

Original Research Article

Low pressure pneumoperitoneum and intraperitoneal infusion of normal saline for reducing shoulder tip pain after gynecologic laparoscopy: randomized controlled trial

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ABSTRACT

Background: To estimate the effectiveness of combined low-pressure pneumoperitoneum (8mmHg) and intraperitoneal normal saline infusion on reducing the incidence and severity of postoperative shoulder tip and upper abdominal pain.

Methods: A prospective randomized controlled study was carried out in Aswan University Hospital, Aswan, Egypt. Author included patients undergoing laparoscopic surgery in the laparoscopy unit either diagnostic or operative. They were randomized into two groups: (intervention group) which comprised of 47 patients who underwent low pressure pneumoperitoneum plus intraperitoneal saline infusion and (control group) which included 47 patients underwent standard pressure pneumoperitoneum. The primary outcome of the study is the difference in the mean shoulder tip and upper abdominal pain score postoperatively between the two groups.

Results: There was significant reduction in the shoulder tip pain and upper abdominal pain 1, 4, 8, 12 and 24 hours post-operatively shown by visual analogue scale pain scores in the intervention group compared to control ($p=0.000$). Additionally, there was a significant reduction in the incidence of nausea and vomiting in the intervention group than control group ($p=0.000$ and $p=0.007$ respectively). There was no significant difference regards abdominal distention, time of resumption of intestinal peristalsis, operation duration and post-operative hospital stay between the two groups.

Conclusions: This study clearly depicts that combined low pressure pneumoperitoneum and intraperitoneal saline infusion is an easy, safe and inexpensive method that significantly reduces the post laparoscopic shoulder tip pain and upper abdominal pain.

Keywords: Laparoscopy, Pneumoperitoneum, Saline, Shoulder tip pain

INTRODUCTION

Laparoscopic surgery in patients with benign gynecological diseases has several advantages compared to open surgery such as faster recovery, reduced hospital stays, lower morbidity and better cosmetic results.¹ Although laparoscopic surgery results in improved

patient satisfaction, a considerable portion of patients have complaints of post-operative shoulder pain. Post-operative shoulder pain is hypothesized to be a result of pneumoperitoneum achieved by carbon dioxide insufflation which induces peritoneal stretching, irritation of the diaphragm and phrenic nerve resulting in referred pain to the shoulder.² Pneumoperitoneum creates the

necessary space in which to perform the operation laparoscopically.³

The incidence of shoulder pain in the first post-operative day is 35 to 61%.^{4,5} The severity ranges from mild to severe, and some patients even have SP for more than 72 h after surgery.⁶ Growing evidence in the field of general surgery has shown that reduction of intra-abdominal pressure during laparoscopy is related to improved postoperative outcomes. Several investigations have reported a decrease in pain perception, length of hospital stay, and analgesic rescue dosage by using low pneumoperitoneum pressure (LPP) compared with standard pneumoperitoneum pressure (SPP).^{7,8} Also the effect of intraperitoneal normal saline infusion, which washes out CO₂ with a physiologic buffer system, maintains longer.⁵

Because the two interventions are mediated through different mechanisms and act in different phases, author hypothesized that combined low pressure pneumoperitoneum and intraperitoneal normal saline infusion may be ideal to reduce post laparoscopic shoulder and upper abdominal pain. Therefore, author conducted this randomized controlled trial to estimate the effectiveness of combined low-pressure pneumoperitoneum (8mmHg) and intraperitoneal normal saline infusion on reducing the incidence and severity of postoperative shoulder-tip pain and upper abdominal pain compared with standard pneumoperitoneum pressure (12-15mmHg) during gynecologic laparoscopy.

METHODS

This study was a randomized open label-controlled study conducted at Aswan University Hospitals from June 2015 to June 2017. All patients who had undergone laparoscopic surgery in the laparoscopy unit, either diagnostic or operative, were included in the study after obtaining informed consent. Patients with medical disorders, preemptive infiltration of trocar sites with local anesthetics, intraperitoneal irrigation with local anesthetics were excluded. Ninety-four patients in the child bearing period with ASA I and undergoing diagnostic (infertility cases) and operative gynecological laparoscopy (ovarian cystectomy, ovarian drilling and adhesiolysis) participated in present study.

They were randomized into two groups: Control group (patients underwent standard pneumoperitoneum pressure from 12-15mmHg) and Intervention group (patients underwent low pneumoperitoneum pressure 8mmHg and intraperitoneal normal saline infusion). A statistician prepared computer-generated randomization tables and placed the allocation data in serially numbered closed opaque envelopes. Each envelope had a card noting the intervention type inside. The envelopes were opened only by the principal investigator administering the study medications according to the order of attendance of women. After acceptance of eligible women to participate

in the study, author assigned them randomly in a 1:1 ratio to both arms of the study.

General anesthesia

Before starting anesthesia, one of the study investigators explained the standard 10cm visual analogue scale (VAS) to the participants for pain scoring. The severity of pain was assessed with VAS (with 0= no pain and 10= worst imaginable pain). For all included patients general anesthesia was induced by intravenous thiopentone sodium of 5mg/kg, and all patients were given intravenous 100mg fentanyl; endotracheal intubation was facilitated using intravenous atracurium besylate 0.5mg/kg.

Maintenance of anesthesia was performed by inhalational isoflurane 0.5-1.5% in 100% oxygen, and a state of muscle relaxation was maintained by infusion of 0.5mg/kg/h atracurium besylate with controlled mode of mechanical ventilation and adjusted parameters to keep end-tidal CO₂ at normal values. All patients were continuously monitored by electrocardiography and pulse oximetry. Intravenous infusion of Ringer's lactate solution BP was given at a rate of 3.6ml per hour.

Recovery was performed by discontinuation of general anesthetics and reversal of neuromuscular blockers, extubation was performed after ensuring adequate motor power and no analgesics were given to patients before recovery. After recovery, patients were monitored for heart rate (HR) and arterial blood pressure measurement every 15 min during the first hour from recovery and then every 4 h for 24 h.

Patients were assessed for severity of pain using VAS after (1, 4, 8, 12, and 24 h) post-operatively. The study investigator who assessed the pain using VAS scores was blinded by the group as to where patients were allocated. The severity of the upper abdominal pain, shoulder tip pain and trocar site pain were assessed using the VAS score and recorded on a separate sheet at each time. If VAS was 3 or more, intravenous infusion of 1gm paracetamol was given. Any complications such as respiratory depression, nausea, vomiting and abdominal distention were also recorded.

Also, intestinal peristalsis auscultation, movement from bed, passing flatus, postoperative hospital stays and the total dose of consumed postoperative analgesics were reported.

Surgical technique

All operations were carried out by the same team. Patients were placed in the Trendelenburg position to facilitate intraoperative exposure of pelvic organs. The bladder was drained via Foley catheterization; the three-trocar technique was used. A Veress needle, introduced through the umbilicus, to create pneumoperitoneum, with

CO₂ infused to distend the peritoneal cavity. Intra-abdominal pressure was initiated and maintained at 12-15mmHg during pneumoperitoneum creation and insertion of trocars, and then was maintained at 8mmHg (intervention group) or 12-15mmHg (control group) according to the randomization.

The flow of CO₂ did not exceed 2L/min. Umbilical port was introduced for 10mm diameter telescope, two ports of 5mm were placed in the left and right iliac fossae for a panoramic view of the pelvis.

The procedures of laparoscopic surgery were (diagnostic for infertility with tubal patency test, ovarian drilling, adhesiolysis and ovarian cystectomy). Ovarian cystectomy was done through incision of the cyst wall then cyst excision and cauterization of any bleeding sources while ovarian drilling was done by electrocautery at four puncture points. The power used for cauterization was adjusted at 40 Watts and maintained for 4 s only at time, irrigation by normal saline and aspiration were done. In the intervention group author filled the upper part of the abdominal cavity with isotonic normal saline (200-250ml) and left in the abdominal cavity. Finally, passive exsufflation of CO₂ through the port site then the patients replaced back in the level position, the ports were removed, and incisions were closed.

Statistical analysis

Data were entered and statistically analyzed using the Statistical Package for Social Sciences (SPSS) version 16. Qualitative data were described as numbers and percentages. Chi-squared test was used for comparison between groups. Quantitative data were described as means (SD) or medians, as appropriate. They were tested for normality by Kolmogorov-Smirnov test. In the normally distributed variables, independent sample t-test was used; while in non-normally distributed variables, Mann Whitney test was used for comparison between groups. P-value ≤0.05 was considered to be statistically significant.

RESULTS

Present study started with one hundred patients who were asked to participate, 3 patients refused, and 3 patients were excluded as they had cardiac or hepatic disease. Therefore, the remaining 94 patients were randomized to: 47 patients underwent laparoscopic surgery with standard pressure pneumoperitoneum (12-15mmHg) (Control group), and 47 patients with low pressure pneumoperitoneum (8mmHg) and intraperitoneal normal saline infusion in the upper abdomen (200-250ml) (Intervention group). The study flowchart is presented in figure 1.

There were no significant differences in demographic data, operation duration and procedures of laparoscopic surgery between the two groups (Table 1).

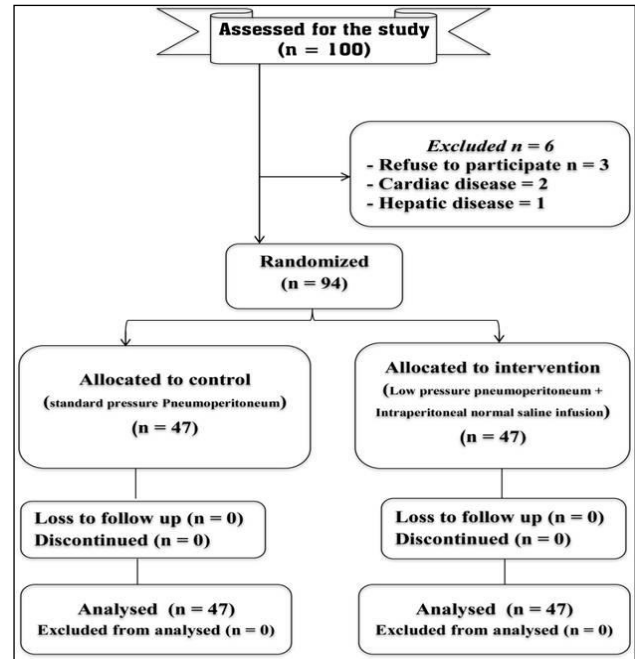


Figure 1: The study flowchart.

Table 1: Demographic and operative data of the study groups.

| Parameter | Control group | Intervention group | p-value |
|------------------------------------|---------------|--------------------|---------|
| Age (year) | 27.7±3.23 | 27.7±2.77 | 1.000 |
| Parity | 0 (0-2) | 0 (0-2) | 0.953 |
| Height (cm) | 163.26±3.98 | 163.21±3.75 | 0.958 |
| Weight (kg) | 59.98±2.19 | 60.3±2.34 | 0.497 |
| BMI | 22.52±1.21 | 22.66±1.22 | 0.559 |
| Previous operation | 7 (14.9) | 6 (12.8) | 0.765 |
| Operation duration (minutes) | 44.13±6.04 | 44.11±6.4 | 0.987 |
| Procedure of laparoscopic surgery: | | | |
| Diagnostic laparoscopy | 15 (31.9) | 17 (36.2) | 0.936 |
| Ovarian drilling | 12 (25.5) | 11 (23.4) | |
| Adhesiolysis | 11 (23.4) | 9 (19.1) | |
| Ovarian cystectomy | 9 (19.1) | 10 (21.3) | |

BMI; Body Mass Index; Data are presented as: Mean±SD, median (minimum-maximum) and number (percentage)

The post laparoscopic pain scores were significantly lower in the intervention group compared with the control group at 1,4,8,12 and 24 hours post-operative in relation to upper abdominal pain and shoulder tip pain (p=0.0001). However, there was no significant difference in relation to trocar site pain at 1,4,8,12 and 24 hours post-operative between the two groups (p= 0.495, p=0.821, p=0.911, p=0.492 and p=0.833 respectively) (Table 2).

Table 2: Visual analogue scale of the severity of pain at 1, 4, 8, 12 and 24 hours postoperatively.

| Parameters (hours) | Control group | Intervention group | p-value |
|------------------------------------|---------------|--------------------|---------------------|
| Upper abdominal pain by VAS | | | |
| 1 st | 8 (6-9) | 3 (1-5) | 0.0001 ^a |
| 4 th | 6 (4-8) | 2 (1-4) | 0.0001 ^a |
| 8 th | 5 (2-6) | 1 (1-2) | 0.0001 ^a |
| 12 | 3 (1-5) | 1 (0-1) | 0.0001 ^a |
| 24 | 2 (0-4) | 0 (0-1) | 0.0001 ^a |
| Shoulder tip pain by VAS | | | |
| 1 st | 8 (6-9) | 3 (1-5) | 0.0001 ^a |
| 4 th | 6 (4-7) | 2 (0-4) | 0.0001 ^a |
| 8 th | 5 (3-6) | 1 (0-3) | 0.0001 ^a |
| 12 | 3 (0-5) | 1 (0-1) | 0.0001 ^a |
| 24 | 2 (0-4) | 0 (0-1) | 0.0001 ^a |
| Trocar site pain by VAS | | | |
| 1 st | 7.34 | | |

a - Statistical significant difference

Table 3: Post-operative parameters in the two groups.

| Parameters | Control group | Intervention group | p-value |
|-------------------------------------|---------------|--------------------|---------------------|
| Nausea | 24 (51.1) | 5 (10.6) | 0.0001 ^a |
| Vomiting | 9 (19.1) | 1 (2.1) | 0.007 ^a |
| Abdominal distention | 28 (59.6) | 22 (46.8) | 0.215 |
| Intestinal peristalsis (h) | 10.81±2.26 | 10.77±2.26 | 0.927 |
| Discharge from hospital (days) | 1.15±0.36 | 1.13±0.34 | 0.768 |
| Upper abdominal pain at 12 h by VAS | 47 (100) | 29 (61.7) | 0.0001 ^a |
| Upper abdominal pain at 24 h by VAS | 44 (93.6) | 19 (40.4) | 0.0001 ^a |
| Shoulder tip pain at 12 h by VAS | 43 (91.5) | 24 (51.1) | 0.0001 ^a |
| Shoulder tip pain at 24 h by VAS | 37 (78.7) | 13 (27.7) | 0.0001 ^a |

Data are presented as number (percentage) and mean±standard deviation.

There was significant reduction in the incidence of nausea and vomiting in intervention group (10.6% and 2.1%) than in the control group (51.1% and 19.1%); $p=0.0001$ and $p=0.007$ respectively. There was no significant difference in the incidence of abdominal distention, time to resumption of intestinal peristalsis and post-operative hospital stay between the two groups. There was significant reduction in the incidence of upper abdominal pain at 12 and 24 hours postoperative in the intervention group (61.7% and 40.4% respectively) than in the control group (100% and 93.6% respectively); $p=0.0001$. Also, there was a significant reduction in the incidence of shoulder tip pain at 12 and 24 hours

postoperative in the intervention group (51.1% and 27.7% respectively) than in the control group (91.5% and 78.7% respectively); $p=0.0001$ (Table 3).

DISCUSSION

This randomized controlled study was conducted and reported a practical intervention that could reduce both the incidence and intensity of shoulder and upper abdominal pain after laparoscopic surgery. Pain after laparoscopy may occur in the upper abdomen, lower abdomen, back, or shoulders. It may be transient or persistent for about 3 days.⁹ CO₂ gas remains in the sub diaphragmatic space after laparoscopy for more than 24 hours.¹⁰ It has been suggested by some that this gas is converted to carbonic acid on the moist peritoneal surfaces, irritating the diaphragm and leading to referred shoulder and neck pain.¹⁰

To avoid this in present study, author placed the patient in Trendelenburg position then author infused normal saline into the upper abdominal area to eliminate the remaining amount of CO₂ between the diaphragm and liver. The total amount of saline infused in each patient was the same (200-250ml). At the end of procedure, author infused saline continuously until the whole liver was submerged. Author did not leave a postoperative drain, thereby avoiding drain-related pain and intraabdominal infection.

Additionally, in present study author evaluated how the use of different intra-abdominal pressure influences surgical-related outcomes in patients undergoing gynecologic laparoscopic surgeries and demonstrated LPP is safe and applicable compared with SPP. Use of LPP reduces both the incidence and severity of shoulder-tip pain laparoscopic surgery for benign gynecological disease.

Several causes of shoulder pain after laparoscopic surgery have been reported, but the mean hypothesis is based on CO₂ in the abdominal cavity. It is thought that pneumoperitoneum causes diaphragmatic irritation by overstretching the diaphragmatic muscle fibers resulting in a pain sensation mediated by the phrenic nerve.¹¹ Jackson et al, investigated the association between the dimension of the gas bubbles in the peritoneal cavity and the severity of pain and found a correlation between the residual gas volume and post-laparoscopic pain.¹²

To support the theory of overstretched diaphragmatic muscle fibers, it has also been shown that low insufflation rate reduces post-operative shoulder pain.¹² Rapid distension is associated with tearing of blood vessels, traumatic traction of the nerves and release of inflammatory mediators leading to post-operative pain.⁴

In present study the frequency of shoulder tip pain after standard pressure pneumoperitoneum (control group) was significantly higher as compared to combined low-

pressure pneumoperitoneum and irrigation of the upper abdomen with normal isotonic saline (intervention group). Out of 47 patients 43 (91.5%) complained of shoulder tip pain in control group as compared with 24 patients (51.1%) out of 47 in intervention group ($p=0.0001$). These results are consistent with the findings of Tsai et al 2011 revealed that at 48 hours postoperatively, the effect of intraperitoneal normal saline infusion was still persistent and led to significantly reduced upper abdominal pain and shoulder pain.⁵

Intraperitoneal normal saline infusion offers a physiologic buffer system; CO₂ dissolves in water, is absorbed into the intravascular space, is transferred to the lung, and is converted back into CO₂ to be expelled.¹³ These results are consistent with the findings of Sarli et al who evaluated the shoulder tip pain in a prospective randomized double blind trial using 9-13mmHg intra-abdominal pressure.⁷ They reported that the frequency and intensity of shoulder tip pain were significantly less in the LPG, and that the dose requirement for analgesic drugs was significantly less with LPG patients. That study is comparable to the current results, in which the VAS score at 12 and 24 h was lower in the LPG.

Joshi et al reported that lower pressures in pneumoperitoneum had significant advantages for postoperative pain, analgesic usage, pulmonary function preservation and hospital stay.¹⁴ Barczynski and Herman reported that surgeons experienced more difficult dissections with lower pressure pneumoperitoneum, which can result in longer operation times against to present study author found that no significant difference in operation times between two groups.⁸

Koc et al found higher levels of pain in their HPGs, but these findings did not reach statistical significance.¹⁵ However Celik et al and Perrakis et al have shown that the pressure levels did not affect pain scores.^{16,17} Wallace et al compared 7.5 and 15mmHg pressure and reported less pain in the LPG.¹⁸

Vilos et al, the intraperitoneal pressure was correlated positively with BMI and weight and negatively with parity.¹⁹ This suggests that using low pressure in patients with higher BMIs and lower parity may result in difficulties during surgery. In present study, there were no statistical differences in BMI and parity among the groups. In addition to the lower pain scores expected, lower abdominal insufflation pressure can also minimize respiratory and heart complications. Some surgeons have used 7mmHg pressures to minimize the effect of pneumoperitoneum on cardiovascular functions.²⁰

European Association for Endoscopic Surgery has been recommended to use the lowest intraabdominal pressure allowing adequate exposure of the operative field, rather than using a routine pressure.²¹ In present study post-operative hospital stay was less in intervention group than

control group. However, these differences did not reach statistical significance ($p=0.589$).

CONCLUSION

Combined intraperitoneal normal saline infusion and low-pressure CO₂ pneumoperitoneum (8mmHg) seems to reduce the intensity and the frequency of shoulder-tip pain and upper abdominal pain in gynecologic laparoscopic surgery. Hence, author advocate its use as a routine procedure during laparoscopic gynecologic surgeries.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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