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Original article

Insufflation pressure and its effect on shoulder tip pain after laparoscopic cholecystectomy – A single-blinded, randomised study on 200 patients

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ABSTRACT

Objective: The origin of shoulder tip pain (STP) after laparoscopic cholecystectomy (LC) is multifactorial and poorly understood. Although many researchers studied the effect of low-pressure pneumoperitoneum on incidence and severity of shoulder pain, the role of low-pressure pneumoperitoneum on shoulder pain remains controversial.

Methods: This was a single-blinded, randomised study to find out correlation of insufflation pressure on STP after LC in a tertiary care hospital in New Delhi. A total of 200 patients were included in the study. One hundred patients were included in the low-pressure group (8–10 mmHg), and 100 patients were part of the standard-pressure group (13–15 mmHg). All the patients were evaluated for the incidence and severity of STP in a time frame of 48 h, i.e., 4 h, 24 h and 48 h.

Results: Incidence of STP was 24.0% in the standard-pressure group and 20.2% in the low-pressure group. The incidence and severity of STP were not statistically significant between standard-pressure and low-pressure groups at 4 h, 24 h and 48 h postoperatively. Operative difficulty due to constraint of space (7.4%) was significantly high in the low-pressure group.

Conclusion: Reducing the pressure of the pneumoperitoneum to 8–10 mmHg did not lower the incidence and intensity of postoperative STP. It can jeopardise the surgeon's comfort because of inadequate exposure. Routine use of low-pressure pneumoperitoneum in LC cannot be recommended.

1. Introduction

Laparoscopic cholecystectomy (LC) is the gold standard surgical treatment for gallstone disease. It has advantages of less postoperative pain, better cosmesis, shorter hospital stays and early resumption to work compared with open cholecystectomy.[1,2] However, postoperative shoulder tip pain (STP) is a troublesome symptom which delays postoperative recovery.[3,4] Possible causes of shoulder pain are sympathetic nervous system stimulation by hypercarbia[5] and residual postoperative carbon dioxide in the peritoneal cavity.[6] Mechanisms proposed to explain STP include diaphragmatic stretching due to rapid insufflation of the carbon dioxide[7] and irritation of the diaphragm due to the local acidity caused by the carbonic acid in the peritoneal fluid.[8] Another factor that could influence STP is the intraabdominal pressure during the surgery. Although several studies emphasised the use of low-pressure pneumoperitoneum in lowering STP, many authors still question its benefit. The aim of this study is to evaluate the correlation of the insufflation pressure on STP after LC.

2. Material and methods

2.1. Study population and design

Ours is a prospective single-blinded randomised trial. The study pool consisted of all patients aged between 18 and 60 years admitted for LC in a single unit of a tertiary care centre in New Delhi. Patients having documented Mirizzi syndrome and/or extensive upper abdominal incisions were excluded from the study.

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Elderly (age > 60 years) patients with American society of anaesthesiologists (ASA) grade > II were also excluded from the study. In total, 200 patients were included in the study and were prospectively enrolled and randomly assigned into study and control groups.

The study group included patients in whom the intraoperative pressure was kept at 8–10 mmHg, and the control group included patients in whom the intraoperative pressure was at 13–15 mmHg. The type of gall bladder and duration of surgery in both the groups was carefully recorded at the end of surgery. Difficulty in surgery pertaining to inadequate exposure or lack of working space in the lower pressure group was also recorded. Patients undergoing this trial were familiarised with the visual analogue scale (VAS) for pain preoperatively after obtaining a proper written informed consent for this trial.

Eligible patients were randomised based on computer-generated random allocations. Patients were evaluated for pain using a VAS explained preoperatively. At 4, 24 and 48 h, patients were asked for presence of STP. If pain presents, severity of such pain was also recorded. Component of local or visceral pain was specifically asked and excluded from the questionnaire. If patients were discharged, telephonic enquiry was conducted regarding STP. The study protocol was approved by our institutional research ethics committee, and all patients provided written informed consent before their enrolment.

2.2. Surgical technique and postoperative management

Under general anaesthesia, pneumoperitoneum was created by inserting a Veress needle through the umbilicus. A 5-mm port was made through the umbilicus, and the rest of the ports were made under direct vision. Epigastric port was made as a 10-mm one and the rest as 5-mm ports. Intraabdominal pressures were maintained at 8–10 mmHg and 13–15 mmHg as per preoperative randomisation. Decision to convert to normal pressure was taken within 15 min from trocar insertion. All these patients were analysed thoroughly for reason for conversion, and these patients were excluded from analysis. After removal of the gall bladder, 10 ml of 0.5% bupivacaine solution was infiltrated into the port sites. All patients were given injectable analgesics (nonsteriodal antiinflammatory drug) at an interval of 8 h. An additional dosage of analgesics was given according to patient requirement and recorded likewise. Residual pneumoperitoneum was completely evacuated at the end of the procedure. The time of arrival at the postoperative recovery ward was defined as zero hour postoperatively.

2.3. Statistical methods

Statistical testing was conducted with the Statistical Package for the Social Science system, version 17.0. Results were expressed as mean ± standard deviation (SD) or median if the data were unevenly distributed; categorical variables were expressed as frequencies and percentages. The comparison of normally distributed continuous variables between the groups was performed using Student's *t*-test. Nominal categorical data between the groups were compared using the Chi-squared test or Fisher's exact test as appropriate. Nonnormally distributed continuous variables were compared using the Mann-Whitney *U* test. $P < 0.05$ was considered statistically significant.

3. Results

Two hundred patients were enrolled into 2 groups after fulfilling the eligibility criteria. The procedure was converted to standard pressure in 6 patients of the study group because of intraoperative difficulty. Those patients were excluded from the study analysis. No patients were converted to open procedure (Fig. 1). Patient baseline demographic and clinical data are presented in Table 1. No difference in age was detected between patients allocated to the two study arms. Gender ratio and the body mass index (BMI) were also comparable in both the groups.

The comparisons of intraoperative characteristics are presented in Table 2. There was no significant difference observed between the mean operative times of the two groups ($p = 0.500$). There was no difference found in both the groups according to the type of the gall bladder. A simple type of the gall bladder constitutes the major component in both groups. But while operating in low-pressure pneumoperitoneum, operating surgeons felt difficulty in surgery because of less operating space in 7 patients (7.4%) out of 94 patients. Still, the procedure continued in low pressure. These observations were found to be statistically significant. ($p = 0.005$).

Detailed evaluation of STP is presented in Table 3. Incidence of STP was higher in the standard-pressure group than in the low-pressure group, but there was no statistically significant difference ($P = 0.526$). The proportion of patients that complained of STP presenting at any time during the first 48 h after surgery was higher in the standard-pressure group than in the low-pressure group. But this was statistically insignificant. In both the groups, the incidence was in an increasing trend until 24 h and declined gradually by 48 h. STP was observed to be most severe at 24 h and least severe at 48 h postoperatively in both the groups. It was also observed that mean VAS score was more in the standard-pressure group than in the low-pressure group at 4 h, 24 h and 48 h postoperatively. But this correlation was found to be statistically insignificant. Additional analgesic requirement for STP was also found less in the low-pressure group ($n = 13$; 13.8%) than in the standard-pressure group ($n = 20$; 20%).

4. Discussion

LC is the preferred treatment for symptomatic cholelithiasis because of the advantages of faster convalescence, short hospital stay and less severe postoperative pain.[9] STP is referred as pain perceived at the shoulder, located away from the surgical site which is peculiar to laparoscopic surgery. STP could be a significant source of postoperative discomfort after LC. The origin of STP is multifactorial and poorly understood. Several researchers studied the effect of low-pressure pneumoperitoneum on incidence and severity of shoulder pain. However, the role of low-pressure pneumoperitoneum on shoulder pain remains controversial.[10–15]

It has been reported that 30–50% of patients suffer from STP after LC.[16] Several RCTs emphasised the role of low-pressure pneumoperitoneum in reducing the incidence of STP.[11,12,17,18,19] A recent meta-analysis reviewed the incidence severity of STP in low-pressure and standard-pressure pneumoperitoneum and concluded that the intensity of the shoulder pain recorded on the VAS was significantly lower in patients undergoing low-pressure pneumoperitoneum.[20] In our study, although the incidence of STP was lower in the low-pressure pneumoperitoneum group (20.2% vs 24%), this difference did not reach statistical significance. The proportion of patients that complained of STP presenting at any time during the first 48 h after surgery was lower in the study group than in the control group. All previous studies evaluating the effect of low-pressure pneumoperitoneum on severity of STP found similar findings. In our study, the severity of STP and additional analgesic requirement were found less in the low-pressure group (13.8% vs 20%). But this was found to be statistically insignificant. Shoulder pain mostly becomes apparent on the first postoperative day when the visceral pain and port site incisional pain

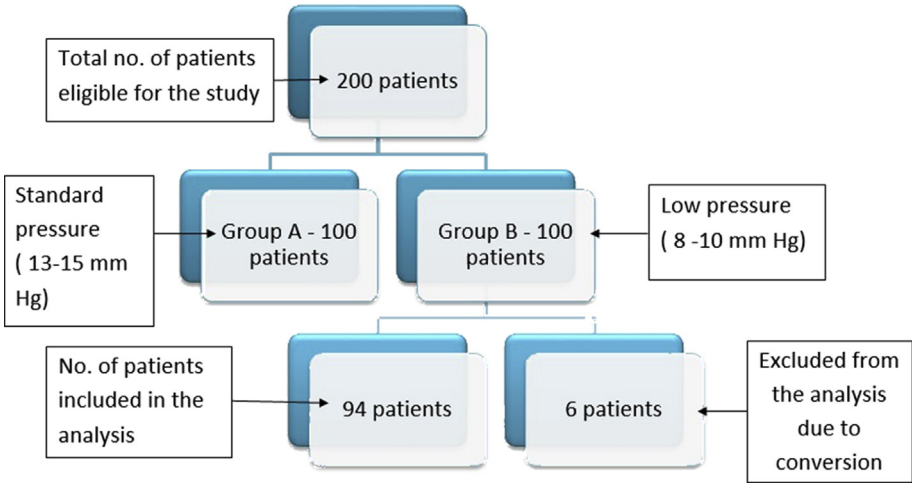

Fig. 1. Illustration depicting distribution of all patients in our study.

Table 1
Demographic data of both the groups.

Demographic data	Study group (pressure, 8–10 mmHg), n = 94	Control group (pressure, 13–15 mmHg), n = 100	P value
Age	40.73 ± 12.51	43.07 ± 10.65	0.162
Male/Female	60/34	66/34	0.752
Body mass index	25.47 ± 3.41	24.82 ± 3.24	0.176

Table 2
Details of intraoperative variables.

Shoulder tip pain score (VAS)	Study group (pressure, 8–10 mmHg), (n = 94)	Control group (pressure, 13–15 mmHg), (n = 100)	P value
Duration of surgery (in min.)*	39.27 ± 13.31	40.63 ± 14.68	0.50
Type of the gall bladder			
Acute cholecystitis	18 (19.1)	26 (26)	0.255
Empyematous GB	1 (1.1)	3 (3)	0.622
Simple	70 (74.5)	63 (63)	0.086
Thick-walled, contracted GB	5 (5.3)	8 (8)	0.456
Intraoperative difficulty due to low space	7 (7)	0 (0)	**0.005**

GB, gall bladder; SD, standard deviation; VAS, visual analogue score. Data expressed as n(%) unless specified; * expressed as mean ± SD.

Table 3
Evaluation of postoperative shoulder tip pain

Shoulder tip pain score (VAS)	Study group (pressure, 8–10 mmHg), (n = 94)	Control group (pressure,13–15 mmHg), (n = 100)	P value
Total incidence	19 (20.2)	24 (24)	0.526
Incidence at			
4 h	17 (18.1)	19 (19)	0.870
24 h	19 (20.2)	24 (24)	0.526
48 h	14 (14.9)	17 (17)	0.689
Severity (as per VAS score)*			
4 h	17 (3.06 ± 1.35)	19 (2.74 ± 1.20)	0.452
24 h	19 (4.74 ± 0.87)	24 (4.46 ± 0.88)	0.308
48 h	14 (1.50 ± 0.94)	17 (1.94 ± 0.83)	0.175
Additional analgesic dose	13 (13.8)	20 (20)	0.253

VAS, visual analogue scale; SD, standard deviation. Data expressed as n(%) unless specified; * expressed as mean ± SD.

components have decreased.[20] Similarly, in our study, STP was observed to be most severe at 24 h in both the groups and the pattern of both incidence and severity was in an increasing trend until 24 h and declined gradually by 48 h. It commonly involves the right shoulder, but the left shoulder can also be affected.[2]

"Patient safety is first" is the conventional teaching in surgical practice. Effective working space and adequate surgical exposure are critical concerns in low-pressure pneumoperitoneum.[20] Theoretically, operating at low pressure could cause increased visceral injury while inserting trocars and increased incidence of procedure-related injuries particularly in difficult gall bladders.[11] If there is evidence that the operative field is not adequate in the low-pressure group, there should be no hesitation in increasing the pressure to standard pressure. In this study, conversion to high-pressure pneumoperitoneum was required in 6 of 100 cases because of intraoperative anatomical difficulty in low-pressure pneumoperitoneum. This difficulty was felt in another 7 patients in the study group, but surgery was continued in low pressure

without conversion to standard pressure. These 13% of cases can be regarded as seriously compromised cases in low-pressure pneumoperitoneum. In this trial, low-pressure pneumoperitoneum was sufficient to perform LC in 87% of patients. This corresponds with the previous studies which reported the median proportion of successful completion of low-pressure LC was 90%, with a range between 71.4% and 100%.[5,10,12,13,14,15,21]

In conclusion, STP is a factor that can significantly influence postoperative recovery of the patient. Currently, the exact cause of STP is still an enigma and so does the mechanisms to prevent it. This study demonstrated that reducing the pressure of the pneumoperitoneum to 8–10 mmHg did not lower the incidence and severity of postoperative STP in patients undergoing LC. Intraoperative difficulty was experienced by operating surgeons because of inadequate exposure in the low-pressure group in a significant number of patients. Our study seriously questions the future role of low-pressure pneumoperitoneum in the routine practice because use of low-pressure pneumoperitoneum can jeopardise the patient's safety and surgeon's comfort.

Conflicts of interest

None.

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None.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.cmrp.2019.05.008.

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