Prospective randomized comparison of low pressure versus standard pressure pneumoperitoneum in laparoscopic cholecystectomy

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ABSTRACT

Background: Postoperative shoulder tip pain occurs frequently following laparoscopic cholecystectomy. The origin of shoulder pain is partly understood, but it is commonly assumed that the cause is overstretching of the diaphragmatic muscle fibers due to high rate of insufflations. The aim of this study is to compare the frequency and intensity of shoulder tip pain between low pressure (7 mmHg) and standard-pressure (14 mmHg) pneumoperitoneum after laparoscopic cholecystectomy.

Setting: Aljumhori Teaching Hospital during the period from January 2011 to June 2012.

Design: A prospective randomized study.

Patients and methods: One hundred and forty consecutive patients undergoing elective laparoscopic cholecystectomy were randomized prospectively into two groups, either low pressure (group A) or standard pressure (group B) pneumoperitoneum, they were blinded to the research doctors who assessed the patients during the postoperative period by the visual analogue scale (VAS) of pain. Comparative analysis between the two groups included gender, mean age, operative time, complication rate and postoperative shoulder tip pain.

Results: The demographic data were nearly similar in the two groups. There were no significant intraoperative complications in both groups, likewise the mean operative time was nearly similar in either group. The mean frequency and intensity of postoperative shoulder tip pain assessed by visual analogue scale was less in group A than in group B.

Conclusion: No difference was found between low pressure and standard pressure pneumoperitoneum in the duration of operation and complication, but low pressure pneumoperitoneum tended to produce lower incidence and intensity of shoulder tip pain.

Keywords: Gall stones, laparoscopy, low pressure, standard pressure.

مقارنة مستقبلية عشوائية بين الضغط الواطئ والضغط القياسي للصفاق فى عمليات إستئصال المرارة بالناظور

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الخلاصة

أهداف الدراسة: هو مقارنة شدة وتكرار الآم الكتف بين الضغط الواطئ (٧ ملم زئبق) والضغط المعياري (١٤ ملم زئبق) داخل الغشاء البروتيني بعد عمليات إستئصال المرارة بالمنظار.

المشاركون وطريقة إجراء البحث: دراسة مستقبلية عشوائية، أجريت في المستشفى الجمهوري على ١٤٠ مريضا ومريضة مصابين بحصى المرارة خلال الفترة من كانون الثاني ٢٠١١ الى حزيران ٢٠١٢، تم تقسيم المرضى إلى مجموعتين كل مجموعة تتكون من ٧٠ مريضا، المجموعة (آ) تم إجراء عملية إستئصال المرارة لهم بواسطة تنظير البطن تحت الضغط الواطئ (٧ ملم زئبق)، والمجموعة الثانية تم إستئصال المرارة بواسطة تنظير البطن تحت الضغط المعياري (١٤ ملم زئبق)، وتم قياس شدة الأم الكتف عن طريق أطباء لايعرفون عن أي مجموعة يعودون هؤلاء المرضى بواسطة المقياس البصري الم النتائج: لا يوجد أي زيادة في فترة إجراء العملية أو المضاعفات في المجموعة (أ) مقارنة بالمجموعة (ب) وهي متقاربة جدا بين المجموعتين. ولكن وجدنا أن معدل شدة الآم الكتف بعد العملية كان أقل في المجموعة (أ) مقارنة بالمجموعة (ب). الإستنتاج: لايوجد فرق في فترة إجراء العملية والمضاعفات بين الضغط الواطئ والضغط المعياري في عمليات إستئصال المرارة بالمنظار، لكن في حالة الضغط الواطئ تكون شدة الآم الكتف أقل. الكلمات المفتاحيه: حصيات المرارة، منظار البطن، الضغط الواطئ، الضغط المعياري.

INTRODUCTION

/ ithin an exceptionally short time, laparoscopic cholecystectomy (LC) has widely replaced open cholecystectomy (OC) as the standard treatment for symptomatic cholelithiasis.¹ Since the introduction of (LC), pneumoperitoneum at 15 mmHg has been commonly used for all laparoscopic procedures. Despite its widespread use, this pressure is not without its problems and disadvantages.² Alternative surgical technique, low- pressure CO₂ maintained pneumoperitoneum, has been used in an attempt to reduce the impact on the cardiopulmonary function associated with the application of conventional pressure (14-15mmHg).^{3,4,5} Serious and potentially lethal complications including DVT, MI, atelectasis and pneumonia, especially in elderly or high risk patients, have been attributed to the physiological effects of pneumoperitoneum at 14 mmHg.²

During laparoscopic cholecystectomy adequate working space is required in the abdomen for good exposure that contributes to satisfactory results and patients safety.⁵ The most common method to create working space in the abdomen is carbon dioxide insufflation into the peritoneal cavity and then holding it at constant pressure.^{5,6} Low pressure pneumoperitoneum (7mmHg) is enough to warrant a sufficient operative space without a need for conversion in a significant percentage of laparoscopic operations.⁷

Shoulder tip pain frequently occurs after (LC) making postoperative recovery less comfortable. The etiology of postoperative pain is extremely complex and a precise evaluation of the various causes is still difficult to achieve. In particular, shoulder-tip pain is presumed to be linked to CO_2 insufflation, and its intensity is often so strong that analgesics must be administered frequently. The reported incidence of shoulder-tip pain following (LC) varies between 30% and 50%.⁶ It is well known that the visceral peritoneum is sensitive-free to pain on sharp cutting and puncture wounds,

on the other hand, it is highly sensitive to distension, tearing and separation.⁸ Visceral pain and shoulder pain account for most of the pain experienced after LC, whereas patients complain more of the parietal pain after laparotomy.¹

An emerging trend has been the use of low pressure pneumoperitoneum instead of the standard pressure pneumoperitoneum in an attempt to lower the impact on the human physiology while providing adequate working space.^{5,9,10}

This method appears to have little adverse effect on the cardiac and respiratory functions. Other possible advantages of low pressures during pneumoperitoneum appear to be lower incidence of shoulder tip pain in the post-operative period and better quality of life in the early postoperative period. ^{5,11,12}

Pain is a subjective sensation, and its measurement and analysis are difficult. Visual analogue scale (VAS) is usually presented as 100mm horizontal line on which the patient pain intensity is represented by points between the extremes of 'no pain at all' and ' worst pain imaginable'. Its simplicity, reliability, and validity, as well as its ratio scale properties make (VAS) the optimal tool for describing pain severity and intensity.¹

Aim of the study is to evaluate the influence of low pressure pneumoperitoneum on the feasibility, safety, and the postoperative shoulder tip pain pneumoperitoneum during laparoscopic cholecystectomy.

PATIENTS AND METHODS

One hundred forty patients with American Society of Anesthesiologists (ASA) grade 1 or 2 having symptomatic gall stones scheduled for elective laparoscopic cholecystectomy during the period from January 2011 to June 2012 were enrolled in this study. The patients were divided into two

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groups (70 in each group) and were randomly allocated to one of the two groups. In group A which represent the odd numbers, low pressure pneumoperitoneum (7 mm Hg) was generated, and in group B which represent the even numbers, standard pressure pneumoperitoneum (14 mmHg) was created. Exclusion criteria included acute cholecystitis, choledocholethiasis, and previous abdominal surgery, in addition five patients who were changed from low to standard pressure pneumoperitoneum because of poor visualization of the surgical field were excluded from the study; four of them were obese females, and one was muscular male. All patients were admitted to the hospital the day before surgery, for investigations, anesthetic consultation, and had an informed consent.

All the surgical procedures were performed under standard general anesthesia, by surgeons experienced in LC. Pneumoperitoneum was created with CO2 insufflation using the open (Hasson) method until abdominal pressure of either (7 mm Hg) low pressure group or (14 mmHg) standard pressure group was reached. In all patients, the routine 4 ports and the standard American technique was achieved. Residual carbon dioxide was evacuated at the end of the procedure, through the open valve trocars, and then removal of the trocars under vision. Duration of surgery, intraoperative complications, and bile spillage were recorded but no drain was left. All patients were prescribed postoperative analgesia with diclofenac 75 mg.

The degree of postoperative shoulder-tip pain was assessed by means of a visual analogue scale (VAS) at 3, 6, 12, and 24 h, postoperatively. The pain scale, with scores ranging from 0 (no pain) to 10 (unbearable pain), was recorded by a doctor who was blind to the group allocation of the patients, allowing patients to mark a point along the scale that represented their pain at that time. The patients were aware and informed that the scale is analyzing the presence and intensity of the shoulder pain alone, but not the postoperative abdominal pain. The postoperative shoulder pain was assessed in a double blinded manner; neither the patient nor the assessor were aware of the technique to which the patients has been randomized. Analgesic requirement and duration of hospital stay were recorded.

RESULTS

The age, gender, and the ASA grade were similar in both groups. There were no differences in the mean duration of surgery, length of hospital stay or intraoperative bile spillage **Table 1**.

The proportion of patients that complained of shoulder tip pain presenting during the first 24 hours after operation was lower in group A than in group B. In group A 12 (19%) out of 70 patients complained of shoulder tip pain in the postoperative period, while in group B 23 (33%) out of 70 patients complained of shoulder tip pain which was highly significant as in **Table 2**. Shoulder tip pain started after 3-6 hours and peaked in both groups after 12 hours, then gradual improvement was felt after that time.

The mean intensity of shoulder tip pain was significantly lower in group A than in group B. Pain score revealed that postoperative shoulder tip pain was significantly less intense at 12 and 24 hours postoperatively. The shoulder tip pain score was very low in group A at 24 h compared with group B, and the mean intensity of the shoulder tip pain exceeded a score of 3 at 24 hour in group B as in **Table 3**.

Table 1. Patients details (mean ±SD).

	Group A Iow pressure	Group B high pressure	p value
Mean age (years) ±SD	41.7± 12.3	39.5± 11.9	0.449
Female/Male	58/12	54/16	0.582
Operation time (min) ±SD	50.7± 12.7	47.4± 10.6	0.729
Postoperative hospital stay	1.23	1.12	0.322
Bile spillage	9	7	0.290
Analgesic (not required)	27	22	0.356

Table 2. No.	of patients with postoperative sl	noulder tip
pain.		

Group	Group A	Group B	p value
Postoperative Shoulder pain	12 (19%)	23 (33%)	0.001

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Time after surgery (h)	Group A (n= 70)	Group B (n=70)	<i>p</i> value	
3	0.83±0.71	2.46±1.31	0.000	
6	3.20±1.51	4.06±2.11	0.055	
12	4.91±1.36	6.37±1.91	0.001	
24	1.14±1.03	4.31±1.51	0.000	

 Table 3. postoperative shoulder tip pain (mean ±SD).

In both groups there were patients who did not require any analgesic medication 27 (38.5 %) in group A, and 22 (31.4 %) in group B, with no significant difference between the two groups. During the first 24 hours 6 patients in the lowpressure group and 10 patients in the highpressure group required extra analgesic medication for severe pain, but also it was not significantly different between the two groups.

Apart from postoperative pain, there were no significant intraoperative or postoperative complications in either group. There was no correlation between duration of surgery and postoperative shoulder tip pain. There were no significant difference between the two groups in terms of time to return to oral food, and discharge.

DISCUSSION

Although pain occurring post laparoscopic surgery is less severe and of shorter duration than that after open surgery, it still causes considerable discomfort and increases stress response in some patients.13 The maintenance of elevated intraabdominal pressure for the duration of the procedure is associated with numerous undesirable consequences including postoperative shoulder tip pain.¹⁴ The etiology and pathogenesis of the shoulder tip pain is only partly understood, but it is commonly assumed that the cause is overstretching of the diaphragmatic muscle fibers owing to the high rate of insufflation, and the low insufflation rate significantly reduces shoulder pain.^{6,13} Some authors claim that it may be caused by diaphragmatic irritation by a chemical material, as carbon dioxide may be transformed by combining with fluid in the peritoneal cavity into an irritative carbonic acid.¹⁵ This opinion is supported by the observation that, patients experience less pain if nitrous oxide is used instead of carbon dioxide in laparoscopic cholecystectomy.¹⁶

This study demonstrated that the incidence of shoulder tip pain after low pressure pneumoperitoneum was significantly lower as compared to the standard pressure laparoscopic cholecystectomy, 23 (33%) patients had shoulder pain in group B, while only 12 (19%) in group A with a (p value 0.001). This result differs from the study done by Kanwer who found no significant difference between the two groups, but he found lower demand for analgesia in the low pressure group.⁵ These results are slightly different from those of Mir Y et al¹⁴ where only 10% of their low pressure group developed shoulder pain. On the other hand, studies conducted by Sandhu T,13 Sarli⁶ and Berczynski¹¹ showed that the incidence of shoulder tip pain in low pressure group is lower than shoulder tip pain in standard pressure group, results did not reach but this statistical significance.

In the present study the mean intensity of postoperative shoulder tip pain at 3, 6, 12, 24 h recorded on VAS was lower in patients who underwent laparoscopic cholecystectomy with low pneumoperitoneum compared pressure with standard pressure. The difference between low pressure and standard pressure was highly significant at 3, 12, and 24 hrs, but did not reach statistical significance at 6 h postoperatively, although the intensity of pain was lower in the low pressure group. These results are different from the results of Sarli L⁶ and Yasir M,¹⁴ also it is different from the study done by Mahmut K et al¹ where the mean intensity pain was lower in the low pressure group than the standard pressure group, but it was statistically not significant. Many centers have reported that LC performed with low pressure pneumoperitoneum resulted in a better quality of life postoperatively as compared to LC performed with standard pressure, this is attributed to lower incidence and intensity of postoperative pain in low pressure pneumoperitoneum group with fewer requirement of analgesics in the postoperative period.⁵

None of our patients needed conversion to open cholecystectomy with no major complication in both groups, and the bile leakage is comparable between the two groups. Likewise the operative time and the duration of hospital stay were comparable in the two groups. These results warrant the feasibility and the safety of low

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pressure LC. The majority of the patients in group A could be operated on easily and safely with good visualization of the Calot's triangle, but when the operative field is not well visualized in low pressure LC, it can be increased to the standard pressure, as in five of our patients who were obese or muscular; and this may be attributed to the thick abdominal wall which requires more pressure to lift. In agreement with our study, Sarli⁶ mentioned that he had no significant complications and no significant difference in the time of operation.

In this study the analgesic requirements for shoulder tip pain were less in low pressure laparoscopic cholecystectomy as compared to standard pressure laparoscopic cholecystectomy, but the difference between the two did not reach statistical significance, this result was comparable with that of Sandhu.¹³

In conclusion, no difference was found between low pressure standard and pressure pneumoperitoneum regarding duration of operation complication, but and low pressure pneumoperitoneum resulted in lower incidence and lesser intensity of shoulder tip pain, although it did reach statistical significance at some not recordings. However, low pressure may affect the visual field especially in obese or muscular patients, therefore it is not recommended in these patients.

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