Randomized, Prospective Comparison of Post-Operative Pain In Low - Versus High -Pressure Pneumoperitoneum in Laparoscopic Cholecystectomy

Submitted: 27/6/2009 Accepted: 1/7/2010

Dr. Ali A. Al-Dabbagh * **Dr. Nabaz Hassan Ismaeel ****

ABSTRACT

Background and Objectives: CO_2 insuflation constitutes the commonest means of creating the pneumoperitoneum (PP), but it is attributed to many post-laparoscopic cholecystecomy adverse effects including pain triggering. The aim of this trial was to evaluate the efficacy of low-pressure CO_2 PP during laparoscopic cholecystectomy (LC) in reducing the incidence of postoperative pain.
Methods: A double-blind, randomized, clinical trial was conducted on 100 patients with symptomatic gall stones. Patients were randomized preoperatively into group A (n=50) who underwent LC with 8 mmHg CO_2 PP throughout the procedure and those in group B (n=50) had LC with 12 mmHg CO_2 PP. Abdominal and shoulder-tip pain were assessed with verbal rating scale (VRS) scoring at 4, 8, 12 and 24 hours postoperatively.
Results: The low-pressure PP did not increase the duration of surgery. There were neither significant peri-operative complications nor conversion to open procedure in either group. A statistical comparison of mean cumulative VRS scores for abdominal and shoulder-tip pain in both groups shows statistical significance at 4, 8, 12 and 24 hours after operation.
Conclusions: A CO_2 PP at 8 mmHg reduces both the frequency and intensity of abdominal and shoulder-tip pain following LC without increasing the rate of intra-operative complications.
Key words: Laparoscopic cholecystectomy, pneumoperitoneum, postoperative pain.

INTRODUCTION:

Within an exceptionally short time, Laparoscopic cholecystectomy (LC) has widely replaced open cholecystectomy (OC) as the standard treatment for symptomatic cholelithiasis for its known advantages [1-3]. Worldwide, LC is most often performed by creating pneumoperitoneum (PP) by pumping CO_2 to the abdominal cavity. The maintenance of elevated intra-abdominal pressure for the duration of the procedure is associated with numerous adverse effects some of these result from a positive intraperitoneal pressure itself, while others are associated with carbon dioxide absorption from the peritoneal cavity to blood [4]. Reduced postoperative pain after LC compared to OC seem to have not satisfied surgeons, therefore efforts have been made to reduce the adverse hemodynamic and pulmonary effects of PP without compromising the efficacy, feasibility and safety of the operation and trials for improvements in the treatment of postoperative pain for patient comfort are ongoing [5,6]. Early pain is the most common complaint after LC, and there is considerable inter-individual variability in its intensity [7]. Carbon dioxide gas is widely considered to be responsible for postoperative pain [8]; therefore the purpose of the present paper was to test the influence of low-pressure PP on the intensity of postoperative pain in patients undergoing LC.

* FICMS, General surgeon, Rizgary Teaching Hospital. College of Medicine/Hawler Medical University .
** DGS ,General surgeon, Mergasor Hospital. .

SUBJECTS AND METHODS:

The study enrolled 100 patients (aged between 23-76 years), mean age 49.5 years, with uncomplicated symptomatic cholecystitis admitted for elective LC in Rizgary Teaching Hospital and Hawler Private Hospital from 15th August 2007 to 5th August 2008. Patients with American Society of Anesthesiology (ASA) III and VI, acute cholecystitis, choledocholithiasis and need for common bile duct exploration, acute pancreatitis, previous major upper abdominal surgeries, , age below 18 years, pregnancy and lactation were excluded from the study. To eliminate the bias caused by preoperative expectation, patients were randomized to low or high-pressure PP groups in the operating room prior to surgery. The patients were divided into two groups of 50 patients each; using a prospective randomized, double blinded clinical trial; group A: underwent LC with 8 mmHg carbon dioxide PP throughout the procedure and group B: underwent LC with 12 mmHg carbon dioxide PP. All LC were performed according to the standard four –ports technique under general anesthesia following a strict protocol. PP was created by an open method through a small skin incision in the umbilical region (usually supra-umbilical). In the low pressure group, the pressure of the PP was set to 8 mmHg from the beginning of the procedure, while in the standard (high) pressure group; the pressure was set to be 12 mmHg. At the end of the operation carbon dioxide was evacuated through the ports by applying gentle pressure all over the abdomen, taking care to keep trocar valves open. None of the procedures were converted to open cholecystectomy, and no operative complications occurred.First post operative analgesic dose was given to all patients (tramadol 100 mg i.m) in the surgical word. Rescue analgesia (tramadol 100 mg i.m), and antiemetic (metoclopramide 10 mg i.m) was administered if the visual rating scale was high, or patient had complained of vomiting respectively. The patients were allowed to assume erect position, mobilized, and given oral diet within 12 hours after the surgery (as soon as possible). Neither the patients, nor the nurses knew the relevant group assignment; thus the patients were not aware which pressure the PP had been set at. Postoperatively, pain was assessed by Verbal Rating Scale (VRS) as follows: (0=absent,1=mild,2=moderate,3=sever, and 4=intractable pain) at 4, 8, 12 and 24 hours postoperatively. Before surgery, all patients were instructed to use a VRS, to register the following three pain components retrospectively as described below:

Intra-abdominal pain: was defined as pain inside the abdomen, which may be deep, dull, and more difficult to localize.

Incisional pain: was defined as a superficial pain, wound pain, or pain located in the abdominal wall.

Shoulder-Tip pain: was defined as a sensation of pain in the shoulder.

All patients were seen by 7 days after the operation, where they were questioned again about pain and any postoperative complications. All data were collected and analyzed by using SPSS (Statistical Package for Social Science) version (15.0). The mean postoperative VRS scores for the two groups were compared at different time's using student's t test. The VRS score was expressed as mean ± standard deviation. Significance was considered at the 0.05 level, with the 0.01 level considered as highly significant. The number of patients required for the study was calculated on the basis of an 80% power to detect a significant difference in a major endpoint such as decrease in postoperative VRS scores at the 5% significance level. The necessary sample size would be 90 patients (45 patients in each group). Thus, we enrolled 100 patients into the study.

RESULT:

Demographic data (sex ratio, age, weight, operative time, and ASA 1 and 2) were similar in both groups with no significant statistical difference (p value > 0.05) as shown in (Table 1).

The overall incidences of intra-abdominal, incisional and shoulder-tip pain in group A versus B in our study were 56% Vs 84%, 60% Vs 62% and 2% Vs 22% respectively (Table 2). There were no difference in overall incidence of incisional pain, which were 60% in group A vs. 62 % in group B, (p>0.05); however, incisional pain was mild and did not contribute substantially to the VRS and the commonest site of pain was at the epigastric port. None of our patients experienced shoulder tip pain before 24 hours postoperatively, and the overall incidence of right shoulder-tip pain in group A 1/50(2%) was significantly lower than that of group B 11/50(22%) p<0.01. The mean intensity of postoperative abdominal pain assessed by the VRS was significantly (p <0.01) lower in group A than group B scored at 4, 8, 12 and 24 hrs postoperatively. The most pronounced differences were seen between 8 and 12 hrs after the operation (Figure 1).The number of patients who required rescue analgesia for the first 24 postoperative hours was significantly lower (p<0.05) in group A 19 (38%) than group B 34(68%), also time delay to rescue analgesics was significantly longer (p<0.05) in group A (10.5± 3.5 hr) than group B (5.30± 3.1).

Table 1: Patient demographic

	Group A	Group B	P value
Number	50	50	NS
Male/Female	6/44	8/42	NS
Age (years)	46.3 ± 15.5	47.9 ± 15.2	NS
Weight (Kg)	66.6 ± 12	64.3 ± 15	NS
Operation time (min)	35 ± 10	34 ± 11	NS
ASA I male/female	7/35	9/34	NS
ASA II male/female	2/6	2/5	NS

Data are expressed as number of patients or mean ± SD, NS = Not significant SD= Standard deviation

Table 2: Percentage of patients expressing intra-abdominal, incisional and shoulder-tip pain.

Pain pattern	Group A	Group B	P value
Intra-abdominal pain	56%	84%	< 0.01
Incisional pain	60%	62%	NS
Shoulder tip pain	2%	22%	< 0.01

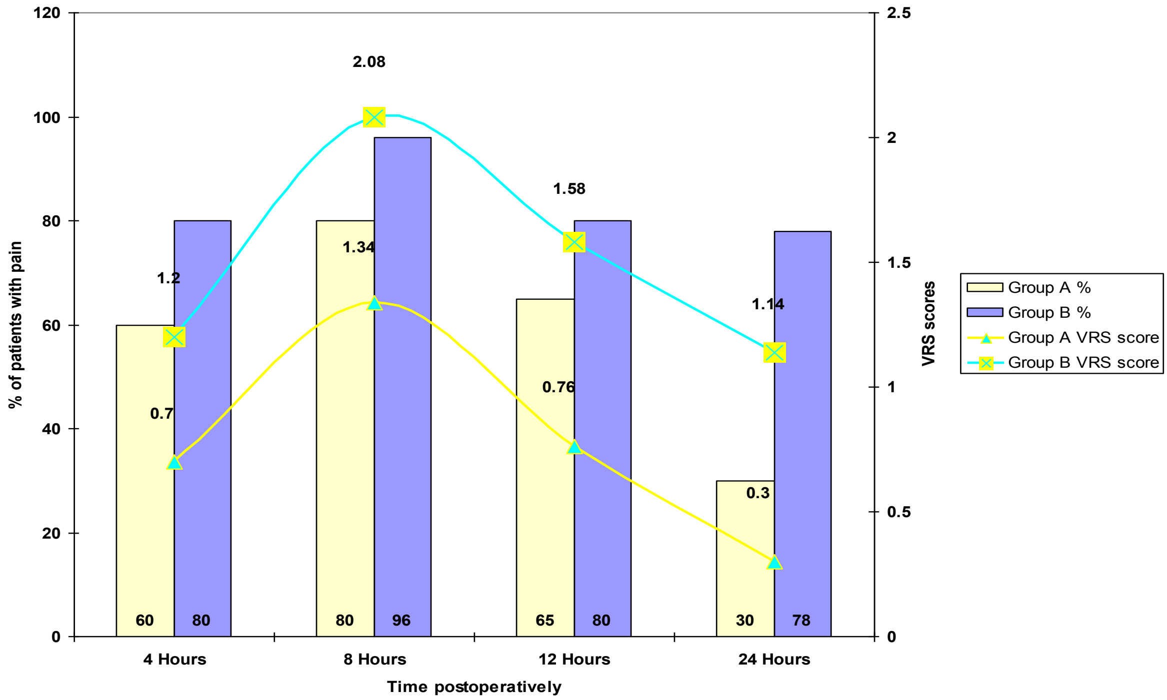

Figure 1: Postoperative pain percentage and VRS pain scores

DISCUSSION:

Although LC reduces pain, it does not completely obliterate it [9-11]. Despite its widespread use, CO2 PP has its problems and disadvantages [12]. It has been shown that an intra-abdominal pressure of 15 mmHg during LC may cause adverse physiological responses in cardiovascular[13], respiratory[14,15] and renal systems[16], in addition to serious and potentially lethal complications, including deep venous thrombosis, myocardial infarction, atelectasis and pneumonia[17,18]. Pressure values that are most often employed in association with PP range between 12 and 14 mmHg[19]. In order to minimize the adverse effects of PP, the clinical practice was extended to include low-pressure PP (7-8 mmHg)[20-22] .Abdominal pain following LC can occur for a number of causes[23]and the reason for the marked variation of pain between individuals remains unclear but could be due to multiple factors, including patient demographics, nature of underlying disease, anesthetic technique, surgical factors and postoperative care[24]. In this study, however, the only difference between the two groups was in the pressure of the PP induced into the peritoneal cavity. Thus the difference in post operative pain can be attributed to the difference in CO_2 pressure. Pain after LC involves three different components with different intensity, time course and pathophysiological mechanisms; intra-abdominal, incisional and shoulder pain[25]. In our study the incidence of intra-abdominal pain was 70% which was the main pain experienced by our patients, followed by incisional pain 61% and shoulder-tip pain 12%. Similar results were obtained in other studies[26,27]. The overall incidence of intra-abdominal pain described by our patients within 24 hours was 56% in group A was significantly less than in group B patients 84%.Similar results were obtained by other authors[17,19,28]. Only in one study the correlation between low pressure PP and post operative pain was not significant

[5], we believe that this insignificance is attributed to the small sample size (50 patients) and the relatively high CO2 pressure they used (10 mmHg). Pain scores assessed by VRS at 4, 8, 12 and 24 hours post operatively were 0.7, 1.34, 0.76 and 0.3 in group A versus 1.2, 2.08, 1.58 and 1.14 in group B (*p* value < 0.01). This significant difference in VRS pain scores are related to the low CO_2 pressure PP used in patients of group A. In our study, intra-abdominal pain scores at 4 hours for both groups A and B were (60% Vs 80%) respectively, and became higher at the 8 hour scores (80% Vs 96%) respectively. This pattern of pain may be attributed to the effects of the anesthetic drugs and the usage of intramuscular tramadol (100 mg) in the recovery period. The pain scores were gradually decreased in both groups at the 24 hours scores, reaching 30% Vs 78% respectively. Although pain was still present in both groups after 24 hours, but the severity was mostly mild. Incisional pain was mild and did not contribute substantially to the VRS score, this could be attributed to the small incisions and limited damage to the abdominal wall [7]. Its incidence in group A (60%) did not differ from that of group B (62%). The commonest site for the incisional was in the epigastric site, while in other studies pain was more in the umbilical port[7,26], this could be attributed to the retrieval of the gall bladder through the epigastric port. The proposed mechanism of shoulder-tip pain seems to be diaphragmatic stretching with phrenic nerve neuropraxia possibly due to the increased concavity of the diaphragm induced by the PP and reference of pain from the traumatized area[29,30]. The overall incidence of shoulder-tip pain in both groups was 12%. The incidence of shoulder-tip pain was significantly lower in group A than group B (2% Vs 22%) respectively (p <0.01), similar results were observed by Sarli et al [8]. Almost all patients in our study did not express shoulder-tip pain before the 24 hours readings. Other studies[31,32], found that shoulder-tip pain was present earlier than the 24 hours scores, but similar to our study, maximum intensity of pain was still recorded at the first 24 hours. The observation that group A patients needed less amount of rescue analgesia with a longer timed delay, observed also by Esmat et al[33], reinforces our results regarding the beneficial effects of low pressure PP. In conclusion, low pressure CO2 PP (8 mm Hg) is effective in reducing both the frequency and intensity of intra-abdominal as well as shoulder-tip pain with neither, increasing the duration of the operation, nor increasing the risk of per - and post operative complications. On the basis of these results, the widespread use of low pressure CO2 PP throughout LC is highly recommended when possible.

REFERENCES:

1. Deirdre M, Sallyann C, Jackie R, et al. Intraperitoneal Pethidine versus Intramuscular Pethidine for the Relief of Pain after Laparoscopic Cholecystectomy: World J. Surg 2002; 26, 1432– 36.
2. Pourseidi B, Khorram-Manesh A. Effect of intercostals neural blockade with Marcaine (bupivacaine) on postoperative pain after laparoscopic cholecystectomy, Surg Endosc 2007;21: 1557–59.
3. Ure B.M, Troid F, Spangenberger W. et al. Pain after laparoscopic cholecystectomy Intensity and localization of pain and analysis of predictors in preoperative symptoms and intraoperative events. Surg Endosc 1994; 8:90-96.
4. Jakimowicz J, Stultiens G, Smulders F. Laparoscopic insuflation of the abdomen reduces portal venous flow. Surg Endosc 1998; 12: 129–32.
5. Koc M, Ertan T, Tez M, et al. Randomized, prospective comparison of postoperative pain in low Vs high pressure pneumoperitoneum. ANZ J. Surg 2005 75: 693-6.
6. Davides D, Birbas K, Vezakis A, et alx. Routine low-pressure pneumoperitoneum during laparoscopic cholecystectomy. Surg Endosc 1999;13: 887–9.
7. Bisgaard T, Kehlet H, and Rosenberg J. Pain and Convalescence after Laparoscopic Cholecystectomy. Eur J Surg 2001; 167: 84–96.
8. Sarli L, Costi G, Sansebeastiano G. et al. Prospective randomized trial of low-pressure pneumoperitoneum for reduction of shoulder-tip pain following laparoscopy. Br J Surg 2000; 87, 1161-5.
9. Neudecker J, Sauerland S, Neugebauer E, et al. The European Association for Endoscopic Surgery clinical practice guideline on the pneumoperitoneum for laparoscopic surgery. Surg Endosc

2001; 16: 1121– 43.

10. Pappas-Gogos G, Konstandinos E. Tsimogiannis Æ et al. Preincisional and intraperitoneal ropivacaine plus normal saline infusion for postoperative pain relief after laparoscopic cholecystectomy: a randomized double-blind controlled trial Surg Endosc 2008; 22:2036– 45.
11. Bonnie PG, Marie JL, Meng KO, et al. Celecoxib premedication in post-operative analgesia for laparoscopic cholecystectomy. Acute pain 2004;6, 23-28.
12. Koivusalo A.-M., Pere P,Valjus M, Scheinin T. Laparoscopic cholecystectomy with carbon dioxide pneumoperitoneum is safe even for high-risk patients Surg Endosc 2007;19: 1988-91.
13. Larsen J, Ejstrud P, Svendsen F, et al .Systemic response in patients undergoing laparoscopic cholecystectomy using gasless or carbon dioxide pneumoperitoneum: A randomized study. J Gastrointestinal Surg 2004; 6: 584- 6.
14. Uzunkoy A, Ozgonul A, Ceylan E, and Gencer M. The effects of isothermic and hypothermic carbon dioxidepneumoperitoneum on respiratory function test results J Hepatobiliary Pancreat Surg 2006; 13:567–70.
15. Bashirov E, Cetiner S, Emre M, et al. A randomized controlled study evaluating the effects of the temperature of insufflated CO2 on core body temperature and blood gases (an experimental study) Surg Endosc 2007; 21: 1820–5.
16. Alijani A, Hanna B, and Cuschieri A. Abdominal Wall Lift Versus Positive-Pressure Capnoperitoneum for Laparoscopic Cholecystectomy Randomized Controlled Trial Annals of Surgery 2004; 239:234-7.
17. Davides D, Birbas K, Vezakis A, et al. Routine low-pressure pneumoperitoneum during laparoscopic cholecystectomy. Surg Endosc 1999;13: 887–9.
18. Rosch R, Junge K, Binnebösel M. Gas-related impact of pneumoperitoneum on systemic wound healing.Langenbecks Arch Surg 2008 393:75–80.
19. Karagulle E, Turk E, Dogan R, Ekici Z, Dogan R, and Moray G. The effects of different abdominal pressures on pulmonary function test results in lapaorsocopic cholecystectomy. Sur laprosc Endosc Percutn Tech 2008;18(4):229-33.
20. Wallace DH, Serpell MG, Baxter JN, et al. Randomized trial of different insufflation pressure for laparoscopic cholecystectomy. Br J Surg 1997 84: 455 –8.
21. Schaube H, ebhardt J.H, Loose D. Pathophysiologische aspekte des CO_2 pneumoperitoneums-die beeinflussung der herz-kreislaufparameter im zeitichen verlauf. Acta. Chir. Au 1995;6: 532- 4.
22. Zuckerman R, Gold M, Jenkins P, et al. The effects of pneumoperitoneum and patient position on hemodynamics during laparoscopic cholecystectomy Surg Endosc 2001;15: 561– 5.
23. Tsereteli Z, Terry ML, et al. Prospective randomized clinical trial compairing nitrous oxide and carbon dioxide pneumoperitoneum for laparoscopic surgery. J Am Coll Surg 2002; 195:173.
24. Gupta A. Local anesthesia for pain relief after laparoscopic cholecystectomy a systematic review. Best practice & research clinical Anaesthesiology2005;19:275–92.
25. Bisgaard T, Klarskov B, Kristiansen VB, et al. Multi-regional local anesthetic infiltration during laparoscopic cholecystectomy in patients receiving prophylactic multi-modal analgesia: a randomized, double-blinded, placebo-controlled study. Anesth Analg 1999; 89: 1017– 24.
26. Joris J, Thiry E, Paris P, et al. Pain after laparoscopic cholecystectomy: characteristics and effect of intraperitoneal bupivacaine. Anesth Analg 1995;81: 379–84.
27. Lepner U, Goroshina J & Samarutel J. Postoperative pain relief after laparoscopic cholecystectomy: a randomised prospective double-blind clinical trial. Scand J Surg 2003; 92: 121–4.
28. Barczyn´ski M, Herman R. M. Low pressure pneumoperitoneum combined with intraperitoneal saline washout for reduction of pain after laparoscopic cholecystectomy: Surg. Endosc 2004; 18: 1368- 73.
29. Louizos A. A, Hadzilia S. J., Leandros E, et al . Postoperative pain relief after laparoscopic cholecystectomy. A placebo-controlled double-blind randomized trial of preincisional infiltration and intraperitoneal instillation of levobupivacaine 0.25%, Surg Endosc 2005;19: 1503–6.
30. Nursal T, Yildirim S, Tarim A, et al. Effect of drainage on postoperative nausea, vomiting, and pain after laparoscopic cholecystectomy. Langenbecks Arch Surg 2003;388:95–100.
31. Vezakis A, Davides D, Gibson JS, et al. Randomized comparison between low pressure laparoscopic cholecystectomy and gasless laparoscopic cholecystectomy. Surg Endosc 1999;13: 890–3.
32. Gupta A, Thorn SE, Axelsson K, et al. Postoperative pain relief using intermittent injections of 0.5% ropivacaine through a catheter after laparoscopic cholecystectomy. Anesth Analg 2002;95: 450–6.
33. Esmat M, Magdy M.A. Magid M.A, et al. Combined low pressure pneumoperitoneum and intraperitoneal infusion of normal saline for reducing shoulder tip pain following laparoscopic cholecystectomy. World J Surg 2006;30: 1969–73.