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ORIGINAL ARTICLE

Randomized controlled trial comparing the effects of usual gas release, active aspiration, and passive-valve release on abdominal distension in patients who have undergone laparoscopic cholecystectomy

Warisara Tuvayanon,[1] Potchanee Silchai,[1] Yongyut Sirivatanauksorn,[2] Porntita Visavajarn,[1] Jaruwan Pungdok,[1] Sununtha Tonklai[1] & Thawatchai Akaraviputh[2]

1 Division of Nursing, Faculty of Medicine, Siriraj Hospital, Mahidol University, Bangkok, Thailand

2 Division of General Surgery, Department of Surgery Faculty of Medicine, Siriraj Hospital, Mahidol University, Bangkok, Thailand

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Correspondence
Yongyut Sirivatanauksorn, Division of General Surgery, Faculty of Medicine Siriraj Hospital, Mahidol University, 2 Wanglang Road, Bangkoknoi, Bangkok 10700, Thailand.
Tel: +66 2 4198006
Fax: +66 2 4121370
Email: yongyut.sir@mahidol.ac.th

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Abstract

Introduction: Residual, intra-abdominal CO_2 contributes to abdominal distension and pain after laparoscopic surgery. The study was designed to assess recovery after gas release in patients who have undergone laparoscopic cholecystectomy (LC).

Methods: A total of 142 patients undergoing laparoscopic cholecystectomy were randomly divided into three groups: (i) group 1 (control group), gas release from the surgical wound without port release ($n = 47$); (ii) group 2, active gas aspiration via a subdiaphragmatic port ($n = 48$); and (iii) group 3, passive-valve release via a subdiaphragmatic port valve opening ($n = 47$). Abdominal distension and shoulder pain levels were assessed postoperatively.

Results: The active aspiration group had significantly reduced postoperative abdominal distensions at 30 min, 4, and 24 h compared with the control group (50.0% vs 80.9%, 43.8% vs 76.6%, 33.3% vs 57.4%, respectively; $P < 0.05$). Similarly, the passive-valve release group had significantly reduced postoperative abdominal distensions at 4 and 24 h compared with the control group (51.1% vs 76.6%, 57.4% vs 36.2%; $P < 0.05$). Both intervention groups had significantly reduced postoperative shoulder pain at 4 and 24 h compared with the control group ($P < 0.001$). In addition, the postoperative ambulation times for the active aspiration group were significantly shorter than those for the control and passive-valve release groups ($P < 0.001$).

Conclusion: Releasing residual CO_2 from the intra-abdominal cavity at the end of laparoscopic cholecystectomy by either the active aspiration or passive-valve release technique is an effective way to reduce postoperative abdominal distension and shoulder pain.

Introduction

Laparoscopic cholecystectomy (LC) is the gold-standard treatment for symptomatic gallstones. It supports faster patient recovery and allows patients to return to activities of daily living quicker than open cholecystectomy (1). Nevertheless, most patients complain about abdominal distension and postoperative pain after laparoscopic surgery. Normally, CO_2 gas is released through the surgical wound, but residual gas in the peritoneal cavity can cause postoperative discomfort and distension (2,3). Moreover, high levels of abdominal distension are associated with high levels of postoperative pain during the recovery period, delaying recovery-room discharge (4).

Abdominal and shoulder pain are very common after laparoscopic surgery. Shoulder pain has been found in up to two-thirds of patients (5). Its intensity increases steadily in the first 3–6 h postoperatively, and it is most intense 12 h after surgery. The mechanism of the shoulder pain is unclear, but it may be caused by diaphragmatic irritation from CO_2 gas, peritoneal stretching, or the release of inflammatory mediators (6,7). There is a strong correlation between residual CO_2 volume and the severity of pain after laparoscopic surgery (6). Therefore, this study aimed to assess the degree of abdominal distension and pain at the end of surgery after using various gas-releasing techniques in patients who had undergone LC.

Materials and Methods

All patients provided written informed consent. The study was approved by the Institutional Research Board Committee of the Faculty of Medicine, Siriraj Hospital, Mahidol University (Si 642/2014).

From 4 November 2014 to 4 November 2015, 150 patients aged 18 years and older were admitted for elective LC at Siriraj Hospital. Patients with pregnancy, previous abdominal surgery, acute cholecystitis, pancreatitis, or cholangitis were excluded. Patients were removed from the study if intraoperative cholangiography, common bile duct exploration, conversion to an open procedure, or drain placement was performed.

The primary outcome was the level of abdominal distension, and the secondary outcomes were level of shoulder pain, abdominal circumference, and the recovery times in the recovery room and the inpatient unit. The sample size was calculated based on a previous study in which the proportion of patients with postoperative abdominal distension in the recovery room was 60% (4).

The pilot study was performed with active gas aspiration at the end of surgery in patient undergoing LC, and 30% of cases did not have postoperative abdominal distension. The level of significance was set at 0.05 to achieve 0.80 power, with a type II error for a two-tailed test. It was determined that the sample size should be 42 per group, with 20% more patients to overcome prevention loss. Therefore, a sample size of 50 patients per group was required.

Randomization was performed using a computer-generated sequence of 1–150 and sealed envelopes, which were opened in the operating room at the beginning of each operation. General anesthesia was employed, and an oral gastric tube was placed in all patients. A subumbilical incision was made using Hasson's technique, and intra-abdominal cavity was insufflated with CO_2 after the introduction of a 10-mm balloon trocar. Another three 5-mm trocars were inserted through subdiaphragmatic, subcostal midclavicular, and subcostal anterior axillary incisions. Pneumoperitoneum pressure was set at 14 mmHg with a CO_2 flow rate of 2 L/min. After the gallbladder was dissected from the liver bed, an antiemetic drug (ondansetron 8 mg) was administered intravenously by the anesthesiologists to minimize postoperative nausea and vomiting. The gallbladder was put in a 7.5 × 15 cm. Endobag™ (Medtronic, Bangkok, Thailand) and retrieved through the umbilical port.

Patient groups

Patients were divided into three groups: (i) group 1 (control group), gas release from the surgical wound without port release (n = 47); (ii) group 2, active gas aspiration via a subdiaphragmatic port (n = 48); and (iii) group 3, -passive-valve release via a subdiaphragmatic port valve opening (n = 47).

In group 1 (control group), the gallbladder was retrieved through the umbilical port, and some CO_2 gas escaped passively via the subumbilical wound. Local anesthesia (0.25% bupivacaine 20 mL) was administered, and the abdominal wall and skin were closed with absorbable suture no. 1-0 (J-shaped needle) and 4-0- (cutting needle), respectively.

In group 2 (active aspiration group), once the gallbladder had been dissected from the liver bed, the subdiaphragmatic port was visualized and pulled up until the cannula tip fit into the intra-peritoneum. The other cannula ports were then removed. Local anesthesia (0.25% bupivacaine 20 mL) was administered, and the abdominal wall was closed with absorbable suture no. 1-0 (J-shaped needle). Next, the subdiaphragmatic port valve was opened, and a suction tip was connected with a negative pressure of 80 mmHg. The skin wounds were closed with absorbable suture no. 4-0 (cutting needle). Subsequently, the subdiaphragmatic port was removed, and the skin was closed.

In group 3 (passive-valve release group), once the gallbladder had been dissected from liver bed, the subdiaphragmatic port was visualized and pulled up until the cannula tip fit into the intra-peritoneum. Next, the port valve was opened to release residual CO_2 from the abdominal cavity. The other cannula ports were removed. Local anesthesia (0.25% bupivacaine 20 mL) was administered, and the abdominal wall was closed with absorbable suture no 1-0 (J-shaped needle). The skin wounds were closed with absorbable suture no. 4-0 (cutting needle). Finally, the subdiaphragmatic port

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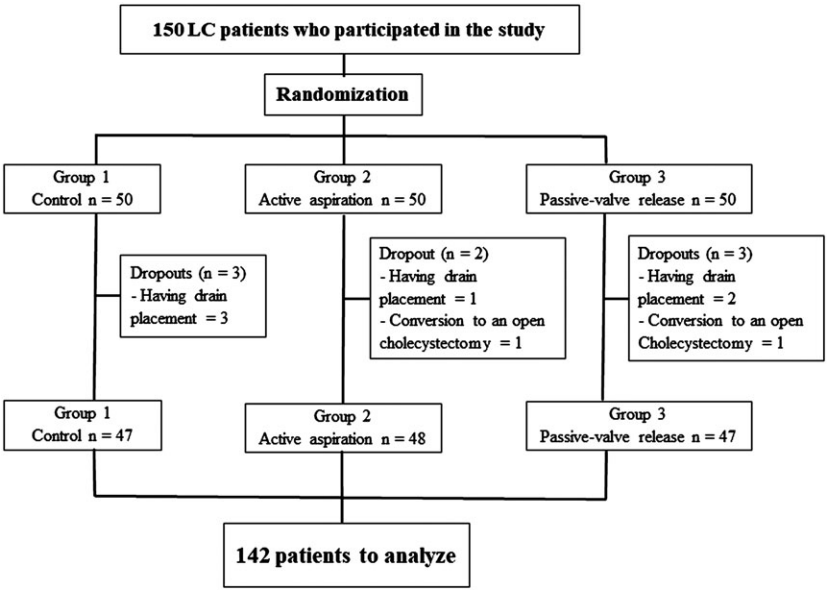

Figure 1 The number of the patients enrolled in the three randomized study groups. LC, laparoscopic cholecystectomy.

Table 1 Demographic and clinical data

	All patients	Group 1: controls	Group 2: active aspiration	Group 3: passive-valve release	*P*-value
Patients (*n*)	142	47	48	47	—
Men/women (*n*)	40/102	14/33	9/39	17/30	0.052
Age (years)	55.0 ± 13.8	51.8 ± 2.1	55.9 ± 1.9	57.5 ± 1.8	0.106
BMI (kg/m^2)	25.9 ± 5.0	26.6 ± 4.9	25.9 ± 5.5	25.1 ± 4.6	0.352
Duration of surgery (min)	67.7 ± 31.5	69.9 ± 34.8	69.0 ± 27.7	64.1 ± 32.2	0.644
Total CO_2 volume (liters)	46.0 ± 34.9	41.8 ± 30.2	49.2 ± 39.9	47.0 ± 34.4	0.570

Unless otherwise noted, all data are mean ± SD.

was removed, and the skin was closed at the end of the operation.

Statistical analysis

The results and descriptive statistics (*n* [%] and mean ± SD) were analyzed using SPSS version 18.0 for Windows (SPSS Inc., Chicago, USA). The normal distribution test of the quantitative data using the Kolmogorov–Smirnov test and comparisons between groups were analyzed using *t*-test, χ^2 test, post-hoc test, and ANOVA.

Results

The 150 patients who participated in the study were divided into three groups: (i) group 1, the control group; (ii) group 2, the active aspiration group; and (iii) group 3, the passive-valve release group. Eight patients were removed because they required either drain placement (*n* = 6) or conversion to open cholecystectomy (*n* = 2). As such, there was data on 142 patients to analyze (Figure 1). The demographic and clinical data of the three groups are summarized in Table 1. The 142 patients comprised 40 men and 102 women, with a mean age of 55.0 ± 13.8 years. Their mean BMI was 25.9 ± 5.0 kg/m^2, the mean surgical duration was 67.7 ± 31.5 min, and the mean insufflated CO_2 volume was 46.0 ± 34.9 L. There was no statistically significant difference between the groups in terms of demographic or clinical data (Table 1).

The proportion of patients with mild to moderate nausea and/or vomiting in either the recovery room or the inpatient unit was higher in the control group than in the active aspiration group or the passive-valve release group (40.4%, 29.2%, and 29.8%, respectively). The total number of patients with postoperative shoulder pain was 59 (41.5%). Interestingly, the control group had a higher proportion of patients with postoperative shoulder pain than the active aspiration group or the passive-valve release group (68.1%, 22.9%, and 34.0%, respectively) (Table 2).

The proportion of patients with abdominal distension was significantly lower in the active aspiration group

Table 2 Main measurable outcomes

	Group 1: controls (n = 47)	Group 2: active aspiration (n = 48)	Group 3: passive-valve release (n = 47)	P-value
Overall abdominal distension (NRS > 0), n (%)	45 (95.7)	36 (75.0)	43 (91.5)	<0.001[†]
Moderate to severe abdominal distension (NRS ≥ 4), n (%)	40 (85.1)	22 (45.8)	34 (72.3)	<0.001[†]
Postoperative abdominal distension, n (%)				
30 min	38 (80.9)	24 (50.0)	31 (66.0)	0.007[†]
60 min	40 (85.1)	31 (64.6)	34 (72.3)	0.071
4 h	36 (76.6)	21 (43.8)	24 (51.1)	0.003[†,‡]
24 h	27 (57.4)	16 (33.3)	17 (36.2)	0.035[†,‡]
Overall shoulder pain (NRS > 0), n (%)	32 (68.1)	11 (22.9)	16 (34.0)	<0.05[†,‡]
Postoperative shoulder pain, n (%)				
4 h	17 (36.2)	1 (2.1)	6 (12.8)	<0.001[†,‡]
24 h	32 (68.1)	10 (20.8)	14 (29.8)	<0.001[†,‡]
Patient ambulation time in inpatient unit, mean ± SD (min)	638.5 ± 368.7	419.9 ± 252.9	576.1 ± 331.9	<0.001[†,§]

[†]Post-hoc comparisons by Bonferroni test: group 1 versus group 2.
[‡]Post-hoc comparisons by Bonferroni test: group 1 versus group 3.
[§]Post-hoc comparisons by Bonferroni test: group 2 versus group 3.
NRS, Numeric Rating Scale.

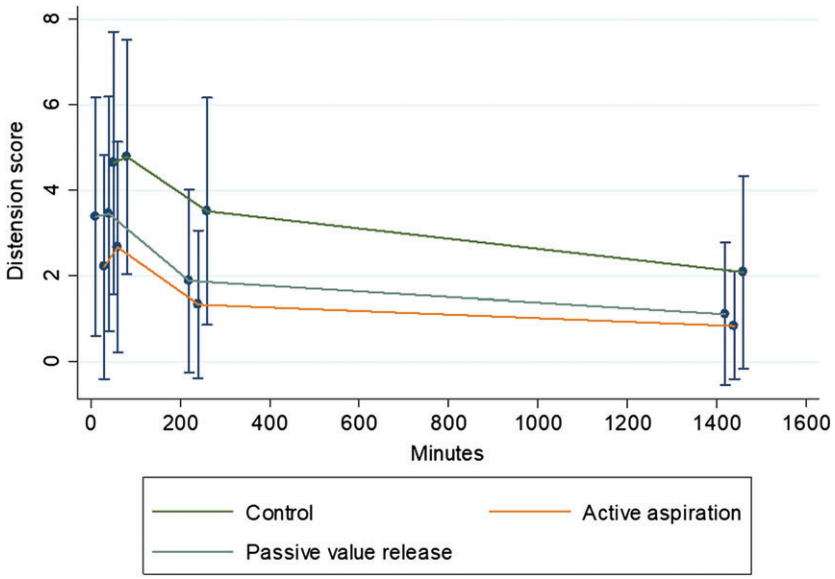

Figure 2 Mean abdominal distension scores.

than in the control group at 30 min, 4 h and 24 h postoperatively (50.0% vs 80.9%, 43.8% vs 76.6%, and 33.3% vs 57.4%, respectively; $P < 0.05$) (Figure 2). Similarly, the proportion of patients with postoperative abdominal distension was significantly lower in the passive-valve release group than in the control group at 4 h and 24 h (51.1% vs 76.6% and 36.2% vs 57.4%, respectively; $P < 0.05$). However, the mean abdominal circumferences of patients in each group were not dissimilar (Table 2).

A significantly smaller proportion of the active aspiration group had postoperative shoulder pain at 4 and 24 h compared to the control group (36.2% vs 2.1% and 68.1% vs 20.8%, respectively; $P < 0.05$). Also a significantly smaller proportion of the passive-valve release group had postoperative shoulder pain at 4 and 24 h compared to the control group (36.2% vs 12.8%, and 68.1% vs 29.8%, respectively; $P < 0.01$). Moreover, a comparison of postoperative shoulder pain levels between the active aspiration group and passive-valve release group indicated that the former had significantly less pain at both 4 and 24 h ($P < 0.001$).

The time to discharge from the recovery room did not differ between the groups (Table 2). The mean

ambulation time for the active aspiration group (419.9 min) was significantly shorter than those for the control and passive-valve release groups (638.5 and 576.1 min, respectively; $P < 0.01$).

Discussion

Standard pneumoperitoneum during LC is usually 12–16 mmHg (8). In this study, the intraperitoneal pressure was set at 14 mmHg because there was no evidence that it was safer to use low pressure rather than standard pneumoperitoneum in low surgical risk patients (8) The operative time in procedures using low-pressure pneumoperitoneum (8–12 mmHg) is significantly longer than that in procedures using standard pneumoperitoneum (14 mmHg). Moreover, Celik *et al.* compared pneumoperitoneum pressure at 8, 12, and 14 mmHg and found no statistically significant difference in pain scores between groups (9).

Although CO_2 gas is generally released via the subumbilical wound at the end of LC, some CO_2 gas remains in the peritoneal cavity. This residual CO_2 can cause abdominal discomfort and distension (2,3). A study by Thomson *et al.* found the radiographic presence of subdiaphragmatic gas in 96% of patients who had undergone laparoscopic surgery, with 24-h postoperative volumes in the range of 2–144 mL (10). Moreover, at 48 h postoperatively, 76% of patients still had subdiaphragmatic gas, with the volumes ranging between 0 and 112.9 mL. Other studies have shown that plain abdominal X-ray images are the low-sensitivity test to demonstrate the amount of residual gas. Smith *et al.* demonstrated that most patients have complete reabsorption of their pneumoperitoneum within 24 h of LC (11). Plain films 24 h after LC showed moderate to large amounts of retained gas intraperitoneally in only 10% of patients who had undergone LC. Another study showed that no residual free intraperitoneal gas was seen by supine and upright abdominal X-rays in 19 of 31 patients (61%) after LC (12); small amounts of free gas were noticed at 24 h postoperatively in the remaining 12 patients (39%) and at 48 h in 6 patients (19%). In comparison, in the present study, patients in the active aspiration and passive-valve release groups had significantly less abdominal distension than the control group at 30 min, 4 h, and 24 h postoperatively ($P < 0.05$) (Table 2).

A previous study showed that the overstretching in the intra-abdominal cavity was a significant source of postoperative pain, and it also indicated that low insufflation pressure significantly reduced shoulder pain (13). Nevertheless, Sandhu *et al.* demonstrated that low-pressure pneumoperitoneum (7 mmHg), when compared with standard pneumoperitoneum (14 mmHg), did not reduce the incidence of shoulder pain (14). Ko-Iam *et al.* found that the combination of low-pressure pneumoperitoneum and preemptive etoricoxib significantly reduced the incidence of shoulder pain (15). However, no study has yet established a relationship between CO_2 pressure and postoperative abdominal distension. There have been no previous randomized studies on abdominal distension after LC; only observational and correlational studies have been published. Ure *et al.* reported that 38.7% of patients who had undergone elective LC had abdominal distension in the first 2 h postoperatively (16). Similarly, Tuvayanon *et al.* found that 57.9% of 126 patients who had undergone LC had abdominal distension during the recovery period, with the degree of moderate- and high-level abdominal distension being 22.2% and 13.5%, respectively (4). In contrast, the present study showed that the incidence of abdominal distension in the control group was up to 80% at 30 min. Significantly reduced levels of postoperative abdominal distension were obtained by using both active aspiration and passive-valve release techniques.

In this study, the ambulation time in the inpatient unit for the active aspiration group was significantly shorter than that for both the control and passive-valve release groups ($P < 0.01$) (Table 2). The proportion of patients who could ambulate early was significantly higher in the active aspiration group than in the control and passive-valve release groups ($P = 0.0012$ and 0.0115, respectively) (Table 3 and Figure 3). The reduced level of residual intraperitoneal gas enhanced patient recovery. Oikkonen *et al.* reported that more than 10% of LC patients had difficulty moving and walking at 48 h postoperatively (17); similarly, the present study found that 10% of patients in the control group were unable to ambulate after 48 h postoperatively.

Residual CO_2 affects the severity of pain in the postoperative period (6), although the pathophysiological pathway has not been explained. One hypothesis is that CO_2 acts as a peritoneal irritant. This theory surmises that CO_2 is converted into carbonic acid when combined with fluid in the abdomen (peritoneal acidosis), and in turn, this irritates the phrenic nerve at the diaphragm, causing shoulder pain (6,18,19). McGrath *et al.* reported that 80% of patients who had undergone laparoscopic surgery later suffered shoulder pain (20). Several studies have found that a reduction in residual CO_2 volume in the peritoneal cavity relieves postoperative pain. The application of an active aspiration technique combined with manual compression of the abdominal wall at the end of laparoscopic surgery has been found to reduce

Table 3 Percentage of patients able to ambulate in the inpatient unit

Postoperative hours	Group 1: controls (n = 47)	Group 2: active aspiration (n = 48)	Group 3: passive-valve release (n = 47)	P-value
8 h	10.6%	8.4%	6.4%	0.0012[†]
16 h	34.0%	60.4%	36.2%	0.3805[‡]
24 h	51.1%	85.4%	59.6%	0.0115[§]
32 h	57.5%	89.6%	70.2%	0.0022[¶]
40 h	78.7%	93.6%	85.1%	—
48 h	89.4%	97.9%	91.5%	—

[†]Log rank test: group 1 versus group 2.
[‡]Log rank test: group 1 versus group 3.
[§]Log rank test: group 2 versus group 3.
[¶]Log rank test: group 1 versus group 2 versus group 3.

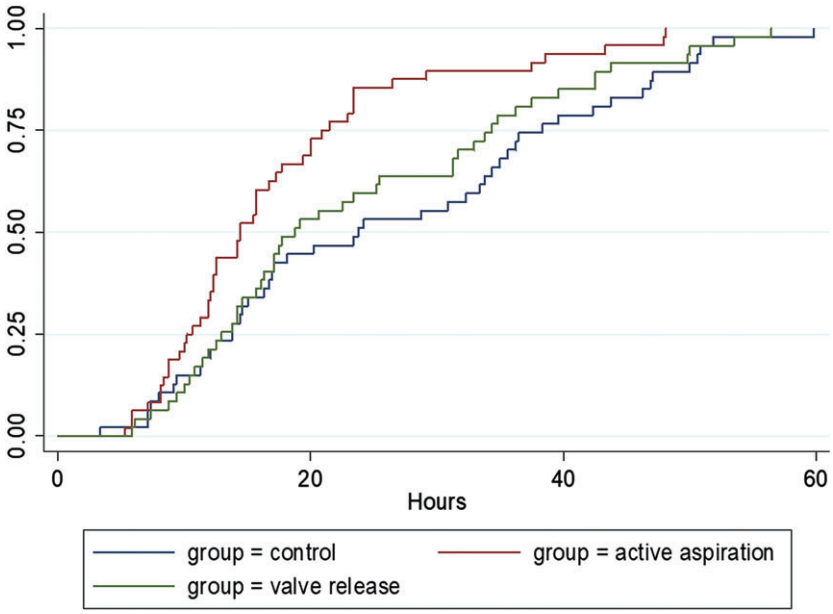

Figure 3 Proportion of patients able to ambulate.

the need for analgesics in the postoperative period (21). Radosa *et al.* reported that 5 min of extended assisted ventilation with an open umbilical trocar valve not only significantly reduced postoperative abdominal pain at 3 h and 24 h after surgery, but it also reduced shoulder pain severity at 24 h after surgery (22). Additionally, Phelps *et al.* found that the use of repetitive pulmonary recruitment maneuvers, with a brief intrapulmonary pressure peak of 60 mmHg, and the opening of the sleeve valve of a trocar port at the end of laparoscopic surgery significantly reduced postoperative pain and nausea levels (23). Our study found that nausea and vomiting in the active aspiration and passive-valve release groups were less frequent than in the control group. The residual CO_2 removal by both active aspiration and the opening of the port valve reduced the incidence and degree of postoperative shoulder pain relative to those in the control group. According to the findings of Salman *et al.* (24), active peritoneal suction at the end of LC removes the residual CO_2 and significantly reduces postoperative shoulder pain 2.5 times more than in the control group. Furthermore, the present study found that shoulder pain levels in the active aspiration and passive-valve release groups were significantly lower than in the control group at both 4 and 24 h postoperatively. It has been speculated that the removal of residual CO_2 reduces the chemical reactions in the peritoneal cavity that cause shoulder pain (6,20).

Several studies have used an the intraperitoneal drain to reduce postoperative pain after laparoscopic surgery, and the technique decreases the need for analgesics to treat shoulder pain in the postoperative period (7,25).

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However, there have been conflicting studies about the benefits of an intraperitoneal drain after laparoscopic surgery, with some reports indicating that it causes postoperative pain and increases the risk of infection (26,27).

To summary, using either the active aspiration or passive-valve release technique to reduce the volume of residual CO_2 in the intraperitoneal cavity at the end of laparoscopic surgery was effective in decreasing the level of abdominal distension and shoulder pain experienced postoperatively. In addition, both techniques reduced the incidences of nausea, vomiting, and abdominal pain in the postoperative period and enhanced patients' recoveries.

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