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A Prospective Randomized Clinical Study of Comparing Low Pneumoperitoneum Pressure Versus Standard Pressure for Reduction of Shoulder Tip Pain in Laparoscopic Cholecystectomy

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Abstract

Introduction: Laparoscopic Cholecystectomy (LC) is the gold standard treatment for gallstone disease. However, despite being a minimal invasive technique the commonest complaint following laparoscopic cholecystectomy is still post operative pain. Pain after laparoscopic cholecystectomy is multifactorial and pneumoperitoneum pressure is thought to be one of the reasons. This study was planned to evaluate the post operative shoulder pain after laparoscopic cholecystectomy using low (10mm Hg) and standard pressure (14 mm Hg) Pneumoperitoneum.

Material & Method: A prospective randomized study was done in 100 ASA grades I and II patients of cholelithiasis in MGM Medical College and hospital, Aurangabad, India. The patients were divided into two groups-Group A patients undergoing laparoscopic cholecystectomy with low pressure (10 mm) and group B patients with standard pressure (14 mm). The intensity of shoulder pain was measured by VAS score and the results in both the groups were compared in terms of pain frequency, intensity, post operative analgesic requirement and hospital stay.

Statistical Analysis: Demographic data and intraoperative complications were analyzed using chi-square test. Frequency of pain, intensity of pain and analgesic consumption was compared by applying ANOVA test.

Results: Four patients of group A with low pressure (10mm) had shoulder tip pain and required rescue analgesia compared to 16 patients in group B with standard pressure. The intensity of pain was statistically significant with mean VAS score of 0.08 in low pressure and 1.00 in standard pressure group (p-value 0.045). There was more analgesic consumption in the post operative period in the standard pressure group. The operating time and complications were similar in both the groups.

Conclusion: Laparoscopic cholecystectomy done under low pressure pneumoperitoneum significantly decreases the intensity and frequency of post-operative shoulder tip pain. It also decreases the demand for post operative analgesia, hospital stay and hence-forth early recovery and better outcome.

Keywords: Laparoscopic cholecystectomy, Low pressure and Post-operative shoulder pain.

Introduction

Laparoscopic cholecystectomy has become the gold standard treatment for gallstones disease [1]. Despite having all the advantages of minimal invasive technique, still many patients complain of significant post-operative shoulder pain, thus prolonging the hospital stay and convalescence. The intra-abdominal pressure created by pneumoperitoneum has been thought to be one of the reasons for post operative shoulder tip pain. Various causes of shoulder tip pain are: peritoneal stretching and diaphragmatic irritation by high intra-abdominal pressure caused by pneumoperitoneum or by CO_2 absorption from the peritoneal cavity [2]. Intra-peritoneal local anesthetic instillation, removal of residual CO_2 before closure, peritoneal washout with saline, ultrasound guided transverse abdominis plane block with local anesthetic are the various techniques that have been studied [3-6] to reduce frequency and intensity of post-operative shoulder pain after laparoscopic cholecystectomy. Many post-operative analgesics, e.g., diclofenac sodium, Fentanyl, Morphine, Ketoprofen, and Ibuprofen have been studied but none of them showed sufficiently positive results for complete analgesia [7]. Pain after laparoscopic cholecystectomy needs multimodal analgesia for complete pain relief.

Since the advent of LC, surgeons have been using the standard 14-15 mm Hg pressure [2] for carbon dioxide pneumoperitoneum with common belief that more pressure creates more working space. Various authors have concluded that low pressure pneumoperitoneum and the amount of gas insufflated significantly reduces the post operative pain [8-11]. However, keeping low pressure of 7 mm Hg or 8 mm Hg surgeons have faced technical difficulties of having less working space, taking longer operating time, higher rate of intraoperative complications and higher conversion to standard pressure. On the contrary higher pressure of 14 or15mmHg leads to inexorable shoulder pain post operatively besides affecting cardiopulmonary functions in borderline patients, thus forcing the surgeon to convert to open procedure thereby loosing the benefit of MIS [12]. There is no mention in the literature about the pneumoperitoneum pressure to be taken as standard pressure and there are different opinions about the ideal standard pneumoperitoneum pressure for LC. Confronting this epoch, the aim of our prospective study was to choose an ideal working pressure for LC, which permits an adequate working space, no adverse effects on cardiopulmonary parameters and significantly reduces post operative shoulder tip pain.

Material and Method

A prospective randomized study was done in the department of general surgery at MGM Medical College & Hospital, Aurangabad, Maharashtra, India after taking approval from hospital ethical committee. 100 ASA grade I and II patients of age Group 20-75 years underwent elective laparoscopic cholecystectomy for uncomplicated symptomatic gallstone disease. Patients were divided into two Groups of 50 each. Group A patients underwent laparoscopic cholecystectomy with low pressure pneumoperitoneum (10 mm Hg) while Group B underwent laparoscopic cholecystectomy with standard pressure pneumoperitoneum (14 mm Hg). Patients having other co-morbid conditions, pregnant patients, patients on NSAIDS or other analgesics, patients undergoing laparoscopic cholecystectomy with CBD exploration or converted to open surgery were excluded from the study. A written informed consent was taken from all the patients. All the patients were educated about the Visual Analogue Scale (VAS) at the time of pre-anaesthetic check-up. Patients were prepared by overnight fasting and premedicated with Tab. Alprazolam 0.25mg orally, on previous night and 0.25 mg orally, on the morning of surgery with sips of water. In the operation theatre, an intravenous line was established. Patients were premedicated with inj. Glycopyrrolate 0.005 mg/kg intravenous before surgery. Monitors were attached to measure Pulse Rate (PR), Blood Pressure (BP), oxygen saturation (SpO_2) and ECG. All the patients were given Inj. Fentanyl 2 μg/kg intravenous for analgesia. Induction of anaesthesia was done with Inj.

Thiopentone 4-5 mg/kg intravenous and endotracheal intubation was facilitated using Inj. Atracurium 0.5-0.7 mg/kg intravenous. Anaesthesia was maintained by using O_2 and N_2O (33% + 66%) along with Isoflurane 0.4% and incremental doses of Inj. Atracurium when required. End tidal CO_2 was monitored throughout the procedure and was maintained between 30-35 mm of Hg. In all patient's surgery was performed following the American technique using standard four working ports. Intraoperative complications like bile spillage, bleeding were noted in both the Groups. Total duration of surgery was also noted. At the end of surgery, residual muscle relaxation was reversed by Inj. Neostigmine 0.05 mg/kg i.v and Inj. Glycopyrrolate 0.01mg/ kg i.v. After completion of surgery all patients were prescribed Inj. Diclofenac sodium intravenous 75mg 8 hourly for the post-operative analgesia and Inj. Ondensetron- 4mg intravenous to prevent post-operative vomiting. Post-operative pain was recorded at 0 min, 3hrs, 6hrs, 12hrs & 24hrs. Post-operative pain was assessed using Visual Analogue Scale (VAS) of pain. Patients marked the intensity of pain with a vertical line on a 10cm scale with the left end described 'no pain' and right end described as worst pain [7]. Patients complaining of pain were treated by rescue analgesic in the form of intravenous doses of inj. Fentanyl 20 μg. Rescue analgesic was repeated on request by patient with minimum interval of 20 minutes. The dosage of Inj. Fentanyl and time of administration were recorded by staff nurse.

Results

Both the Groups were comparable with respect to age, gender and duration of illness. There was female preponderance for gallstone disease (Table 1).

	Group A	Group B	p-value
Age (yrs.)	50.60+/- 13.95	53.76+/- 13.80	0.258
Male/female ratio	Dec-38	20/30	0.086
Operating time	39.16+/- 5.14	39.36+/- 5.43	0.851

Table 1: Demographic data of patients in group A and group B.

In both the Groups, there was no pain immediately after surgery.

At 3 hrs, 6hrs, 12hrs and 24 hrs interval, pain frequency was higher in Group B as compared to Group A with p-value < 0.05. At 24 hrs, no patient from Group A complained of pain. But in Group B, 16 patients complained of pain (Table 2).

Time interval	Group A-Number	Percentage	Group B-Number	percentage	p-value
0	0	0.00%	0	0.00%	0
3 hrs.	4	8.00%	16	32.00%	0.0462
6 hrs.	4	8.00%	16	32.00%	0.0462
12 hrs.	4	8.00%	16	32.00%	0.0462
24 hrs.	0	0.00%	16	32.00%	0.00836

Table 2: Comparison of number of patients requiring analgesic at various time intervals.

Intensity of pain was assessed by VAS score at specified interval. At all the intervals Mean VAS score was higher in Group B as compared to Group A with statistically significant difference. Mean of total VAS score of Group A was 1.42 and of Group B was 7.88 with p-value of 0.001. Thus, intensity of pain measured by VAS was significantly higher in Group B (Table 3).

Time interval	Group A Mean VAS	Group A Standard deviation	Group B Mean VAS	Group B Standard deviation	p-value
0	0	0	0	0	
3 hr	0.28	0.970	1.26	1.901	0.002
6 hrs	0.32	1.096	1.56	2.323	0.001
12 hrs	0.24	0.822	2.16	3.228	0.000
24 hrs	0.08	0.274	1.0	1.565	0.000

Table 3: Comparison of intensity of pain in two groups.

Only four patients in Group A and sixteen patients in Group B were given rescue analgesic. Maximum demand of rescue analgesic during 4th to 6th hour was 30 µg in Group A and 45 µg in Group B. It was statistically significant difference with p-value of 0.045. During rest of the intervals rescue analgesic demand was higher in Group B but it was not statistically significant. Overall analgesic consumption was higher in Group B (Table 4).

Time Interval	Group A Total Dose (µg)	Mean (µg)	Standard deviation	Group B Total Dose (µg)	Mean (µg)	Standard deviation	p-value
1st -3rd hrs	80	20	0	480	30	10.328	0.074
4th-6th hrs	120	30	0	720	45	13.663	0.045
7th-9th hr	120	30	11.547	560	35	13.663	0.511
10th-12th hr	40	10	11.547	400	25	8.944	0.011
13-24th hr	0	0	0	320	20	0	-

Table 4: Comparison of analgesic consumption in two groups (Inj. Fentanyl µg /day).

There was no significant difference in the rate of complications between the two Groups. So, low pressure pneumoperitoneum did not interfere with the surgical procedure (Table 5).

Complications	Group A Number	Group A Percentage	Group B Number	Group B Percentage	p-value
I/O bleeding	6	12	6	12	0.505
I/O bile spillage	4	8	4	8	0.505

P/O nausea/ vomiting	4	8	8	16	0.218

Table 5: Comparison of intraoperative complications.

Discussion

Major benefit of the laparoscopic cholecystectomy has been in reducing post operative pain, morbidity related to upper abdominal incision and early postoperative recovery. However still significant number of patients have post operative shoulder pain which at times is very excruciating. Shoulder tip pain after laparoscopic cholecystectomy is usually felt at the right or left shoulder and around the neck of the patient (Figure 1,2).

Figure 1: Patient pointing at Right Shoulder pain following laparoscopic cholecystectomy.

Figure 2: Patient pointing pain at and around the neck following laparoscopic cholecystectomy.

Going by the patho- physiology and the mechanism of shoulder pain it is thought to be because of the gas insufflated and pneumoperitoneum pressure. As of now whether low pressure pneumoperitoneum is associated with less post operative pain is still controversial [9, 13-16]. Most of the studies [14-19] have shown that keeping low pressure pneumoperitoneum during laparoscopic cholecystectomy significantly reduces post operative shoulder pain. The results of our study also show that post-operative pain after laparoscopic cholecystectomy is significantly reduced both in frequency and intensity in low pressure group. The Mean VAS score came down to 0.08 at 24 hrs in low pressure group, whereas it was 1.00 in standard pressure Group. These results are in agreement with the observation from different studies [2, 13,17,20,21] in a systemic review and meta-analysis by Hua et al in 2014 [22]. In their results the pain score decreased at almost all intervals 0-6 hrs, 7-12 hrs and 13-24 hrs.

The incidence of shoulder pain was higher in the standard pressure group compared to low pressure group. 4 patients in Group A and 16 patients in Group B required additional analge-sia in the form of injection Fentanyl 20 mcg IV bolus at various intervals. A similar observation of having low incidence of shoul-der pain has been reported in various studies in a meta-analysis [11,14-17,19-21] reviewed data on low and standard pressure and concluded that the low pressure is the best documented method for decreasing post operative shoulder pain during LC. On the other hand Koc M et al (10 and 15 mm hg pressure) and Perrakis et al (8 and 15 mm hg pressure) in their study didn't find any significant difference in post operative shoulder tip pain [9, 13]. Some authors have combined low pressure with saline wash and have found that the combination of saline wash with low pressure to be more ef-fective in reducing post operative pain rather than low pressure alone [6]. Though we have not specifically studied saline wash with low pressure, but this practice of saline wash was a routine in all our patients. Therefore, it is difficult to comment on the benefit of either of these two techniques used. Total consumption of injec-tion Fentanyl was significantly less in Group A. Consumption of Fentanyl per patient, out of four, who required additional analgesia in Group A was 110 µg, whereas it was 175 µg per patient out of 16 in Group B [21] in his series of 100 patients comparing low verses standard pressure had similar observation in term of fre-quency and intensity of shoulder tip pain. Another data from six studies [2,9,14,16,20,21] including 568 patients showed that low pressure group had lower analgesic requirements than standard group. Incidence of complications like bile spillage, intraoperative bleeding, post-operative nausea and vomiting were similar in both the groups. The same was observed [2,9,11,14,23].

Operating time in low pressure pneumoperitoneum is also a concern to the surgeon as more the operating time, more consump-tion of carbon dioxide and hence higher incidence of shoulder tip pain. In our study operating time was similar in both the groups. Some studies [2,9,11,13,14,16,20,21,23] have reported longer op-erating time in low pressure group than the standard group. How-ever, in all those studies no statistical significant difference was observed [15] studied all these parameters at 8,10,12 and 14 mm Hg pressure and concluded that patients in whom surgery lasted for more than 45 minutes had significant shoulder tip pain though there was no relation to the volume of gas used. The reason of hav-ing almost similar operating time in our study could be because of

the experience and skill of the surgeon who could operate comfort-ably in the available space of 10mm pressure.

Another important parameter related to the benefit of low pressure is the hospital stay, which was significantly less in lower pressure group compared to standard pressure i.e. 2.68 days verses 3.6 days. Six studies from meta-analysis [2,11,14,20,21,23] also reported the hospital stay to be less in low pressure pneumoperi-toneum group.

Though our focus in this study was specifically to address the issue of post operative shoulder pain by keeping the pressure low but it still remains a matter of concern for safe surgery with a limited working space and on the other hand its benefits to the borderline cardio-pulmonary patients which could benefit of being taken up for laparoscopy. Guruswamy KS, Samraj K [18] searched cochrane central register of trials and collected data from fifteen randomized trials. They found that intensity of pain was lower in low pressure Group. The analgesic consumption was also lower. But due to high risk of bias due to incomplete outcome data in seven trials, it was not possible to conclude about the safety of low pressure pneumoperitoneum. All studies were done in ASA grade 1 & 2. However, in our study we did not find any difficulty in operating under low pressure and no patient required conversion to standard pressure. On the contrary seven studies [2,9,14,16,20,23,24**]** in a meta-analysis review have reported the requirement for in-creased pressure [22]. As our study was confined to uncomplicated cholelithiasis, the complicated cases were excluded and in case of unexpected occasions, gall stone ileus with fistula can pose a problem for which a one stage surgery has been recommended [25].

Analyzing the results of our study, we found that the low-pressure pneumoperitoneum results in decrease in intensity as well as frequency of post-operative pain and less requirement of an-algesia as compared to standard pressure. Further studies can be planned by combining low pressure techniques with other tech-niques like local anesthetic infiltration of wounds and intraperito-neal instillation of Ropivacaine or Bupivacaine to decrease anal-gesic requirement. Thus, there is a need for further research into ways to improve the quality of the post-operative care of these patients.

Conclusion

The results of our study demonstrated that the use of simple expedite of decreasing the pressure to 10 mm Hg works well and is safe for laparoscopic cholecystectomy. It significantly decreases post operative shoulder tip pain both in frequency and intensity. Also, there is a marked decrease in analgesic requirement postoperatively with a benefit of shorter hospital stay. We recommend wide spread use of low pressure of 10 mm Hg as a standard pneumoperitoneum pressure for uncomplicated gallstone disease.

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