ORIGINAL ARTICLE

Randomized Controlled Trial of Conventional Carbon Dioxide Pneumoperitoneum versus Gasless Technique for Laparoscopic Cholecystectomy

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Abstract

Concerns about pathophysiologic changes and disadvantages associated with carbon dioxide pneumoperitoneum during laparoscopic cholecystectomy have led to the introduction of gasless laparoscopy employing abdominal wall lifting (AWL) method. However, AWL has been criticized for its complexity and technical difficulty. We have used AWL method for gasless laparoscopic cholecystectomy and compared it with laparoscopic cholecystectomy with respect to operation performance, postoperative course, and pathophysiologic changes. During a four-month period, 40 consecutive patients with symptomatic gallstones were randomly assigned to receive laparoscopic cholecystectomy with conventional CO2 pneumoperitoneum (PP group; N=20) or the AWL method (AWL group; N=20). Operative results and operative time were recorded. Cardiopulmonary and ventilatory functions were assessed during the surgery. Postoperative pain and presence of nausea and vomiting were assessed for 48 hours after surgery. Postoperative time to recovery of flatus, tolerance to a full oral diet, and full activity were also determined. The intraoperative cardiopulmonary and ventilatory functions deteriorated significantly less in the AWL group. The preparation time for surgery and total operative time were significantly greater in the AWL group. None of the patients in either group required conversion to open surgery. Technique related morbidity was minimal and there was no mortality in either group. Although AWL method required a longer operation time, our results suggest that the technique is valuable in high-risk patients with cardiorespiratory disease. AWL technique of laparoscopic cholecystectomy is a feasible, safe and effective alternative to CO_2 pneumoperitoneum. It probably costs less and is therefore, more useful in developing countries.

Key words

Cholecystectomy, Laparoscopic, Abdominal wall lift, Pneumoperitoneum.

Introduction

Laparoscopic cholecystectomy is currently a standard procedure for symptomatic gallstones and has revolutionized surgery. Laparoscopic cholecystectomy restores pulmonary function better and enables less painful recovery, shorter hospitalization and faster return to normal activities than open cholecystectomy (1). The most common approach to laparoscopic cholecystectomy today is to use carbon dioxide (CO_2) insufflation, so-called pneumoperitoneum, to obtain surgical view. However, CO_2 insufflation can cause various complications resulting from increased intra-abdominal pressure (IAP) and peritoneal absorption of CO_2; resulting in cardiopulmonary compromise, venous stasis, gas embolism, and thromboembolic problems (2-5). In attempts to develop alternative methods to obtain a surgical view without the hemodynamic disadvantages of pneumoperitoneum, devices have been introduced to lift the abdominal wall mechanically by means of a U-shaped retractor (6), or by using subcutaneous wires placed in the right upper quadrant (7). One of the most widely employed systems

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has been the Laparolift (TM 8), in which an intraperitoneal fan-shaped retractor is used to lift the abdominal wall. Nevertheless, concerns about AWL remain, namely, the difficulty in obtaining sufficient working space, the complexity of lifting instruments, and increased inflammatory and stress responses (9). The present study was designed to compare the effects of CO_2 insufflation and AWL on surgical performance, postoperative course, and metabolic response in patients undergoing laparoscopic cholecystectomy.

Material and Method

Between January 2004 and April 2004, forty consecutive patients in American Society of Anesthesiology (ASA) grade I scheduled for laparoscopic cholecystectomy for symptomatic gallstones were included in the study after obtaining their informed consent. Approval was obtained form the Hospital Ethics Committee. Patients with liver dysfunction, acute inflammation, cardiopulmonary or metabolic disease, or previous upper abdominal surgery were excluded from the study. The subjects were randomly allocated to either CO_2 pneumoperitoneum (PP) or the abdominal wall lifting method (AWL) group for their laparoscopic cholecystectomy. Selection took place on the day before the surgery using numbered and sealed envelopes. The two groups were demographically comparable (Table 1).

Anaesthesia : All patients were anaesthetized according to the same protocol, which entailed fasting for 8 hours, followed by anesthesia with fentanyl (1 mg/kg), thiopentone (4-6 mg/kg) and succinylcholine (2mg/kg) administration for induction and atracurium (0.5 mg/kg), 66% nitrous oxide in oxygen and 1% isoflurane for maintenance. Breathing was maintained using a mechanical ventilator (Ohmeda 7800) starting at a rate of 12 breaths per minute with a tidal volume of 10 ml/kg. The aim was to keep the arterial CO_2 partial pressure less than 45 mmHg. During anaesthesia, ECG, blood pressure, heart rate, pulse oximetery, peak airway pressure and end-tidal CO_2 (Et CO_2) were monitored continuously. Et CO_2 was monitored by a sidestream capnometer (ULT-S-23-01, Datex Instrumentation Corp. Helsinki, Finland). Fluid replacement during and for 24 hours after surgery was similar in two groups.

Surgery : All procedures were performed by a single surgeon (MPA) who was quite familiar with the techniques of both AWL and pneumoperitoneum.

The CO2 pneumoperitoneum group (PP) : The pneumoperitoneum was established by the closed technique using a veress' cannula and CO_2 insufflated to a pressure of 12-14 mmHg. A 10 mm trocar was introduced infraumbilically through which the laparoscope was introduced. Another 10 mm trocar was introduced in the epigastrium and two 5 mm trocars were introduced laterally in the right subcostal space. Cholecystectomy was carried out using the standard techniques and the specimen was extracted through the epigastric port.

The abdominal wall lift group (AWL) : A 15 mm infraumbilical midline laparotomy wound was made and a LaparofanTM OMS-LF15 (Origin Medsystems Inc, CA, USA) was introduced using an open technique. This was connected to a Laparolift^{TM} (Origin Medsystems Inc, CA, USA), which lifted the abdominal wall. A 10 mm trocar sheath with the laparoscope was introduced through the same infraumbilical incision. Another 10 mm trocar was introduced in the epigastrium and two 5 mm trocars were introduced laterally in the right subcostal space. Dissection, cholangiography and extraction of the gall bladder were performed as in the pneumoperitoneum group.

On demand, postoperative discomfort or continuing pain was treated with an intramuscular injection of 75 mg of diclofenac. Patients were discharged from the hospital according to the usual routine of the department: when they had passed flatus and were physically and psychologically healthy.

Recording of Parameters

Operative Data : Preparation time was defined as the time taken from skin incision to the beginning of gall bladder dissection and operating time was defined as the time following preparation until skin closure.

Haemodynamic and ventilatory responses : All haemodynamic and ventilatory parameters, including arterial blood gas values were recorded after induction of anaesthesia (before pneumoperitoneum or AWL), at 30-minute intervals during surgery, and at 10 minutes after desufflation or release of the lifting device.

Subjective responses : Pain was assessed using a self-rating 10 cm visual analog scale at rest every 12 hours for 48 hours after surgery. Analgesic usage was recorded as the total number on intramuscular diclofenac injections required after surgery. The nursing staff assessed nausea and vomiting. The hospital stay following surgery was determined for each group. Finally, patients were asked to record how many days it took to return to normal activity, and this information was collected at each patient's postoperative follow up attendance by the same investigator (NT). Both patients and staff were blind to the operative technique used.

Statistical analysis : Data are expressed as the mean ± standard deviation (SD) for each study group. Student's unpaired t-test was used to analyze the data. P values <0.05 were considered to be statistically significant

Results

A total of 40 patients were included in the comparative study (Table 1). There were no significant differences between the two study groups in demographics or relevant medical history.

Operative results : Both preparation and total operating times were significantly longer in patients undergoing AWL than in those undergoing CO_2 insufflation. The results are summarized in (Table 2). None of the patients required conversion to open surgery.

Morbidity and mortality : None of the patients in either of the two study groups had a major complication like injury to the bowel or the bile ducts. Six patients in the pneumoperitoneum group had minor perioperative complications: slight operative bleeding in two and persistent shoulder pain in four. This compared with eight patients in the AWL group who had minor perioperative complications: slight operative bleeding in three, umbilical trocar wound infection in two and persistent shoulder pain in three. No significant intergroup differences in morbidity were seen (Table 3). Neither the pneumoperitoneum group nor the AWL group suffered any deaths.

Subjective response : There was no statistically significant difference between the two groups during the first 24 hours in terms of pain scores or analgesic consumption. But after 24 hours of surgery the pain and analgesic consumption was higher in patients of pneumoperitoneum group and the difference between the two groups was statistically significant (Table 4).

Table 1. Demographic data

	Pneumoperitoneum (N = 20)	Abdominal wall lift (N = 20)
Sex (M:F)	18/2	17/3
Age (years)a	34.5 ± 8.8	35.4 ± 7.6
BMI (kg/m2) a	25.3 ± 2.4	24.3 ± 2.2
Smokers (n)	5	4
ASA grade (I/II)	18/2	19/1

*Mean ± SD

None of the differences between the groups is statistically significant.

Table 2. Operative Results

	PP	AWL	P value*
Preparation time (mins)	4.55 ± 0.51	5.4 ± 0.68	<0.05
Total operative time (mins)	31.55 ± 4.25	41.8 ± 7.89	<0.05
Blood transfusion (n)	0	0	-

* Student's t-test.

Table 3 Complications

	PP	AWL	P value*
Major complications			-
Bile duct injury	0	0	
Bowel injury	0	0	
Minor complications			-
Intraoperative bleeding	2	3	
Wound infection	0	2	
Subcutaneous emphysema	0	0	
Shoulder pain	4	3	
Total	6	8	0.43

* χ^2 test.

Table 4. Postoperative pain scores and diclofenac requirements (mean ± SD)

	PP	AWL	P value*
Pain scores (analogue scale) 12 hours	6.33 ± 0.602	5.97 ± 0.605	0.060
24 hours	5.57 ± 0.52	5.29 ± 0.42	0.098
36 hours	4.4 ± 0.57	3.70 ± 0.493	0.0002
48 hours	3.79 ± 0.52	3.18 ± 0.35	0.0002
Doses of diclofenac (n)	8.26 ± 0.81	7.35 ± 0.67	0.0002

* Student's t-test.

Patients in the pneumoperitoneum group had significantly more nausea after surgery. But there was no significant intergroup difference in postoperative chest distress and vomiting. The intervals between extubation and the passage of flatus and tolerance to full oral intake were similar for two groups. The hospital stay after surgery and the interval between surgery and a return to full activity were also similar (Table 5).

Table 5. Postoperative assessment

	PP	AWL	P value*
Chest discomfort (n)	4	3	0.65
Persistence of nausea (hrs)	5.3	3.7	0.021
Time to passage of flatus (hrs)	10.1	10.05	0.94
Persistence of vomiting (hrs)	1.6	0.84	0.02
Time to full diet (days)	4.4	4.8	0.74
Postoperative hospital stay (hrs)	47.4	48.9	0.52
Return to normal activity (days)	5.35	5.1	0.33

* Student's t-test.

Intraoperative haemodynamic and ventilatory functions : The change in haemodynamic and ventilatory parameters and arterial blood gas values during surgery are shown in (Table 6). The $EtCO_2$ and $PaCO_2$ values did not change from the baseline in the AWL group during the study. In contrast, in the pneumoperitoneum group, there was a significant and sustained increase in both levels after CO_2 insufflation. The intraoperative mean arterial pressure (MAP) was significantly higher in the patients of pneumoperitoneum group. But there was no statistically significant difference in heart rate, systolic blood pressure, arterial oxygen saturation (SpO2) and arterial partial pressure of oxygen (PaO_2). After establishment of pneumoperitoneum significant increases were seen in peak airway pressure (PAP) and minute ventilation (MV).

Table 6.

Ventilatory parameters in anaesthetized patients during laparoscopic cholecystectomy with CO2 pneumoperitoneum (PP) or Abdominal wall lifting technique (AWL).

	Preoperative*		Intraoperative**		Postoperative***	
	PP	AWL	PP	AWL	PP	AWL
HR (per min)	84 ±9	87 ±10	88 ±10	86 ± 9	86 ± 9	86 ± 10
MAP (mmHg)	67 ± 6	68 ± 9	97 ± 13§	82 ± 10	72 ± 8	71 ± 6
SpO2 (%)	100 ± 1	99 ± 1	100 ±1	99 ± 1	99 ± 1	99 ± 1
EtCO2 (mmHg)	31.6±2.1	31.7±3.1	37.6±1.3a	31.8±2.6	34.3±1.2a	32.6±2.3
PAP (mmHg)	15.9±1.1	31.7±3.2	37.6±1.3a	31.8±2.6	34.3±1.1a	32.6±2.4
MV (L/min)	5.73±0.36	5.56±0.42	6.56±0.47a	5.61±0.39	5.91±0.29a	5.66±0.34
PaO2 (mmHg)	158.1±27.8	153.2±26.9	152.4±27.9	154.7±23.9	158.8±25	155.3±26.5
PaCO2 (mmHg)	35.1±1.2	35.6±3.2	40.7±2.5a	35.6±2.7	37.6±1.3a	35.8±2.2

*Parameter measured after induction of anaesthesia, prior to pneumoperitoneum or AWL. **Measured 30 minutes after pneumoperitoneum or application of AWL device. ***Measured 10 minutes after desufflation or release of AWL device. (a) significantly different from the AWL group ($P<0.05$) using Student's t-test. HR, heart rate; MAP, mean arterial pressure; SpO2, oxygen saturation; EtCO2, End tidal carbon dioxide concentration; PAP, peak airway pressure; MV, minute ventilation; PaO2, PaCO2, arterial partial pressure of oxygen and carbon dioxide, respectively.

Discussion

Elevation of the intra-abdominal pressure (IAP) is the primary cause of the complications that occur during laparoscopic surgical procedures. The pressure elevation is well tolerated by young and otherwise healthy patients. However, patients with underlying cardiovascular or pulmonary diseases are susceptible to adverse effects caused by this elevation. This can lead to serious hemodynamic changes (10-11). Significant changes in mean arterial pressure, heart rate, systemic vascular resistance, cardiac index, and ejection fraction caused by an elevated IAP have been reported in previous studies (12-14). These changes are brought about by the compression of inferior vena cava and elevation of the diaphragm by a raised IAP (15). In the present study, the mean arterial pressure increased significantly after CO_2

insufflation in comparison to the AWL group. An increase in the IAP also causes an elevation in the intrapleural pressure by elevating the diaphragm and abdominal part of the chest wall, restricting lung expansion. In fact, an IAP of 14 mmHg leads to an elevation of 6 mmHg in the intrapleural pressure (15). Increased minute volume is necessary for adequate ventilation. Lung restriction and increased minute volume increase airway pressures and decrease pulmonary dynamic compliance. This may cause hemodynamic instability, especially in obese patients (16). In the present study, the peak airway pressure (PAP) and minute ventilation (MV) were also significantly higher after CO_2 insufflation compared to mechanical lifting of the abdominal wall.

Another factor affecting the hemodynamic parameters is hypercapnia due to CO_2 insufflation. Hypercapnia causes metabolic acidosis and results in increased intracerebral pressure during operation (13). CO_2 also causes direct and indirect hemodynamic effects. CO_2 directly dilates peripheral arterioles and depresses myocardial contractility. Indirectly, CO_2 activates the central nervous system and evokes symphathoadrenal activation, increasing myocardial contractility and causing tachycardia and hypertension (16). In the present study, the mean $EtCO_2$ and $PaCO_2$ values did not change significantly from the baseline in the AWL method. In contrast, in the CO_2 pneumoperitoneum group, a statistically significant and sustained increase of both $PaCO_2$ and $EtCO_2$ was observed. Less ventilatory effort is needed during and after laparoscopy when the AWL method is used.

Gasless laparoscopic cholecystectomy using the mechanical lifting of the abdominal wall is not widely accepted because of two issues of special concern. The first issue is the possibility of greater wound pain and surgical stress. But our analysis showed that patients undergoing gasless laparoscopic cholecystectomy had significantly less pain after 36 and 48 hours of surgery. They also required lower doses of analgesics. The second issue is the difficulty of obtaining sufficient working space in the peritoneal cavity and increase in the theater time with AWL. In the present study, all the procedures were completed successfully and none required conversion to open surgery. The complication rate between the two groups was not statistically significant. The increased operative time associated with AWL was due to the time spent in open cannulation of the initial umbilical trocar, the complexity of the lifting instrument preparation and closure of the somewhat complicated umbilical fascial wound.

The AWL method has several advantages: because there is no gas insufflation, the operator can apply unlimited suction and use conventional instruments to facilitate laparoscopic procedures. The threat of sudden loss of vision following a gas leak is also eliminated. Expenditure on CO_2 insufflators and CO_2 cylinders is also not required. Recurring expenses of specially designed laparoscopic ports is also reduced, since simple valve less 5.5 mm diameter steel tubes can be used for the lateral ports.

Postoperative nausea and vomiting occurred significantly more often in patients with carbon dioxide insufflation. Carbon dioxide is a potent vasodilator of cerebral vessels. Increased intracranial blood flow has been seen during laparoscopic procedures (13). Increased intracranial pressure is known to cause nausea and vomiting (17) which may be one reason for PONV in our and in earlier studies (11).

Four patients in the pneumoperitoneum group and three in the AWL group suffered from right shoulder pain, which is referred pain caused by distension of the right phrenic nerve. Pain in some patients may be severe enough to warrant opioids (18). In our study, however, the AWL method did not totally abolish right shoulder pain, probably because of diaphragmatic stretching produced by the laparofan.

To conclude, hemodynamic changes caused by CO_2 pneumoperitoneum can easily be tolerated by a young patient without concomitant heart or pulmonary disease. However, gasless laparoscopic cholecystectomy using the AWL technique is a safe and applicable form of minimally invasive surgery for higher-risk patients, as it does not cause harmful hemodynamic changes. Although the gasless technique took longer than laparoscopic cholecystectomy, this technique may still prove valuable for high-risk patients with cardiorespiratory disease. It also has the promise of causing lesser postoperative discomfort to the patient. Furthermore, the fact that it allows conventional operative instruments to be used under laparoscopic guidance is an additional advantage over the technique that requires CO_2 insufflation.

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