภาคม ถึง 20 สิงหาคม พ.ศ.2557 ผู้ป่วยที่ได้รับการผ่าตัดส่องกล้องทางนรีเวช จำนวน 62 คน สุ่มเป็น 2 กลุ่มโดยใช้คอมพิวเตอร์ กลุ่มทดลอง จำนวน 31 คน ได้รับการล้างน้ำเกลือใต้กระบังลม และกลุ่มควบคุม จำนวน 31 คนไม่ได้รับการล้างน้ำเกลือใต้กระบังลม ประเมินผลด้วยการวัดคะแนนปวดไหล่ที่ 12, 24 และ 48 ชั่วโมงหลังการผ่าตัด โดยใช้ visual analog scale จำนวนครั้งของยาแก้ปวดที่ขอเพิ่ม ภาวะแทรกซ้อน เช่น อาการแน่นท้อง ไข้ ภาวะแผลติดเชื้อ และภาวะหัวใจเต้นช้าผิดปกติ*
***ผลการวิจัย:*** *คะแนนปวดไหล่หลังการผ่าตัดในกลุ่มทดลองน้อยกว่าในกลุ่มควบคุมอย่างมีนัยสำคัญทางสถิติ ที่ 12 และ 24 ชั่วโมงหลังการผ่าตัด [2(0-3) และ 5(0-6); P= 0.01, 0 และ 2(0-4); P=0.004] นอกจากนี้ อาการแน่นท้องยังพบได้มากกว่าในกลุ่มควบคุม [74.2% และ 48.4% ; P=0.03] และจำนวนครั้งของยาแก้ปวดที่ขอเพิ่มในกลุ่มทดลองน้อยกว่ากลุ่มควบคุมอย่างมีนัยสำคัญทางสถิติ [2.1±1.5 และ 3.6±1.6 ; P=0.001] โดยไม่พบภาวะแทรกซ้อนใดๆ*
***สรุป:*** *การล้างน้ำเกลือใต้กระบังลมสามารถช่วยลดอาการปวดไหล่หลังการผ่าตัดส่องกล้องทางนรีเวชได้โดยไม่พบภาวะแทรกซ้อน*