

Original Article

The Use of Peritoneal Suction Drainage to Reduce Shoulder Pain Caused by Gynecological Laparoscopy

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Abstract

Purpose: To compare the outcomes of patients undergoing uncomplicated laparoscopic gynecologic procedures with and without drainage, and investigate the effects of drainage on postoperative shoulder pain, hospital stay and analgesic medications.

Patients and Methods: In this randomized clinical trial, 92 patients undergoing uncomplicated laparoscopic gynecologic procedures at Pars Hospital, Tehran, Iran, between April 2012 and July 2014 entered the study. Patients were randomly divided into two groups: one group received a drain at the end of operation, whereas the second group didn't receive a drain. For patients closed with drainage, Hemovac plastic passive drains were inserted without negative pressure. Severity of the patients' postoperative shoulder pain was evaluated at rest using the 10-point visual analogue scale (VAS) at 12 h, 24 h, and 48 h after surgery.

Results: There was no difference between the two groups regarding age, weight, height, BMI, the cause of surgery and the blood loss during the surgery. At 12 h and 24 h after surgery, the shoulder pain was statistically lower in the group with drainage ($P < 0.001$ for both). There was no statistically significant difference between mean VAS scores of the case and control group at 48 hours post-surgery ($P = 0.806$). A significantly higher postoperative demand for analgesics was observed in the control group ($P < 0.001$). There was no statistically significant difference between two groups regarding the length of hospital stay.

Conclusion: Our findings suggest that drainage may be useful to prevent postoperative shoulder pain among patients undergoing gynecological laparoscopic surgeries and decrease the need for pain medication. Further studies are recommended to assess the feasibility and cost effectiveness of using this method for reducing the postoperative shoulder pain.

Keywords: Drainage, gynecology, laparoscopy, pain, shoulder, surgery

Cite this article as: Haghgoo A, Chaichian S, Ghahremani M, Nooriardebili S, Akbaian A, Moazzami B. The use of peritoneal suction drainage to reduce shoulder pain caused by gynecological laparoscopy. *Arch Iran Med.* 2016; **19**(3): 173 – 178.

Introduction

The widespread use of diagnostic laparoscopy and continued utilization of operative laparoscopy by gynecologists necessitates further refinement of pain management following these procedures.¹ Laparoscopic postoperative pain is a complex and multifactorial phenomenon.² The various sources of pain in this procedure, include shoulder tip pain, operative disruption of tissues, and port site pain.² The incidence of shoulder pain following laparoscopy has been reported to vary between 35% and 80% decreasing the patient's satisfaction.^{3,4}

During laparoscopic procedures carbon dioxide is insufflated in order to distend the peritoneal cavity creating a pneumoperitoneum and some residual gas inevitably remains in the peritoneal cavity.⁴⁻⁶ It has been suggested that post laparoscopic shoulder pain is mainly produced by this CO₂ retention in peritoneal cavity.⁵⁻⁷ Other causes of shoulder pain are thought to be peritoneal irritation by carbonic acid and losing the suction support of the liver by creation of a subdiaphragmatic space.^{1,7} One study has compared the volume of residual gas with the severity of pain that women

experience after gynecologic laparoscopic procedures and found that the amount of residual gas volume and the severity of pain are correlated.^{5,7}

Various techniques have been attempted to decrease the pain following laparoscopy;^{3,4} pulmonary recruitment maneuver,^{8,9} gasless laparoscopy,¹⁰ intraperitoneal local anaesthesia,^{11,12} intraperitoneal infusion of saline,¹³ and reduction in insufflation pressure.¹⁴ However, none of these techniques have shown reliable results.¹⁵

The use of a peritoneal gas drain in the first 4–6 hours following laparoscopy has been reported to decrease the volume of residual intraperitoneal gas and consequently reduce the pain during the recovery period,^{4,16,17} but a consensus regarding the effect of this method has not yet been reached.^{1,18}

In this randomized clinical trial, we compared the outcomes of patients who underwent uncomplicated laparoscopic gynecologic procedures with and without drainage, to investigate the effects of drainage on postoperative shoulder pain hospital stay and analgesic medications.

Patients and Methods

This was a randomized clinical trial approved by the local ethics committee and all patients gave their informed consent. The study included 92 patients between 22 and 64 years of age undergoing uncomplicated laparoscopic gynecologic procedures at Pars Hospital, Tehran, Iran, between April 2012 and July 2014, and who did not develop any intraoperative complications. Patients

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Accepted for publication: 17 December 2015

were randomly divided in two groups of 46 patients, one with a drainage and the other without a drainage. The randomization was based on a computerized block randomization table and before the surgery a closed envelope indicating the type of surgery was handed to the surgeon. The study excluded patients with preoperative shoulder, abdominal or pelvic pain, systemic disease, severe abdominal and pelvic adhesions and tubo-ovarian abscess, before or during the operation.

The patients were operated on by the same surgical team. All patients were given 1 g Cefazolin intravenously as a prophylactic antibiotic after induction of general anesthesia. Laparoscopy was performed by direct trocarization and CO₂ insufflation, using a standard four-port method as follow: one 11 mm port was inserted through the umbilicus for telescope insertion and the other two 5.5 mm ports were inserted through outer upper margins of bilateral rectus muscle sheaths, and an 11 mm suprapubic trocar was also inserted. The gas pressure was set at 12 – 16 mmHg during the procedure.

In all patients the abdominal cavity was washed with 1.5 liters of warm saline (body temperature serum) at the end of the operation. After the completion of surgery the abdomen was closed with or without drainage based on a pre-generated randomization table. The surgeon used a randomized sequence concealed in a closed envelope at this point. Patients who needed drainage because of organ injury, bleeding or infection were excluded from the study.

For patients closed with drainage, Hemovac plastic passive drains were inserted in suprapubic position in a way that the opening of the drain was tangent to the peritoneum, without negative pressure. Intra peritoneal placement of the drain was performed under direct visualization. The drain was in place for at least 24 h. Hemovac drain is a very thin drain which causes less pain and can be easily retracted.

We applied gentle abdominal pressure to all patients to remove carbon dioxide passively through the port side. Postoperative pain was controlled with Diclofenac 100 mg. Doses of Diclofenac 100 mg were given orally postoperatively if the patients complained about pain after pain scaling was performed. The following variables were evaluated and recorded for all patients: age; body mass index (BMI); surgical details, including operation time, time to first gas passing and nausea and/or vomiting; length of postoperative hospital stay; and postoperative complications. These data were compared between the drainage and non-drainage groups.

Severity of the patients' postoperative shoulder pain was evaluated at rest using the 10-point visual analogue scale (VAS) at 12 h and 24 h and 48 h after the surgery. The VAS consists of a non-graduated 10 cm line ranging from 0 for 'no pain' to 10 for 'pain as bad as it could be'. Patients were asked to give a score corresponding to their perceived pain. The observers documenting the pain scores were not aware of this study design and objectives.

The primary aim of this study was to compare the differences between the drainage and non-drainage groups considering the shoulder pain scores at 12 h and 24 h and 48 h after surgery and demand for analgesic medications among patients.

Sample Size Calculation and Statistical Methods

A sample size of 88 (44 per group) was required to detect at least a 1-point difference at 12 h, and 24 h between groups, with a power of 80% at the 5% significance level, when the standard deviation of the pain was assumed to be 1.7 and 1.6 in drain and no drain groups respectively.³ We entered 46 in each group con-

sidering a 5% chance of patients being lost to follow up.

All the statistical analysis performed by SPSS Version 23 (IBM SPSS Statistics for Windows, Armonk, NY: IBM Corp.). To check the normal distribution of data, we used Q-Q plot and Kolmogorov-Smirnov test. To present data we used mean, standard deviation, median and range. Comparison of the data in the groups was performed by *t*-test, Mann-Whitney, Chi-Square test and Fisher exact tests. *P*-value less than 0.05 considered statistically significant.

Results

In drainage group we lost two patients and in non-drainage group one patient to follow up, so in drainage group 44 patients and in the non-drainage group 45 patients completed the study (Figure 1).

Table 1 shows patients characteristics for the two groups. There was no difference between the two groups regarding age, weight, height and BMI, the cause of surgery and the blood loss during the surgery.

Table 1 also shows the mean duration of surgery, which indicates a statistically significant difference between the case and control groups showing a longer mean duration of surgery in the case group.

At 12 h after surgery, considerable shoulder pain (VAS reading higher than 2) was detected in 29 patients (65.9%) in the drainage group and in 44 patients (97.8%) in the non-drainage group ($P < 0.001$). At 24 h after surgery, considerable shoulder pain was observed in 6 patients (13.6%) in the drainage group and 38 patients (84.4%) in the non-drainage group ($P < 0.001$), and at 48 h after surgery, considerable shoulder pain was observed in 2 (4.5%) and 2 (4.4%) patients in the case and control groups, respectively ($P = 0.982$), (Table 2).

At 12 h after surgery, the mean shoulder pain score was 4.4 ± 1.5 and 3.6 ± 1.5 in the case group and the control group respectively indicating a significant difference ($P < 0.001$) (Table 2), (Figure 2). Similarly, at 24 h after surgery, the mean shoulder pain was 1.4 ± 1.7 and 3.9 ± 1 in the case group and the control group, respectively indicating a significant difference ($P < 0.001$) (Table 2), (Figure 2). There was no statistically significant difference between mean VAS scores of the case and control group at 48 hours post-surgery ($P = 0.806$) (Table 2), (Figure 2).

Table 3 shows the number of pain medications in two groups in the first and second day after the laparoscopic procedure indicating a significantly higher demand for analgesics in the control group in both days.

There was no statistically significant difference in duration of hospitalization between the case and control group ($P = 0.764$). Also, there was no serious complication observed in either group one week after laparoscopy.

Discussion

Patients who undergo laparoscopy as a minimally invasive surgery expect less postoperative pain and any kind of pain makes them more anxious, but shoulder pain is common after laparoscopic surgery as a result of retained carbon dioxide causing phrenic nerve irritation. The severity of pain is proportional to the residual gas volume.^{5,7} Different mechanical and pharmacological methods, including drainage, have been used to relieve this pain.^{3,19} Drain-

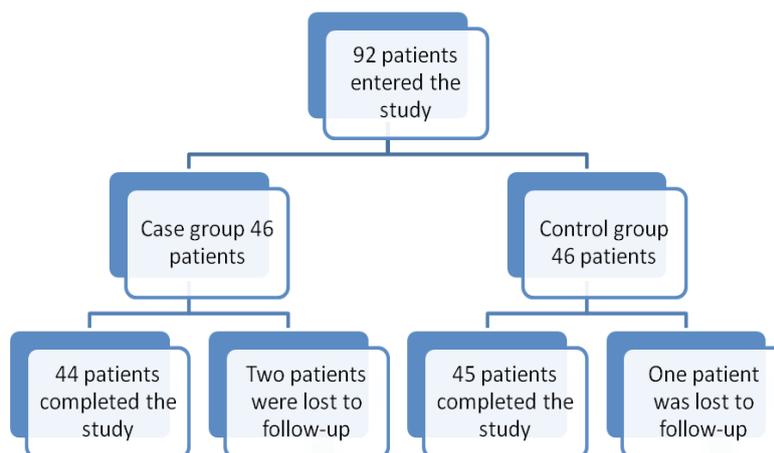


Figure 1. This flowchart shows the number of patients entering the study and also the number of patients completing the study in the case and control groups.

Table 1. Baseline demographic data of patients entering the study.

Parameter	Group			P
	Total	Case	Control	
Age (years)				0.411†
Mean ± SD	37.5 ± 8.5	38.3 ± 8.9	36.8 ± 8.1	
Median (range)	36.5 (22 to 64)	37.5 (24 to 62)	35.5 (22 to 64)	
Weight (kg)				0.514†
Mean ± SD	65.9 ± 12.2	66.7 ± 11.2	65 ± 13.1	
Median (range)	65 (7 to 117)	65 (46 to 117)	66.5 (7 to 90)	
Height (cm)				0.446†
Mean ± SD	162 ± 7	163 ± 9	162 ± 5	
Median (range)	162 (119 to 179)	163 (119 to 179)	162 (151 to 175)	
BMI				0.687†
Mean ± SD	25.2 ± 5.2	25.4 ± 5.3	24.9 ± 5.2	
Median (range)	24.5 (2.7 to 47.5)	24.1 (17.7 to 47.5)	25.5 (2.7 to 33.1)	
Lower than < 18.5	12 (13.6%)	9 (20.9%)	3 (6.7%)	
b 18.5–24.9	42 (47.7%)	25 (58.1%)	17 (37.8%)	
b 25–29.9	29 (33.0%)	8 (18.6%)	21 (46.7%)	
More than > 30	5 (5.7%)	1 (2.3%)	4 (8.9%)	
Type of laparoscopy				0.089*
Endometriosis resection	8 (9.0%)	6 (13.6%)	2 (4.4%)	
Resection of other ovarian cysts walls	25 (28.1%)	8 (18.2%)	17 (37.8%)	
Myomectomy	9 (10.1%)	6 (13.6%)	3 (6.7%)	
Hysterectomy	16 (18.0%)	10 (22.7%)	6 (13.3%)	
Other	11 (12.4%)	3 (6.8%)	8 (17.8%)	
Combined	20 (22.5%)	11 (25.0%)	9 (20.0%)	
Blood missing (cc)				0.051‡
< 200	53 (59.6%)	22 (50.0%)	31 (68.9%)	
400–20	28 (31.5%)	16 (36.4%)	12 (26.7%)	
600–400	8 (9.0%)	6 (13.6%)	2 (4.4%)	
Duration of surgery (hour)				0.024‡
1–0.5	18 (20.2%)	5 (11.4%)	13 (28.9%)	
2–1	40 (44.9%)	20 (45.5%)	20 (44.4%)	
3–2	29 (32.6%)	17 (38.6%)	12 (26.7%)	
4–3	2 (2.2%)	2 (4.5%)	0 (0.0%)	

†Based on t-test; ‡Based on Mann-Whitney test; *Based on Fisher exact test.

Table 2. Pain outcomes in two groups of patients.

Parameter	Group			Diff	95% CI		P
	Total	Case	Control		Lower	Upper	
Pain 12 hours				-1.6			< 0.001‡
Mean ± SD	4.4 ± 1.5	3.6 ± 1.5	5.2 ± 1.1		-2.1	-1.0	
Median (range)	4 (0 to 6)	4 (0 to 6)	6 (2 to 6)				
VAS > 2	73 (82.0%)	29 (65.9%)	44 (97.8%)	-31.9%	-46.8%	-17.0%	< 0.001**
Pain 24 hours				-2.5			< 0.001‡
Mean ± SD	2.6 ± 1.8	1.4 ± 1.7	3.9 ± 1		-3.1	-1.9	
Median (range)	2 (0 to 6)	1 (0 to 6)	4 (2 to 6)				
VAS > 2	44 (49.4%)	6 (13.6%)	38 (84.4%)	-70.8%	-85.6%	-55.8%	< 0.001**
Pain 48 hours				-0.1			0.806‡
Mean ± SD	0.5 ± 1	0.4 ± 1	0.5 ± 1.1		-0.5	0.4	
Median (range)	0 (0 to 4)	0 (0 to 4)	0 (0 to 4)				
VAS > 2	4 (4.5%)	2 (4.5%)	2 (4.4%)	0.1%	-8.7%	8.9%	0.982*

‡Based on Mann-Whitney test; *Based on Fisher exact test; **Based on Chi-Square test.

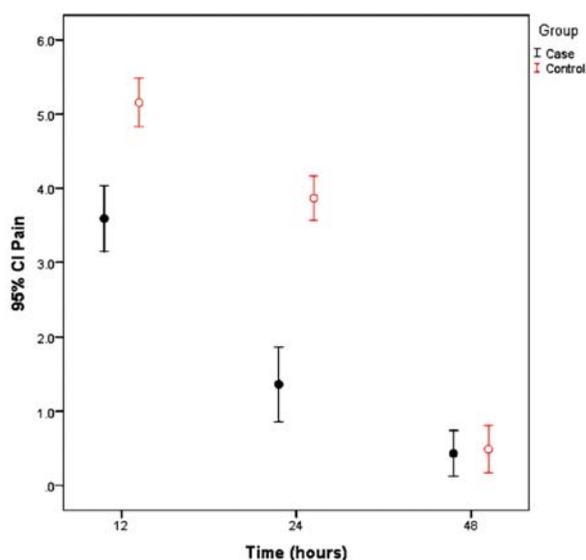


Figure 2. Pain outcomes in two groups of patients.

Table 3. Analgesic usage in two groups of patients.

Parameter	Group			Diff	95% CI		P
	Total	Case	Control		Lower	Upper	
First 24 hours				-1.0	-1.2	-0.7	< 0.001‡
Mean ± SD	1.7 ± 0.8	1.2 ± 0.7	2.2 ± 0.6				
Median (range)	2 (0 to 3)	1 (0 to 3)	2 (0 to 3)				
No	8 (9.0%)	7 (15.9%)	1 (2.2%)				
One	22 (24.7%)	21 (47.7%)	1 (2.2%)				
Two	47 (52.8%)	15 (34.1%)	32 (71.1%)				
Three	12 (13.5%)	1 (2.3%)	11 (24.4%)				
Second 24 hours				-0.3	-0.6	-0.1	0.007‡
Mean ± SD	0.4 ± 0.6	0.3 ± 0.5	0.6 ± 0.7				
Median (range)	0 (0 to 2)	0 (0 to 2)	1 (0 to 2)				
No	56 (62.9%)	34 (77.3%)	22 (48.9%)				
One	27 (30.3%)	8 (18.2%)	19 (42.2%)				
Two	6 (6.7%)	2 (4.5%)	4 (8.9%)				
Total				-1.3	-1.7	-0.8	< 0.001‡
Mean ± SD	2.1 ± 1.2	1.5 ± 1.1	2.8 ± 0.9				
Median (range)	2 (0 to 5)	1 (0 to 5)	3 (0 to 4)				

‡Based on t-test; †Based on Mann-Whitney test; *Based on Fisher exact test.

age is believed to reduce postoperative pain by removal of gas in the peritoneal cavity.³ In the present study, we found that the drainage after uncomplicated gynecological laparoscopic procedures has a significant effect on shoulder pain. Our findings are similar to those of Abbott J.⁷, who observed decreased severity of shoulder pain within the first 4 h after gynecological laparoscopic procedures. On the other hand, some other studies have indicated that drainage does not significantly reduce the postoperative shoulder pain. For example Georgiou, et al.²⁰ performed a randomized study and found that there was no statistically significant difference between patients with and without drain implementation after cholecystectomy regarding the shoulder pain, while drain implementation increased the severity of postoperative pain, prolonged the operation duration and increased the length of the postoperative hospital stay.

Some other studies have reported that drainage use reduces overall postoperative pain.^{21,22} Also a randomized study by Abbott, et al.⁷ categorized the effect of drainage use on postoperative shoulder pain after minor gynecological laparoscopic surgery and found that, although drainage use did not change the severity of shoulder pain preoperatively or at 4, 24, and 48 hours postoperatively, its use decreased the incidence of pain. This study also showed that simple use of an analgesic was more cost-effective compared with drainage use and did not recommend routine use of drains to prevent postoperative shoulder pain.⁷

In a recent review article by Craciunas, et al.⁴ only five studies evaluating the effect of gas drain following gynecological laparoscopy on pain has been chosen by the authors as being conducted with acceptable methodology. Out of these three RCTs^{1,7,22} two studies^{7,22} reported lower incidence of shoulder pain in the experimental group compared to the control group at 4 h ($P < 0.05$ and $P < 0.02$, respectively), while the remaining study,¹ reported no difference. We found statistically lower pain at 12 hours after laparoscopy.

At 24 h, the pain was reported to be similar between the groups in 2 RCTs,^{7,22} but the third RCT¹ found less pain in the experimental group ($P = 0.008$) compared to the control group. In the present study, we found statistically lower pain at 24 hours after the laparoscopy.

At 48 h, one study reported no difference between the groups²² and 2 studies^{1,7} reported less pain in the experimental group ($P = 0.0047$ and $P = 0.03$) respectively. In the present study, we found no difference between the two groups at 48 hours.

They also reported that some RCTs^{22,23} reported similar requirement of analgesia between the groups and 1 study⁷ reported increased analgesia requirement in the control group at 24 h and 48 h post laparoscopy. We found a higher need for analgesia in the control group in the first 24 hours, but not on the second day.

It should be noted that the indications for surgery widely varied in the studies that have examined drainage after gynecological laparoscopic surgeries and their effect on shoulder pain. The present study suffers from a similar limitation due to including patients with a variety of gynecologic diseases, which might be the reason for the discrepancy in the results. The present study has some other limitations, such as the relatively small sample size, as well as not considering the effect of drainage on abdominal pain. It seems that larger prospective randomized studies are needed to re-evaluate the effect of drainage on postoperative pain after gynecological laparoscopic procedures.

In conclusion, our findings suggest that drainage may be useful

to prevent postoperative shoulder pain among patients undergoing gynecological laparoscopic surgeries and decrease the need for pain medication. Further studies are recommended to assess the feasibility and cost effectiveness of using this method for reducing the postoperative shoulder pain.

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