ORIGINAL ARTICLE

Randomized Trial of Low-pressure Carbon Dioxide-elicited Pneumoperitoneum Versus Abdominal Wall Lifting for Laparoscopic Cholecystectomy

Yih-Huei Uen[1,2,3], Yi Chen[1], Chen-Yi Kuo[1], Kuo-Chang Wen[4], Lok-Beng Koay[5]*

[1]*Division of General Surgery, Department of Surgery, and* [5]*Department of Internal Medicine, Chi Mei Foundation Medical Center, Tainan,* [2]*Taipei Medical University,* [3]*Southern Taiwan University of Technology, Tainan, and* [4]*Department of Obstetrics and Gynecology, Taipei Veterans General Hospital, Taipei, Taiwan, R.O.C.*

Background: Two alternative surgical techniques for elective laparoscopic cholecystectomy (LC), low-pressure insufflation of the peritoneal cavity and abdominal wall lifting (AWL), have been developed over time to minimize the disadvantages associated with CO_2-elicited pneumoperitoneum. To the best of our knowledge, the 2 methods have seldom been compared as regards their relative advantages and disadvantages.

Methods: Eighty patients scheduled for elective LC were randomized into either a low-pressure (8 mmHg) CO_2 insufflation method (LPLC) group, or a gasless technique using a subcutaneous abdominal wall lifting device (GLC group). The duration of the surgical procedure, the surgical results including level of postoperative pain, and perioperative cardiopulmonary function changes experienced by the members of both groups were compared.

Results: Laparoscopic surgery was completed for all but 1 patient from each group due to an inadequate surgical-site exposure. There was no mortality for study participants, and no major complications were noted for members of either group. The LPLC group evidenced a shorter surgical duration as compared to the GLC group (77 ± 28 minutes *vs.* 98 ± 27 minutes, respectively; $p < 0.01$) and a lower incidence of postoperative shoulder pain (2/38 *vs.* 8/39, respectively; $p < 0.05$), although significant differences in intraoperative pulmonary function were noted (an increased $PaCO_2$, $PetCO_2$ and peak-airway pressure and decreased arterial blood pH; $p < 0.01$) for the LPLC group compared to the GLC group.

Conclusion: Both alternative methods for this type of surgery appeared feasible and safe for LC. Low-pressure CO_2 pneumoperitoneum had a shorter surgical duration and less postoperative shoulder pain compared to the GLC technique, but did not feature any other advantage over the AWL technique with regard to impact on cardiopulmonary function.
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Key Words: abdominal wall lifting, laparoscopic cholecystectomy, low-pressure pneumoperitoneum

Introduction

To the best of our knowledge, laparoscopic cholecystectomy (LC) using a carbon dioxide (CO_2)-elicited pneumoperitoneum would appear to be the current gold standard for surgical management of cholelithiasis.[1–3] The deleterious effects on cardiopulmonary function of the establishment of a pneumoperitoneum as registered by a variety of cardiopulmonary variables have been well established in previous clinical studies.[4–9] Two alternative surgical techniques, low-pressure CO_2-maintained pneumoperitoneum and abdominal wall lifting, have been used to attempt to reduce the adverse cardiopulmonary effects associated with the application of conventional-pressure (14–15 mmHg) CO_2 pneumoperitoneum as a surgical technique; both alternative procedures feature some demonstrated advantages.[10–13] To the best of our knowledge, however, the relative

*Correspondence to: Dr Lok-Beng Koay, No. 41, Alley 2, Lane 84, Section 3, Linsen Road, North District, Tainan 704, Taiwan, R.O.C.
E-mail: d750101@mail.chimei.org.tw • Received: December 20, 2006 • Accepted: July 9, 2007

advantages and disadvantages of these 2 methods have rarely been compared.[14]

In an attempt to collect data useful for the clinical selection of an appropriate surgical technique for LC management, we designed this study to compare the surgical results including duration of surgery and level of associated postoperative pain, and the perioperative cardiopulmonary function changes arising in patients undergoing either of these 2 alternative methods of surgical access and surgical-site exposure.

Methods

Patients

Between November 2002 and October 2003 inclusively, the surgical and postoperative details pertaining to 80 consecutive patients, who were classified according to the American Society of Anesthesiologists (ASA) physical status as grade I and II standard, and who underwent elective LC for symptomatic gallstones were investigated. All these patients were free of any signs of acute cholecystitis or bile-duct stones, and none revealed any previous history of upper abdominal surgery or pregnancy. Subjects were randomly allocated to either the low-pressure LC (LPLC) group featuring a CO_2-insufflation pressure that was maintained at 8 mmHg, or to a gasless LC group that featured the use of an abdominal wall lifting device (GLC) during surgery. This study was approved by the local hospital ethics committee and informed consent was requested and obtained from all participating patients prior to their surgical procedure being undertaken. Patient group allocation took place on the day prior to the study commencing, using randomly distributed, numbered and sealed envelopes.

Technique

Anesthesia was induced using fentanyl (3 μg/kg) and thiopentone (5 mg/kg), and tracheal intubation was facilitated with succinyl choline (1.5 mg/kg). Anesthesia was maintained with atracurium (0.5 mg/kg), 50% nitrous oxide in O_2, and 2% sevofluorane. Monitoring of surgical progress included ECG, and noninvasive assessment of blood pressure, heart rate, pulse oximetry, peak-airway pressure, compliance of airway, and end-tidal CO_2 ($PetCO_2$). $PetCO_2$ was measured using a side-stream capnometer (Cardiaco II; Datex-Ohmeda Inc., Madison, WI, USA). Respiration was maintained using a mechanical ventilator (Cato; Dräger AG, Lübeck, Germany), commencing at a rate of 10 breaths/min and featuring a tidal volume of 10 mL/kg. Subsequent to the induction of anesthesia, and during the surgical procedure, minute ventilatory volume was actively adjusted to maintain the $PetCO_2$ and arterial CO_2 partial pressure ($PaCO_2$) at levels less than 40 and 45 mmHg, respectively.

LC was performed using the standard 4-trocar technique, and the trocar diameters selected for surgery (12-mm, 10-mm, and 2 5-mm devices) were the same for both groups. Intraoperative cholangiography (IOC) was also performed for all participating patients in order to assess its feasibility in these 2 kinds of surgical exposure. For LPLC-group patients, the first umbilical trocar used for the laparoscopic procedure was introduced using a "closed" technique, and the intra-abdominal pressure was subsequently maintained at a constant pressure of 8 mmHg using a high-flow (40 L/min) CO_2 insufflator (Stryker, Berkshire, England). For the GLC group, the umbilical trocar was inserted through a 12-mm laparotomy wound using an "open" technique, following which 2 curved wires were inserted subcutaneously into the right hypochondrium via a small skin incision, and retracted upwards using the purpose-designed lifting devices developed and reported by Hashimoto et al in 1993[12] (Figure 1). Patients were placed in a reverse Trendelenburg position (20° incline) and featured a left lateral tilt (5°). All procedures were performed by 1 surgeon, an individual who was quite familiar with the surgical techniques associated with both abdominal wall lifting and insufflation procedures.

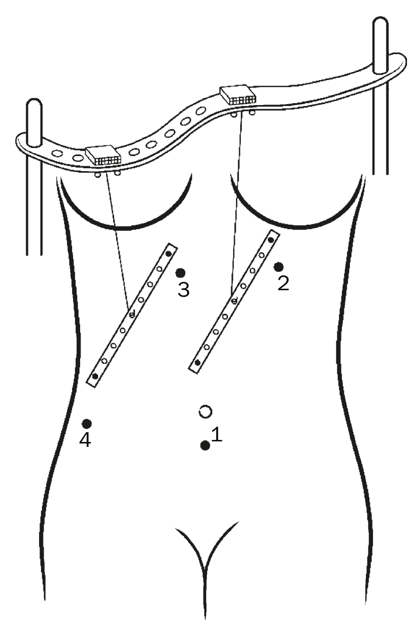

Figure 1. Hashimoto's method of subcutaneous abdominal wall lifting. Arabic numerals indicate the locations and sequence of trocar cannulation.

Continuing postoperative pain was treated on an on-demand basis, using an intramuscular injection of 50 mg of meperidine and/or the provision of oral analgesics.

Demographic and surgical data

The body weight and height of each patient was measured preoperatively in order to calculate their body mass index (BMI), which was defined as weight (kg)/[height (m)]^2. Preparation time was defined as the time from the commencement of the first skin incision to the beginning of gallbladder dissection, and the working time was defined as the time from completion of the preparation period to desufflation or the removal of the abdominal wall lifting device.

Cardiopulmonary responses

All cardiopulmonary parameters, including arterial blood-gas (ABG) values and minute ventilatory requirements, were determined and recorded prior to insufflation or abdominal wall lifting (both of which constituted the baseline data), and continued so at 30-minute intervals during the conduct of surgery, and also for up to 10 minutes subsequent to desufflation or the release of the lifting device. All such perioperative data were checked while patients underwent endotracheal anesthesia.

Pulmonary function testing

Pulmonary function studies were performed using a spirometer (Vitalograph Ltd., Maids Moreton, Buckingham, England). Forced vital capacity (FVC), forced expiratory volume in 1 second (FEV_1) and peak expiratory flow rate were measured within the 24-hour period immediately prior to surgery and the 48-hour period immediately following the completion of surgery. ABG levels were evaluated prior to the commencement of surgery at the bedside and also 12 hours subsequent to the completion of surgery.

Postoperative pain and analgesic requirements

Postoperative wound pain was assessed using a self-rating 10-cm visual analog scale with the patient at rest, assessment being conducted every 12 hours for the 48-hour period immediately following surgery. The presence and level of shoulder pain within the postoperative period was also assessed. Analgesic usage was recorded as the total number and dosage of intramuscular meperidine injections and/or oral analgesics required by patients following surgery. All data were collected by the same investigator. Both patients and staff were blinded to the specific surgical technique used for individual patients.

Statistical analysis

Data were expressed as mean ± standard deviation (SD) for each study group. Fisher's exact test, Mann–Whitney *U* test, and Wilcoxon signed rank test were used, where appropriate, to analyze the resultant data. Data were analyzed using SPSS version 10.0 (SPSS Inc., Chicago, IL, USA). A *p* value of less than 0.05 was considered to represent statistically significant difference between tested groups.

Results

One patient from the LPLC group was withdrawn from the study as the patient had to undergo an additional procedure for initially unsuspected choledocholithiasis, this condition being noted incidentally during IOC. A total of 79 patients were included in this comparative study. Patient characteristics are summarized in Table 1. There appeared to be no significant difference in patient characteristics between the 2 study groups. All of the items described below, apart from the duration of surgery, changes in intraoperative pulmonary function and the severity of postoperative shoulder pain, failed to exhibit any significant difference when comparison between the 2 test populations was made.

Conversion to conventional LC (Table 2)

For 1 relatively obese patient (BMI, 32 kg/m^2) from the LPLC group, the working pressure used to maintain

Table 1. Study-involved patient characteristics*

	LPLC† (*n* = 39)	GLC† (*n* = 40)
Gender (M/F)	15/24	13/27
Age (yr)	48.3 ± 12.9	51.9 ± 14.2
Body mass index (kg/m^2)	24.0 ± 3.0	25.5 ± 4.8
ASA grade (I/II)	22/17	20/20
Smokers	6	8
Preoperative PFT		
Forced vital capacity (L)	2.81 ± 0.76	2.64 ± 0.97
FEV_1 (L)	2.41 ± 0.63	2.61 ± 0.81
Peak expiratory flow rate (mL/sec)	6.50 ± 1.47	6.17 ± 2.04

Data are presented as mean ± standard deviation or n; †no significant difference was noted between the 2 groups. LPLC = low-pressure (8 mmHg) laparoscopic cholecystectomy; GLC = gasless laparoscopic cholecystectomy using an abdominal wall lifting device; ASA = American Society of Anesthesiologists; PFT = pulmonary function tests; FEV_1 = forced expiratory volume in 1 second.

pneumoperitoneum was increased from the intended 8 mmHg to 12 mmHg, and, for a somewhat muscular patient from the GLC group, the surgical technique of abdominal wall lifting was converted to a conventional CO_2-elicited pneumoperitoneum (14 mmHg) in order to obtain adequate surgical exposure for dissection of Calot's triangle.

Results of surgery (Table 2)

One patient from the GLC group required the creation of an additional port for the insertion of an intestinal retractor, although this appeared to elicit no significant difference as regards total number of trocar ports when compared with the LPLC group ($p > 0.05$). However, 9 of 38 patients (24%) from the GLC group required repeated tightening of winch retractors to further lift the anterior abdominal wall, in order to improve the exposure of the surgical field. IOC was successfully performed for all patients. Both mean surgery-preparation time and mean surgical working time, which included the time required for performing IOC, were significantly longer for the GLC group than for the LPLC group ($p < 0.01$).

Morbidity and mortality (Table 2)

Three patients from the LPLC group suffered from minor perioperative complications: minor bleeding in 2 patients and ecchymosis of the umbilical wound in the other. Three patients from the GLC group experienced minor perioperative complications: a controllable surgical vessel-bleeding in 1 patient, and abdominal wall bruising in the other 2. The morbidity rate and length of hospital stay were similar for both groups ($p > 0.05$), and there was no mortality in either group.

Cardiopulmonary function during surgery (Table 3)

During surgery, increase in both heart rate and blood pressure was noted for members of both patient groups, although between-group differences did not prove to be statistically significant.

The mean values of $PetCO_2$, $PaCO_2$ and peak-airway pressure during surgery did not change significantly from the baseline values ($p > 0.05$) for members from the GLC group. Conversely, for individuals from the LPLC group, a significant and sustained increase in the level of all 3 parameters was observed ($p < 0.001$ for all comparisons); also, a substantial decrease in pH ($p < 0.001$) was noted following CO_2 insufflation, a decrease that remained so until desufflation was completed. Significant intergroup difference was found for a number of parameters, with the LPLC group exhibiting greater mean values of $PetCO_2$, $PaCO_2$, and peak-airway pressure ($p < 0.001$ for all comparisons), while a lower pH was recorded for the LPLC group ($p < 0.01$). The mean minute volume revealed a significant decrease in value during surgery for members of the GLC group ($p < 0.05$) but not for individuals from the LPLC group.

Postoperative pain and analgesia consumption levels

No significant difference was noted with regard to the level of postoperative wound pain or analgesia consumption between the 2 groups ($p > 0.05$). Shoulder pain developed in 2 patients following low-pressure CO_2 insufflation and in 8 patients following abdominal wall lifting ($p = 0.045$).

Table 2. Surgical results and complications*

	LPLC ($n = 39$)	GLC ($n = 40$)	p
Conversion to conventional technique	1	1	1.000†
Additional port required during surgery	0	1	1.000†
Failed cholangiography	0	0	1.000†
Preparation time (min)	7.5 ± 5.0	10.6 ± 3.5	0.008‡
Working time (min)	61.2 ± 20.0	84.5 ± 28.3	0.008‡
Total surgical duration (min)	77.4 ± 27.7	98.3 ± 27.2	0.008‡
Complications			
Intraoperative bleeding	2	1	0.615†
Wound ecchymosis	1	2	1.000†
Hospital stay (d)	3.1 ± 1.4	3.3 ± 1.3	0.512‡

**Data are presented as mean ± standard deviation or n; †Fisher's exact test; ‡Mann–Whitney U test.*

Table 3. Perioperative changes in ventilatory parameters and arterial blood-gas values during laparoscopic cholecystectomy*

	LPLC ($n = 38$)	GLC ($n = 39$)	$p^{\dagger}$
Minute ventilatory volume (mL/kg/min)			
Pre	98.75 ± 9.10	98.86 ± 8.44	0.501
Post 30 min	100.36 ± 10.45	96.10 ± 7.02	0.127
Post 60 min	101.34 ± 11.56	94.05 ± 7.78‡	0.008
Peak airway pressure (cmH_2O)			
Pre	18.10 ± 5.01	18.07 ± 4.40	0.726
Post 30 min	23.42 ± 5.32§	17.85 ± 4.56	< 0.001
Post 60 min	22.63 ± 5.66§	17.48 ± 4.37	0.002
Arterial pH			
Pre	7.43 ± 0.04	7.43 ± 0.06	0.711
Post 30 min	7.36 ± 0.05§	7.41 ± 0.07‡	0.007
Post 60 min	7.36 ± 0.06§	7.42 ± 0.07‡	0.006
$PaCO_2$ (mmHg)			
Pre	38.87 ± 6.09	36.74 ± 4.34	0.518
Post 30 min	42.71 ± 6.79§	36.93 ± 6.52	0.002
Post 60 min	43.54 ± 5.63§	37.52 ± 6.77	0.002
$PetCO_2$ (mmHg)			
Pre	31.20 ± 3.85	31.81 ± 4.11	0.827
Post 30 min	36.19 ± 5.09§	31.93 ± 4.93	0.003
Post 60 min	35.92 ± 3.50§	32.09 ± 4.88	0.007

*Data are presented as mean ± standard deviation; †comparison between the 2 study groups using Mann–Whitney U test; ‡$p < 0.05$ vs. baseline (Wilcoxon test); §$p < 0.001$ vs. baseline (Wilcoxon test). Pre = prior to the commencement of surgery; Post = subsequent to the commencement of surgery.

Cardiopulmonary function following surgery

Patients' heart rate and blood pressure values at 12, 24, 36 and 48 hours post-surgery and their arterial blood-gas data at 12 hours post-surgery demonstrated no significant differences between the groups ($p > 0.05$). The decreases in FVC, FEV_1 and peak expiratory flow rate at 48 hours following surgery all revealed no significant intergroup difference ($p > 0.05$).

Discussion

Since the introduction of laparoscopic surgery by Mouret in 1987, efforts have been made to obviate, or to at least minimize, the adverse cardiopulmonary consequences of the establishment of a CO_2-maintained pneumoperitoneum for surgical purposes.[10–13] While attempts have continually been made to reduce the pressure of insufflation as much as is practicable for such a surgical maneuver, there still exists a need to maintain sufficiently good exposure of the surgical site during surgery without compromising the efficacy, feasibility and safety of the surgical procedure. Such considerations would appear to have led to the introduction of 2 derivative methods of surgical-site exposure as alternatives to the standard procedure for creating a pneumoperitoneum.[14] Firstly, a mechanical abdominal wall lifting device can be used to enable the surgical procedure to be carried out without the need for insufflation of the abdominal cavity, or, alternatively, a reduced-from-normal insufflation pressure may be used in order to conduct the surgical procedure.[11–13] Secondly, the pressure of the pneumoperitoneum can be further reduced if a sensitive high-flow automatic insufflator is available and is used during surgery, since the pressure detector of the insufflator will trigger promptly in the event of an inappropriately low intra-abdominal pressure arising, such as often occurs when a suction irrigation device is used within the peritoneal cavity.[10]

By comparison to a conventional CO_2-elicited pneumoperitoneum procedure for LC, gasless laparoscopy employing the use of abdominal wall lifting devices has been demonstrated to be feasible for LC, and its application has been shown to reduce the adverse cardiopulmonary effects arising from abdominal insufflation.[15,16] Similarly, the application of a low-pressure CO_2-elicited pneumoperitoneum has been shown to not only significantly reduce the adverse cardiovascular effects associated with the use of a greater insufflation pressure, but also lessen the level of postoperative pain that occurs and accelerate patient recovery.[9,17,18] Although the impact of the application of both of these 2 alternative methods has been compared to the corresponding outcome for more conventional pneumoperitoneum-elicited LC, to the best of our knowledge, it appears that the relative impacts of each of these 2 alternative techniques have seldom been compared.[14]

The major finding of this study is that LPLC appears to feature a shorter surgical duration, including both preparation and working time, when compared to analogous gasless surgery. The difference in preparation time is due to LPLC not having lengthy procedures in setup of hanging system and subcutaneous wiring. The difference in working time is due to our observation that LPLC features a lower likelihood of suboptimal exposure of the surgical field than is the case for GLC. For example, such a featured enhanced surgical-field exposure contrasts with the approximately 25% of GLC procedures in this study that warranted an additional surgical procedure in order to improve the visualization of the surgical site. This enhanced feature of LPLC appeared to ensure that the surgical procedure continued more smoothly than would have been the case with GLC, and that the surgical duration was shorter for this alternative than for GLC.

It is noteworthy to mention here that although the pressure of CO_2-maintained pneumoperitoneum during the LPLC procedure could be reduced from a conventional higher value to a value as low as 8 mmHg, significant differences in respiratory function test results during surgery between the 2 study groups still existed. Irrespective of active adjustment of the minute ventilatory volume to maintain the values of $PetCO_2$ and $PaCO_2$ within an appropriate level, low-pressure pneumoperitoneum was still associated with an increased $PetCO_2$ and $PaCO_2$, and a decreased pH in this study. There is a possibility here that due to the fact that all study subjects had a rather favorable ASA physical status, the postoperative sequelae of intraoperative impairment of cardiopulmonary function for individuals from the LPLC group was minimized and did not appear to cause any significant postoperative cardiopulmonary complication and/or undue prolongation of these patients' hospital stay. Our findings, however, support the recommendation for surgeons to adequately monitor the cardiopulmonary consequences associated with CO_2-elicited pneumoperitoneum, especially for high-risk patients who feature compromised cardiopulmonary function, irrespective of whether or not low insufflation pressures are used for laparoscopic surgery.

In our study, there were no apparent differences in mean postoperative wound pain score and analgesia consumption by patients between the 2 study groups; however, patients did appear to experience shoulder pain more frequently following GLC (28%) than following LPLC (7%). The etiology and mechanism of post-laparoscopic shoulder pain, to the best of our knowledge, is currently still not clearly understood. The presumption that this type of shoulder pain in some patients from the GLC group, for whom the surgeon had eliminated the use of a pneumoperitoneum, is probably the result of diaphragmatic stretching resulting from extreme upward retraction of the abdominal wall during the surgical procedure cannot be fully supported in the present study.

In consideration of the relative benefits and shortcomings of the 2 alternative surgical techniques compared in this study, the following guidelines for choosing a laparoscopic approach for cholecystectomy are suggested. The first is, for patients featuring severely compromised cardiorespiratory function, a gasless procedure associated with abdominal wall lifting should be initially considered as the procedure of choice in order to completely avoid any potential adverse cardiopulmonary effects of a CO_2-maintained pneumoperitoneum. The second is, for patients who have a rather high BMI, low-pressure procedures should be selected to minimally compromise the exposure of the surgical field and to decrease surgical duration as much as is practicable. Clearly, there exists a need for a larger, more comprehensive study regarding/concerning the benefits and shortfalls of the various methods for laparoscopic surgery available to the surgeon at the time of surgery.

In conclusion, both LPLC and GLC are feasible alternatives for undertaking conventional LC. By comparison with the GLC technique, the LPLC technique is less time-consuming, but would appear to be associated with more unwanted intraoperative pulmonary function changes.

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