



A Novel Strategy of Laparoscopic Insufflation Rate Improving Shoulder Pain: Prospective Randomized Study

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Received: 6 March 2018 / Accepted: 20 July 2018 / Published online: 8 October 2018
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Abstract

Background Laparoscopic surgery is the main trend method in a variety of surgical fields. Post-operative shoulder pain remains a bothersome issue although many surgical techniques have been applied to minimize it. A simple novel approach to reduce shoulder pain without adverse effects during and after laparoscopic surgery is desired.

Methods This prospective randomized controlled study was conducted to enroll a total of 140 patients to evaluate the efficacy of low flow rate (1 L/min) for induction followed by high flow rate (10 L/min) for maintaining 12 mmHg pneumoperitoneum (group A, $n = 70$) during laparoscopic cholecystectomy (LC), compared to the continuous high flow rate group (group B, $n = 70$) in postoperative shoulder pain and other clinical features. The 10-visual analog scale (VAS) was applied for the severity of shoulder pain and scores were obtained at 1, 6, 12, 24, and 48 h after LC.

Results There was no obvious difference in baseline characteristics as well as operative time, occurrence of bradycardia, or hospital stay between groups. The incidence of shoulder pain was not significantly different (group A 45.7% vs group B 48.6%, $p = 0.866$). However, the patients in group A with shoulder pain reported significantly less pain scores ($p < 0.001$) at 12 and 24 h after surgery, compared with those in group B.

Conclusions Applying the strategy of low flow rate to induce pneumoperitoneum followed by high flow rate to maintain the pressure provides advantages to reduce the severity of shoulder pain for patients who underwent LC and then experienced shoulder pain.

Keywords Insufflation rate · Laparoscopy · Shoulder pain

Introduction

Laparoscopic surgery has played an important role in advancement of modern surgery since it was applied in the diagnostic procedure and then in surgical territory.¹ Along with development in the surgical instruments, image system, and training course of surgeons, laparoscopic surgery has become

the gold standard approach in a variety of organs, particularly in digestive and gynecological system.²

The advantages of laparoscopic surgery are well known as the excellent operative visibility, minimizing surgical wound pain, rapid recovery, and shorter hospital stay.³ However, shoulder pain is a distinctive characteristic of laparoscopic surgery whereas it is absent following conventional laparotomy. It has been considered as the major postoperative discomfort, which affects the quality of the patient's life.⁴ In clinical practice, low-pressure pneumoperitoneum is widely accepted to reduce the incidence and severity of shoulder pain following laparoscopic surgery whereas other intraoperative methods, including drainage and abdominal wall lifting are not recommended.⁵ However, low-pressure pneumoperitoneum increased the difficulty of procedure due the limited surgical space. A simple feasible method to reduce shoulder pain without adverse effects during and after laparoscopic surgery is desirable. A strategy of low flow rate for induction followed

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by high flow rate for maintaining the pneumoperitoneum (12 mmHg) was adopted and investigated on the incidence and intensity of shoulder pain, compared to the conventional procedure (continuous high flow rate).

Methods

Study Period, Recruitment of Patients

Approval for this study was obtained from institutional review board of Tri-Service General Hospital as No.100-05-096, and informed consent was obtained from each patient. We enrolled patients registered at the Tri-Service General Hospital from July 2011 to June 2012. Patients who were all Chinese and diagnosed as having gallstones with biliary colic or chronic cholecystitis and subsequently underwent the elective laparoscopic cholecystectomy were considered eligible for this study. Exclusion criteria include patients classified as American Society of Anesthesiologists (ASA) physical status IV or above, obstructive jaundice, body mass index > 40 or < 16, bleeding tendency, pregnancy, malignancy, and previous upper gastrointestinal tract surgery. Patients who had drains or experienced the conversion to open cholecystectomy or the surgical complications such as bile leakage, bleeding were also excluded. This study was performed according to a randomized, controlled design involving 140 patients. All patients (64 men and 76 women) between 19 and 84 years of age (mean age, 56.9 years) were blinded and randomly divided into low flow rate (1 L/min) for induction followed by high flow rate (10 L/min) for maintaining 12 mmHg pneumoperitoneum (group A, $n = 70$) and the continuous high flow rate group (group B, $n = 70$) by computer-based sequential allocation.

Surgical Procedures

All operations were conducted by three appropriately qualified and experienced surgeons (performed > 500 LC). Patients were prepared in the supine position and underwent the same procedure of general anesthesia and endotracheal intubation.

Laparoscopic cholecystectomy was performed as steps described in the literature, using the three-port technique.⁶ Carbon dioxide (CO₂) insufflation was initiated with a 10-mm port placed above the umbilicus (open method for placement of the trocar). The pressure of pneumoperitoneum was set at 12 mmHg. Patients in group A and B received different insufflation rate as described above. Reversed Trendelenburg position was used after the induction of pneumoperitoneum. Another 10-mm port was inserted below the xiphoid process, and a 5-mm port was installed in the right subcostal area near the midclavicular line. The rigid 10-mm 0° laparoscope and straight instruments were used. The Calot's triangle was

exposed to get the critical view, and then the cystic duct and the artery were identified and ligated with titanium clips.⁷ The gallbladder was dissected from the hepatic bed, using an electrocoagulation hook. At the end of surgery, the trocars were opened to eliminate CO₂ and the abdomen was compressed by the surgeons' hands to evacuate the residual gas. No local anesthetic was used in all patients. Following surgery, patients received oral acetaminophen (500-mg tablet) three times per day for wound pain during the first 2 days and were advised with early oral intake and off-bed activity.

Data Collection and Assessment of Shoulder Pain

The perioperative variables, including insufflation time to gain the pressure of 12 mmHg pneumoperitoneum, bradycardia during insufflation, and operative time as well as hospital stay for all patients were recorded in detail. After surgery, patients were observed and interviewed for the 2-day duration of shoulder pain evaluation by nurses who were blinded to the patient's group. The 10-visual analog scale (VAS) was applied for the severity of shoulder pain (0 = none, 10 = severe), and scores were obtained at 1, 6, 12, 24, and 48 h after laparoscopic cholecystectomy. Observers were blinded to patient groupings while measuring the shoulder pain scores.

Statistical Analysis

Statistical analyses of the data were performed using SPSS 20.0 (IBM Corp., Armonk, NY, USA). Student's *t* test and the chi-square test were performed to compare continuous variables and categorical variables between the two groups. Visual analog scale (VAS) for shoulder pain was compared between groups by the Mann–Whitney U test. Data are presented as mean ± standard deviation. A *p* value < 0.05 was considered statistically significant.

Results

Demographic, Perioperative Data, and Hospital Stay

A total of 140 patients participated in this study, and no one was excluded due to violation of the protocol design. All patients completed the follow-up period of the study and data were collected for all participants. Baseline characteristics of patients including age, gender, body mass index, and ASA classification were compared between groups, which revealed no significant differences (Table 1). Perioperative data are listed in Table 2. The insufflation time to reach the setting of 12 mmHg pneumoperitoneum in group A and group B were 194.2 ± 42.3 and 28.8 ± 3.5 s, respectively ($p < 0.0001$). Notably, bradycardia during the induction of pneumoperitoneum happened in one patient from group A and four patients

Table 1 Clinical features in low flow rate following high flow rate (group A) and continuous high flow rate (group B)

	Group A (n = 70)	Group B (n = 70)	p value
Age (years)	59.6 ± 11.6	56.3 ± 14.2	0.164
Gender, M/F	33/37	31/39	0.865
Body mass index	24.9 ± 4.03	24.8 ± 4.64	0.894
ASA classification			0.776
Class I	9	12	
Class II	46	44	
Class III	15	14	

Data are presented as mean ± standard deviation

from group B although there was no significant difference ($p = 0.174$). There was no significant difference in the operative time (53.2 ± 16.5 vs 51.5 ± 18.7 min, $p = 0.725$). There was no significant difference in hospital stay between groups A and B (52.8 ± 21.6 vs 57.6 ± 16.8 h, $p = 0.201$). No other insufflation-related adverse event was observed in either group during the study.

Analysis of Shoulder Pain

Thirty-two of 70 patients (45.7%) in group A were reported to have postoperative shoulder pain, present at any time during the hospitalization while 34 of 70 patients (48.6%) in group B experienced shoulder pain. The incidence of shoulder pain following laparoscopic cholecystectomy was not significantly different between groups A and B. Shoulder pain was generally recorded to occur at 1–6 h and reached the peak at 12 h after surgery in both groups (Fig. 1). Also, shoulder pain was improved obviously 48 h after surgery. As to the severity of shoulder pain, the record showed VAS scores in group A ($n = 32$) at 1, 6, 12, 24, and 48 h after LC were 0.97 ± 1.32 , 3.24 ± 2.01 , 3.72 ± 1.60 , 1.28 ± 1.2 , and 0.66 ± 0.81 , respectively, while VAS scores in group B ($n = 34$) at 1, 6, 12, 24, and 48 h after LC were 0.93 ± 1.22 , 3.50 ± 2.19 , 5.82 ± 1.39 , 2.61 ± 1.62 , and 0.93 ± 0.81 , respectively (Table 3). Significant less shoulder pain scores at 12 and 24 h following LC were observed for patients in group A relative to patients in group B ($p < 0.001$). Furthermore, 12.5% of group A with shoulder pain (4 of 32 patients) presented with VAS scores of

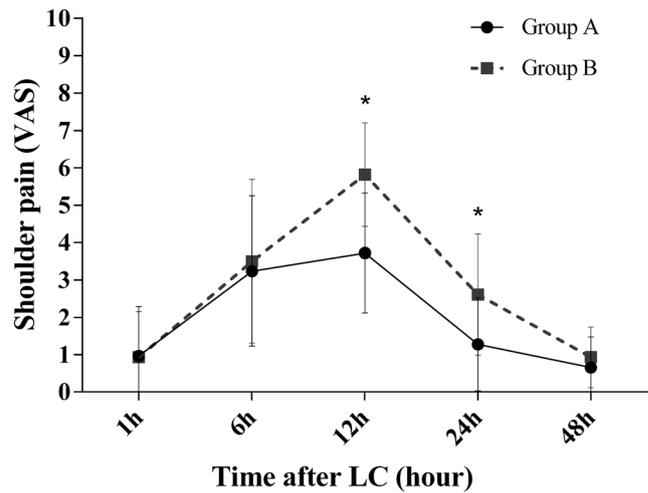


Fig. 1 Postoperative shoulder pain scores recorded on visual analogue score (VAS: 0 = none, 10 = severe) for patients with shoulder pain in group A ($n = 32$) and group B ($n = 34$) at 1, 6, 12, 24, and 48 h after laparoscopic cholecystectomy. Values are presented as mean (SD); * $p < 0.001$

≥ 5 at 12 h after surgery whereas 79.4% of group B with shoulder pain (27 of 34 patients) experienced the same level of shoulder pain. These patients who experienced VAS scores of ≥ 5 for shoulder pain required additional analgesics (intramuscular meperidine) to relieve moderate to severe shoulder pain.

Discussion

In the era of minimal invasive surgery, laparoscopic surgery has become the first choice for patients who are judiciously evaluated as candidates.⁸ However, this does not guarantee a pleasant postoperative period. Shoulder pain emerges to become a main source of unpleasant, disturbing experience in the field of laparoscopic surgery.⁴

To improve the overall satisfaction of laparoscopic surgery, solving or reducing shoulder pain is the important subject. In the literature, three pathogeneses of shoulder pain after laparoscopic surgery are generally accepted. First, the stretch of diaphragmatic muscle fibers causes the injury of supplying blood vessels and phrenic nerve traction followed by release of inflammatory cytokines, which results in shoulder pain.⁹

Table 2 Operative variables and hospital stay in low flow rate following high flow rate (group A) and continuous high flow rate (group B)

	Group A (n = 70)	Group B (n = 70)	p value
Insufflation time (seconds) to gain the pressure of 12 mmHg	194.2 ± 42.3	28.8 ± 3.5	< 0.0001
Bradycardia during insufflation	1	4	0.174
Operative time (min)	53.2 ± 16.5	51.5 ± 18.7	0.725
Hospital stay (h)	52.8 ± 21.6	57.6 ± 16.8	0.201

Data are presented as mean ± standard deviation

Table 3 The severity of shoulder pain evaluated by visual analogue scale (0–10) in low flow rate following high flow rate (group A) and continuous high flow rate (group B) during 1–48 h after laparoscopic cholecystectomy

Postoperative time (h)	Patients in group A with shoulder pain (n = 32)	Patients in group B with shoulder pain (n = 34)	p value
1 h	0.97 ± 1.32	0.93 ± 1.22	0.913
6 h	3.24 ± 2.01	3.50 ± 2.19	0.644
12 h*	3.72 ± 1.60	5.82 ± 1.39	< 0.001
24 h*	1.28 ± 1.25	2.61 ± 1.62	< 0.001
48 h	0.66 ± 0.81	0.93 ± 0.81	0.210

Data are presented as mean ± standard deviation

* $p < 0.05$

Second, residual CO₂ forms gas pocket between the diaphragm and viscera, leading to the loss of negative pressure and following suction support of viscera, inducing shoulder pain.¹⁰ The last, the production of carbonic acid transformed from CO₂ in the moist peritoneal cavity, irritates the diaphragm and then causes shoulder pain.¹¹

Based on the above-mentioned theories, surgeons and researchers made efforts to find effective maneuvers on reducing shoulder pain. Among these techniques, the use of drain and abdominal lifting instead of pneumoperitoneum are controversial on reducing the incidence and severity of shoulder pain.^{12–15} The application of low-pressure insufflation focuses on minimizing the stretch of diaphragmatic muscle fibers and has been shown to reduce shoulder pain effectively in a number of studies.^{16–18} However, low-pressure (≤ 10 mmHg) pneumoperitoneum limits the space and would increase the difficulty and danger of laparoscopic surgery. Suprahepatic suction drain, active gas aspiration, or instillation of saline is aimed at elimination of residual CO₂ and has been reported to significantly reduce shoulder pain in each individual study.^{19,20} Nonetheless, the use of drain increases abdominal pain sensation and prolongs hospital stay.²¹ One small study showed nitrous oxide (N₂O) was substituted for CO₂ as insufflation gas and reduces the severity of shoulder pain.²² CO₂ is still used as an ideal, standard gas for creation of pneumoperitoneum in consideration of its safety and cost.

In this study, the pressure was set at 12 mmHg, not low-pressure (≤ 10 mmHg) or common 15 mmHg due to the consideration of surgical working space and high pressure induced more shoulder pain.⁵ After the induction of pneumoperitoneum to the pressure of 12 mmHg, the high flow rate was used to keep the steady, balanced pneumoperitoneum for optimal operative field in the case of gas leakage.²³ We demonstrated the impact of insufflation rate on shoulder pain. Our data showed significantly lower shoulder pain VAS scores in patients receiving low flow rate for induction of pneumoperitoneum than patients with continuous high flow rate. The process of stretch of diaphragmatic muscle fibers during the induction of pneumoperitoneum with the setting pressure by low flow (1 L/min) or high flow insufflation rate (10 L/min) was considered as a key factor that resulted in significantly

different levels of shoulder pain. High flow rate for induction of pneumoperitoneum induced more tissue trauma of diaphragm than low flow rate, contributing to the higher degree of shoulder pain. However, the incidence of shoulder pain in both groups was not significantly different. The same setting pressure of peritoneum and high flow rate for maintaining abdominal volume in both groups may be associated with similar incidence of shoulder pain in both groups. The result from one previous study in 1998 was similar to our study in a certain extent and showed low flow rate of 2.5 L/min throughout the whole procedure of laparoscopic cholecystectomy significantly reduced shoulder pain, compared with high flow rate of 7.5 L/min.²⁴ Our data also showed that fewer bradycardia events occurred in group A (1 of 70 patients) than group B (4 of 70 patients) during the induction of pneumoperitoneum although there was no significant difference. It implied that low-flow insufflation rate causes less influence of cardiopulmonary system. In addition, no significant difference was observed in operative time between both groups even longer time for induction of peritoneum in group A than group B. The abdominal space maintained by high-flow insufflation rate at 12 mmHg in both groups provided similar surgical field for surgeons, resulting in the comparable operative time in groups.

The limitations of this study include the fact that it was conducted at a single center and was a single-blinded study resulting in biases in terms of operation-related characteristics between the two groups. In addition, routine administration of oral acetaminophen for postoperative wound pain may interfere with the assessment of postoperative shoulder pain.

Conclusions

In the study, the patients who received the insufflation strategy of low flow rate followed by high flow rate during laparoscopic cholecystectomy experienced significantly less level of shoulder pain to those receiving continuous high flow rate insufflation although the incidence of shoulder pain is similar in both groups. We have applied this simple novel strategy of insufflation for many years in all patients who underwent the

variety of laparoscopic surgery. The clinical practice experience is compatible with this prospective randomized controlled study. Therefore, we suggest that our insufflation strategy can be routinely used in laparoscopic surgery to provide an advantage to reduce postoperative shoulder pain while maintaining the optimal operative field for surgeons.

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2. Material support: Teng-Wei Chen, Chung-Bao Hsieh, and De-Chuan Chan

3. Study concept and design and analysis and interpretation of data, drafting of the manuscript, statistical analysis, and writing: Kuo-Feng Hsu, Si-Yuan Wu, Bao-Chung Chen, and Chih-Wei Yang

Compliance with Ethical Standards

All patients (64 men and 76 women) between 19 and 84 years of age (mean age, 56.9 years) were blinded and randomly divided into low flow rate (1 L/min) for induction followed by high flow rate (10 L/min) for maintaining 12 mmHg pneumoperitoneum (group A, $n = 70$) and the continuous high flow rate group (group B, $n = 70$) by computer-based sequential allocation.

Conflict of interest The authors declare that they have no conflict of interest.

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