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A simple clinical maneuver to reduce laparoscopy induced shoulder pain: A randomized clinical trial

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Summary

Objective. To estimate the efficacy of a simple clinical maneuver that facilitates removal of residual abdominal CO_2 after laparoscopic surgery in order to reduce shoulder pain. ***Methods.*** 116 female outpatients who were scheduled for elective gynecologic laparoscopic surgery were randomly allocated to either the current standard (control group) or to additional efforts to remove residual CO_2 at the end of surgery. In the control group, CO_2 was removed by passive deflation of the abdominal cavity through the cannula. In the intervention group, CO_2 was removed by means of Trendelenburg position (30 degrees) and a pulmonary recruitment maneuver consisting of 5 manual inflations of the lung. Postoperative shoulder pain was assessed prior to discharge and 12, 24, 36 and 48 hours later using a visual analog scale (VAS, 0-100). In addition, positional characteristics of the shoulder pain and incidence of postdischarge nausea and vomiting (PDNV) were recorded until 48 hours after discharge. ***Results.*** Pain scores in the control and intervention groups were 30.3±4.5 vs. 15.6±3.0, 25.7±4.7 vs. 10.8±2.4, and 21.7±4.3 vs. 9.1±2.5 at 12, 24 and 36 hours after discharge, respectively (all $p < 0.05$). The intervention reduced positional pain from 63% to 32% ($p<0.05$) and the incidence of PDNV from 56.5% to 20.4% ($p<0.001$). ***Conclusions.*** This simple clinical maneuver at the end of surgery appears to reduce shoulder pain as well as PDNV after laparoscopic surgery by more than half. *Anestezjologia i Ratownictwo 2008; 2: 243-249.*

Keywords: laparoscopic surgery, shoulder pain, PDNV, anesthesia, residual CO_2 , postoperative pain

Introduction

Laparoscopic procedures, compared to laparotomies, are associated with lower morbidity, shorter hospitalizations, smaller incisions, earlier return to normal activity, and less postoperative pain [1-3]. While pain at the surgical site is reduced and hastens recovery, laparoscopic procedures are often associated with shoulder pain that may cause more discomfort to the patient than the pain at the incision sites. The incidence of shoulder pain varies from 35% to 80% and ranges from mild to severe [4-6]. In some cases, it has been reported to last more than 72 hours after surgery [7,8].

Even though the precise mechanism of shoulder pain after laparoscopy remains unclear, the leading

hypothesis is that CO_2-induced phrenic nerve irritation causes referred pain to C4 [9-11].

In this study, we investigated a simple clinical maneuver at the end of surgery to remove residual CO_2 from the peritoneal cavity to test the hypothesis that doing so would significantly reduce the frequency and intensity of shoulder pain after gynecologic laparoscopy.

Material and Methods

- **Study Design**

The design of the study was a randomized, double-blind clinical trial. With IRB approval and after obtaining written informed consent, 117 patients scheduled for elective outpatient gynecologic laparoscopic surgery in a hospital affiliated ambulatory care center (Inland Valley and Rancho Springs Medical Centers) were enrolled in the study. Inclusion criteria were: females age 15-65, American Society of Anesthesiologists (ASA) physical status classification I-II and no previous laparotomy. Patients were excluded from analysis if they required hospitalization after the laparoscopic surgery, the procedure required conversion to laparotomy or if a 48h follow-up was not feasible (Figure 1).

For randomization, we prepared sealed envelopes which were manually shuffled and inserted into numbered envelopes. A single envelope was opened directly prior to the operation by the anesthesiologist. Only the anesthesiologist for the specific case was aware of the treatment allocation until the end of the surgical procedure, when either the control or intervention maneuver was performed. The patient, post-anesthesia care unit (PACU) staff and the investigator obtaining postoperative scores were blinded to the patient`s group allocation. The patients were anesthetized and the investigator who assessed the outcomes was not present in the operating room during the intervention.

All procedures were performed under general anesthesia following a standardized anesthetic regimen. Anesthesia was induced with propofol (2mg/kg) and fentanyl (1.5μg/kg). A non-depolarizing muscle relaxant was used to facilitate endotracheal intubation. All patients were placed on mechanical ventilation and anesthesia was maintained with sevoflurane in oxygen-enriched air, with repeated boluses of fentanyl

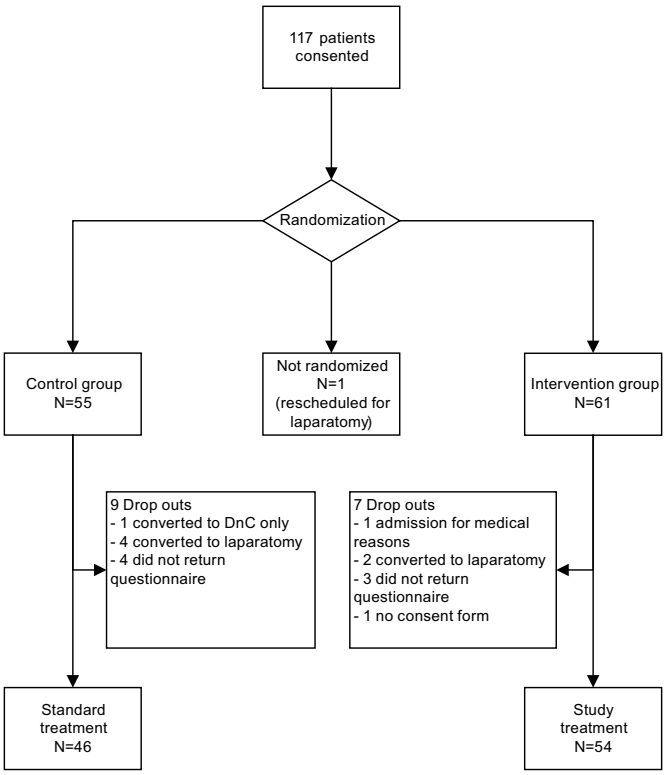

Figure 1. Flowchart of randomization and group allocation

according to clinical needs. Patient`s vital signs were monitored according to clinical standard.

Laparoscopy was performed using CO_2 gas. The distension medium was initially introduced through a Veress needle placed infraumbilically. Either a 5 or 10mm trocar was placed once abdominal pressure was greater than 10mmHg, and a 0 degree laparoscope was inserted through the cannula. A second trocar incision was made, usually 5mm, and the trocar was inserted under direct visualization in either the supra-symphyseal midline or left/right iliac fossa. For more complex surgeries, a third trocar was inserted.

After all the trocars had been placed, the flow rate and intra-abdominal pressure were adjusted to sustain a maximum pressure of 15 mm Hg. The pressure was monitored throughout the procedure and maintained at this level. The flow of CO_2 did not exceed 2L/min when creating the capnoperitoneum and throughout the procedure. After the surgical procedure, hemostasis was performed and all secondary trocars were removed under direct visualization.

At the end of surgery, in the control group CO_2 was removed by passive desufflation through the port site. Gentle abdominal pressure was applied to evacuate as much gas as possible. In the intervention group, the patients were placed in the Trendelenburg position (30 degrees) and a pulmonary recruitment maneuver consisting of five manual pulmonary inflations was performed with a maximum pressure of 60 cm of H_2O. The anesthesiologist held the 5^{th} positive pressure inflation for approximately 5 seconds. During these maneuvers, the surgeon was instructed to ensure that the trocar sleeve valve was fully open to allow the CO_2 gas to escape. The patients were then placed back in the level position, the trocar was removed and the abdominal incisions were closed.

In the recovery room, postoperative pain control was provided with meperidine as needed. Nonsteroidal anti-inflammatory agents were not used. Patients were discharged from the ambulatory center according to standard clinical practice.

Patients were asked to fill out questionnaires up to 48 hours after surgery to determine the frequency and severity of their shoulder pain. The Patients were instructed to only report pain scores regarding their shoulder pain, as opposed to pain e.g. from incision. The scores were assessed prior to discharge from the ambulatory center and then 12, 24, 36, and 48 hours after discharge using a visual analogue scale (VAS) from 0 (no pain) to 100 (worst possible pain). Additionally, the patients were asked about any occurrence of nausea and vomiting and about whether pain was positional.

- **Statistical Methods**

For each normally distributed variable, the mean and SEM were determined for both groups. Normality was assessed by means of the Kolmogorov-Smirnov test. Differences between the groups were analyzed by using an unpaired two-tailed t-test for continuous variables and the chi-square-test for binomial outcomes (StataCorp LP, 10 Edition for Windows, College Station, TX). The pain scores over time and their interaction with the intervention were analysed by means of the ANOVA for repeated measures (SPSS 15.0.0, SPSS Inc., Chicago, IL). Effects were considered statistically significant for $p < 0.05$. Since we expected drop outs due to conversion to laparatomy for surgical reasons, a per-protocol analysis was selected. Expecting that the incidence of shoulder pain may be reduced from 80% to 50% by this maneuver, we determined a required sample size of 45 patients per group for a two-tailed chi-square test with 80% power and a p level of 0.05. Thus a total of 100 analyzable patients were obtained for this study.

Results

From 02-18-2003 to 02-03-2005 a total of 117 patients consented to participate in the study. Of those excluded from the final analysis, 7 were converted to laparotomy, 1 was rescheduled to only receive a dilation and curettage and 1 patient was admitted for medical reasons. In 1 the informed consent could not be located, and 7 did not return the questionnaire (Figure 1). This resulted in 100 randomized patients with analyzable data, 54 in the intervention group, 46 in the control group. The two groups were similar with respect to age, weight, body mass index, length and type of surgery, CO_2 pressure settings, and total volume of CO_2 used during surgery (Table 1).

Overall, 73% of patients reported shoulder pain over the 48-hour assessment period. In the control group, 83% reported pain compared to 63% in the intervention group ($p<0.05$). 63% of the patients in the control group stated that their pain was positional; in the intervention group this number was only 31%. ($p<0.05$).

Table 1. Patient Characteristics (Mean ± SEM)

	Control n=46	Intervention n=54	p
Age [yrs]	35±1.17	33.8±0.9	0.43
Weight [kg]	71.4±2.4	68.2±2.3	0.34
Height [cm]	163.6±1.1	162.9±1.0	0.62
Body Mass Index [cm/m^2]	26.6±0.8	25.6±0.8	0.37
Length of surgery* [min]	44.5±2.9	41.8±2.9	0.51
CO_2 pressure setting [cmH_2O]	14.8±0.1	14.9±0.1	0.39
Total volume CO_2 used [L]	27.5±6.6	19.6±2.5	0.23
Total amount of Meperidine in PACU [mg]	36.3±4.8	40.9±3.7	0.44
Type of Surgery • Diagnostic Laparascopy • Tuboligation • Ovarian Cystectomy • Salpingo-Oophrectomy • Fulguration Endometrium • Oophrectomy • Umbilical Hernia Repair	 21 13 4 4 2 2 0	 22 26 3 1 1 0 1	0.17

* time from incision until end of skin closure

The postoperative pain scores were significantly higher in the control group compared to the intervention group at 12 (30.3±4.5 vs. 15.6±3.0), 24 (25.7±4.7 vs. 10.8±2.4), and 36 (21.7±4.3 vs 9.1±2.5) hours after discharge ($p < 0.05$). However, there were no statistically significant differences in VAS pain scores prior to discharge between the two groups. In both groups, shoulder pain peaked at 12 hours, and at 48 hours an improvement in pain was reported.

ANOVA for repeated measures confirmed a within-subject effect of time ($p<0.01$) and the in-between subject effect of the intervention ($p<0.01$). It also revealed an interaction for time*intervention ($p=0.02$; Figure 2).

The incidence of post-operative nausea and vomiting (PDNV) after surgery was also significantly lower in the intervention group, 20.4% vs. 56.5% ($p<0.001$).

There were no cardiovascular or pulmonary complications as a result of the maneuver. Aside from postoperative pain, rare surgical complications occurred including a punctured bladder due to laparotomy and a nicked bowel requiring general surgery. However, these events occurred before the intervention and were not related to the study. Because of conversion to laparatomy prior to the intervention, these patients were excluded from the analysis.

Discussion

The incidence of postoperative shoulder pain in the control group of our study was comparable to the numbers found in the literature [4-6]. Compared to control, use of the intervention reduced the frequency and severity of shoulder pain. Thus, this simple clinical maneuver was effective in preventing and reducing shoulder pain after gynecologic laparoscopic surgery.

The exact mechanism of shoulder pain after laparoscopic surgery still remains unclear. Most authors believe it is an irritation of the phrenic nerve causing referred pain of C_4 projected to the shoulder [9,11,12]. The irritation might be caused by local acidosis, distension of the diaphragm, or irritation secondary to CO_2 remaining in the abdomen.

The hypothesis that the remaining CO_2 is a major contributor to shoulder pain is supported by investigations such as a study by Jackson et al. [9] who found a correlation between the size of the remaining gas bubble and the intensity of pain. Also, in studies that have used NO_2 instead of CO_2, patients reported less pain when no CO_2 was used [13].

Therefore, various techniques have been investigated to reduce shoulder pain by addressing the phenomenon of remaining CO_2 irritating the phrenic nerve [14-22]. Most have shown some effectiveness; however, many of these techniques are impractical or not effective enough to merit routine clinical use. For example, a phrenic nerve block after the onset of anesthesia significantly reduced shoulder tip pain [23]. A bupivacaine infusion under the right hemidiaphragm decreased the incidence of shoulder pain from 42% to 7% [24]. And intraperitoneal subdiaphragmatic normal saline infusions significantly

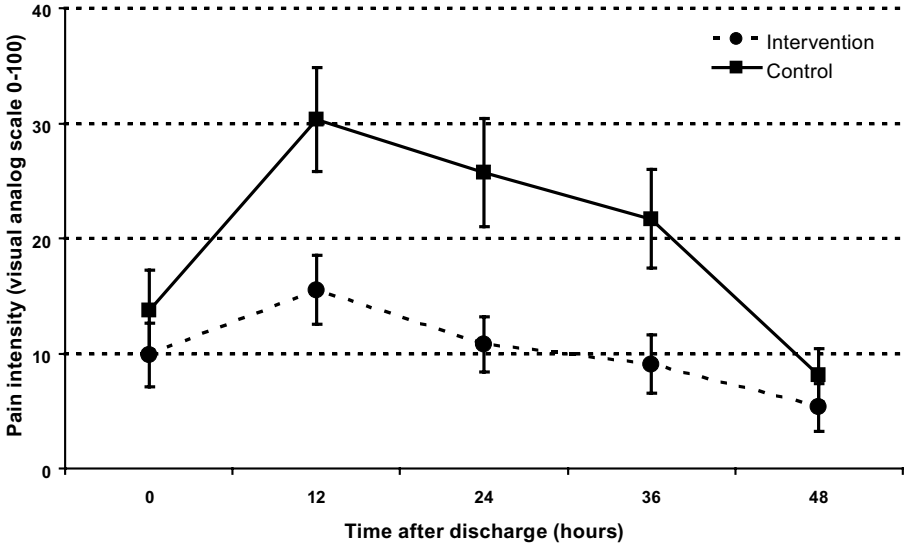

Figure 2. VAS scores over time

reduced shoulder pain after laparoscopic cholecystectomy, likely by reducing CO_2 between the liver and diaphragm, limiting irritation and stretch [22]. Normal saline infusion plus bupivacaine irrigation of the diaphragm had a better result than normal saline alone [21].

However, the most important technique to reduce shoulder pain is to allow escape of the CO_2 gas from the abdominal cavity at the end of surgery [12], either by gas drain or forced aspiration [4,14,16]. Kafali and colleagues [17] showed that forced aspiration of residual CO_2 gas by an aspiration cannula after minor gynecologic laparoscopic surgery significantly reduced the intensity of shoulder pain and analgesic requirements up to 24 hours after surgery. A separate study in which residual gas was removed by active aspiration by suction and manual compression of the abdomen (rather than gas drains) reported less morphine use 1 hour postoperatively, though VAS scores were similar over the 4-hour study period. Pain scores after discharge were not assessed [16].

Most of these studies relied on additional drugs or devices, which have not only additional costs but also risks of side-effects or need for follow up, such as removal of a CO_2 drain. The maneuver we propose does not need any additional resources and requires minimal time. Positive pressure ventilations performed at the end of surgery inflate the lungs and lower the diaphragm, which is known to increase intraperitoneal pressure. Increasing intraperitoneal pressure causes the elimination of CO_2 gas from the peritoneal cavity at the end of laparoscopic surgery, resulting in less intra-abdominal acidosis and its consequent phrenic nerve or peritoneal irritation.

In our study, 63% of patients described the shoulder pain as positional. This supports our hypothesis that at least part of the pain appears to be related to retained CO_2 in the peritoneal cavity. When patients are standing, the CO_2 bubble may work its way under the diaphragm, irritating the phrenic nerve and resulting in referred pain to the shoulder. When patients are in a supine position, the CO_2 bubble moves away from the diaphragm and the pain eases. Pain relief by lying down has also been reported by other investigators [7].

Interestingly enough, our study also found that the percentage of patients experiencing PDNV within 24 hours after surgery was significantly less in the intervention group (20% vs. 57%). A lower incidence of PDNV has been reported after laparoscopic cholecystectomy when abdominal wall lifting devices were utilized instead of CO_2 [25]. In contrast, Nursal and colleagues [18] found that the presence of a gas drain to remove residual CO_2 did not significantly change the incidence and severity of PDNV up to 72 hours after laparoscopic cholecystectomy. In the present study, the relative increased incidence of PDNV in the control group may be related to the fact that those patients

experienced more shoulder pain and subsequently received more postoperative opioids; however, we did not assess medications used after discharge.

There are some limitations to our study. First, we did not record the amount of pain medication taken by the patients after discharge because it would have increased the burden for the patient's self-report. It is conceivable that there was in fact a difference between the two groups in regard to the amount of pain medication taken. However, since patients who have more pain would more likely also take more analgesics, the result would more probably diminish than emphasize the difference in pain levels. Hence, the probability that our findings are false positive due to difference in pain medication use is rather unlikely.

Second, shoulder pain has been reported to last up to 7 days or even 5 weeks in a small number of patients [7]. Since our follow-up period lasted 48 hours after discharge, we cannot draw conclusions about the lasting effects of the maneuver we investigated.

The problem of shoulder pain has also frequently been reported in other types of laparoscopic surgery, e.g. after cholecystectomies [5,6] and gastric banding [7]. Our study only included gynecologic patients. However, based on the assumption that the underlying cause for shoulder pain is the residual CO_2, the maneuver we investigated would be expected to be similarly effective in other clinical settings.

Lastly, one may question whether our recruitment maneuvers with high, but relatively short, airway pressures carry a risk for a pneumothorax. However, the literature suggests that an alveolar recruitment maneuver of 40 cmH_2O is a safe and efficient way of improving arterial oxygenation during anesthesia [26-28]. Also, physiologic processes such as coughing and sneezing can raise intrapulmonary pressures up to 80-130 cmH_2O [29,30]. Additionally, we did not observe any cardiovascular or pulmonary adverse effects.

An airway pressure of 60cmH_2O was well tolerated in the healthy ASA I-II patients in our study, but it remains unclear whether similar efficacy can be achieved with lower pressures. A dose-response study to determine the minimally effective pressure appears warranted.

In conclusion, this study describes a simple clinical maneuver that significantly reduces shoulder pain and PDNV after gynecologic laparoscopic surgery. It is easy enough to be implemented in daily clinical practice and might have additional benefits as well, such as reducing atelectasis induced by the laparoscopic technique.

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