Original Article

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Surgery Section

Pain Management after Laparoscopic Cholecystectomy-A Randomized Prospective Trial of Low Pressure and Standard Pressure Pneumoperitoneum

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ABSTRACT

Background: Abdominal pain and shoulder tip pain after laparoscopic cholecystectomy are distressing for the patient. Various causes of this pain are peritoneal stretching and diaphragmatic irritation by high intra-abdominal pressure caused by pneumoperitoneum . We designed a study to compare the post operative pain after laparoscopic cholecystectomy at low pressure (7-8 mm of Hg) and standard pressure technique (12-14 mm of Hg).

Aim : To compare the effect of low pressure and standard pressure pneumoperitoneum in post laparoscopic cholecystectomy pain . Further to study the safety of low pressure pneumoperitoneum in laparoscopic cholecystectomy.

Settings and Design: A prospective randomised double blind study.

Materials and Methods: A prospective randomised double blind study was done in 100 ASA grade I & II patients. They were divided into two groups -50 each. Group A patients underwent laparoscopic cholecystectomy with low pressure pneumoperitoneum (7-8 mm Hg) while group B underwent laparoscopic cholecystectomy with standard pressure pneumoperitoneum (12-13 mm Hg). Both the groups were compared for pain intensity, analgesic requirement and complications.

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

Results: Post-operative pain score was significantly less in low pressure group as compared to standard pressure group. Number of patients requiring rescue analgesic doses was more in standard pressure group . This was statistically significant. Also total analgesic consumption was more in standard pressure group. There was no difference in intraoperative complications.

Conclusion: This study demonstrates the use of simple expedient of reducing the pressure of pneumoperitoneum to 8 mm results in reduction in both intensity and frequency of post-operative pain and hence early recovery and better outcome.This study also shows that low pressure technique is safe with comparable rate of intraoperative complications.

Keywords: Standard pressure pneumoperitoneum, Post laparoscopic cholecystectomy pain

INTRODUCTION

Laparoscopic cholecystectomy is the gold standard procedure for cholelithiasis. As compared to open cholecystectomy, it is less painful, needs shorter recovery time and shorter hospital stay [1]. Recovery after laparoscopic cholecystectomy depends upon several factors such as abdominal pain, shoulder tip pain, nausea, vomiting and fatigue. These side-effects are due to peritoneal stretching and diaphragmatic irritation caused by high intra-abdominal pressure and by CO_2.[2]. Keeping this in mind, it was assumed that lower intra-abdominal pressure will decrease these complications. Traditionally, the pressure used to create pneumoperitoneum is around 15mm of Hg [3]. There are a few studies done using low pressure pneumoperitoneum (less than 12 mm of Hg) and showed decrease in pain post-operatively [2,4,5]. But, all the studies are not equivocal in this respect [6]. Further, the safety of low pressure pneumoperitoneum is not established. We designed a study to compare the post-operative pain after laparoscopic cholecystectomy at low pressure (7-8 mm of Hg) and standard pressure technique (12-14 mm of Hg) and also to compare the duration of surgery and intraoperative complications between these two techniques.

MATERIALS AND METHODS

A prospective randomised double blind study was done in 100 ASA grade I and II patients of age Group 20-75 years who underwent elective laparoscopic cholecystectomy for uncomplicated symptomatic gall stone disease. The study was conducted in a tertiary care centre, after taking approval from hospital ethical committee. Patients were divided into two Groups of 50 each. Group A patients underwent laparoscopic cholecystectomy with low pressure pneumoperitoneum (7-8 mm Hg) while Group B underwent laparoscopic cholecystectomy with standard pressure pneumoperitoneum (12-14 mm Hg). Patients having other co-morbid conditions, pregnant patients, patients on NSAIDS or other analgesics, patients undergoing laparoscopic cholecystectomy and 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 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 patients surgery was performed using standard four working ports technique. As per the computer generated randomisation

chart, patients were operated on low pressure or standard pressure technique of pneumoperitoneum. Intraoperative complications like bile leak and 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 and associated problems like nausea and vomiting were noted at 0min, 1hr, 2hr, 4hr, 8hr, 12hr & 24hr. Post-operative pain was assessed using Visual Analogue Scale of pain (VAS). 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 noted by staff nurse.

STATISTICAL ANALYSIS

Continuous variables were presented as mean (± SD). The Demographic data was analysed using chi-square test except male/female ratio which was analysed using ANOVA test. Frequency of pain, intensity of pain and analgesics consumption between two Groups was compared by applying ANOVA test. Intraoperative complications and post-operative nausea vomiting was analysed using chi-square test. Significance was defined as $p < 0.05$.

RESULTS

Both the Groups were comparable with respect to age, gender, weight and duration of surgery. There was female preponderance for gall stone disease [Table/Fig-1]. In both the Groups, there was no pain immediately after surgery.

At 1 hr., 2 hr, 4hr, 8hr and 12 hr. 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/Fig-2].

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. So intensity of pain measured by VAS was significantly higher in Group B [Table/Fig-3].

Only four patients in Group A and sixteen patients in Group B were given rescue analgesic. Maximum demand of rescue analgesic was during 3rd and 4th hour with mean demand of 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/Fig-4].

Rate of complications was comparable between two Groups. So, low pressure pneumoperitoneum did not interfere with the surgical procedure [Table/Fig-5].

DISCUSSION

Major benefit of the laparoscopic cholecystectomy is the avoidance of upper abdominal incision resulting in less post-operative pain and early recovery. But even laparoscopic cholecystectomy is not free from discomfort and pain. Patients usually have abdominal pain and shoulder tip pain after laparoscopic cholecystectomy. Various causes of this 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]. Several research studies are done to find out the ways to reduce frequency and intensity of post-operative pain after laparoscopic cholecystectomy.

	Group A.(LP) n=50	Group B.(SP) n=50	p-value
Age (yrs.)	50.60 ± 13.95	53.76 ± 13.80	0.258
Male/Female ratio	12/38	20/30	0.086
Weight (Kgs)	60.16 ± 9.71	59.32 ± 9.96	0.670
Duration of Surg. (mins.)	39.16 ± 5.14	39.36 ± 5.43	0.851

[Table/Fig-1]: Demographic profile of patients and duration of surgery
Age, weight, duration of surgery, presented as mean±standard deviation. Test done was ANOVA for age, weight and duration of surgery and chi-square test for male/female ratio. (n is no. of patients,yrs is years,kgs is kilograms,mins is minutes)

Time interval	Group A (LP) n=50		Group B (SP) n=50		p-value
	No.	Percentage	No.	Percentage	
0 min.	0	0.00%	0	0.00%	0
1 hr.	4	8.00%	16	32.00%	0.0462
2 hr.	4	8.00%	16	32.00%	0.0462
4 hr.	4	8.00%	16	32.00%	0.0462
8 hr.	4	8.00%	16	32.00%	0.0462
12 hr.	4	8.00%	16	32.00%	0.0462
24 hr.	0	0.00%	16	32.00%	0.00836

[Table/Fig-2]: Comparison of number of patients who required rescue analgesics at various time intervals
Data is presented as number and percentage. Test done was ANOVA. n is no. of patients, (hr is hours.) p< 0.05 is statistically significant

Time interval	Group A (LP) n=50		Group B (SP) n=50		p-value
	Mean VAS	Standard deviation	Mean VAS	Standard deviation	
0 min.	0	0	0	0	
1 hr.	0.14	0.485	0.46	0.727	0.011
2 hr.	0.28	0.970	1.26	1.901	0.002
4 hr.	0.36	1.241	1.44	2.196	0.003
8 hr.	0.32	1.096	1.56	2.323	0.001
12 hr.	0.24	0.822	2.16	3.228	0.000
24 hr.	0.08	0.274	1.00	1.565	0.000
Total	1.42	4.88	7.88	11.76	0.001

[Table/Fig-3]: Comparison of Intensity of Pain (VAS) in two Groups
VAS is visual analogue scale, hr is hours, n is no. of patients, (SP is standard pressure, LP is low pressure.) Test applied is ANOVA . p< 0.05 is statistically significant

Time Interval	Group A (n=4)			Group B (n=16)			p-value
	Total Dose (µg)	Mean (µg)	Std Deviation	Total Dose (µg)	Mean (µg)	Std Deviation	
Ist hour	80	20	0.000	320	20	0.000	_
Ist - 2nd hr.	80	20	0.000	480	30	10.328	0.074
3rd - 4th hr.	120	30	0.000	720	45	13.663	0.045
5th - 8th hr.	120	30	11.547	560	35	13.663	0.511
9th - 12th hr.	40	10	11.547	400	25	8.944	0.011
13th - 24th hr.	0	0	0.000	320	20	0.000	_

[Table/Fig-4]: Comparison of Analgesic consumption in two Groups (Inj. Fentanyl µg/day)
(n is number of patients, hr is hour, µg is microgram.)Test applied is ANOVA. p< 0.05 is statistically significant

Complication	Group A (LP) n=50		Group B (SP) n=50		p-value
	Number	Percentage	Number	Percentage	
I/O Bleeding	4	8.00	6	12.00	0.505
I/O Bile Leak	6	12.00	4	8.00	0.505
Nausea/Vomiting	4	8.00	8	16.00	0.218

[Table/Fig-5]: Comparison of Complications
I/O is intraoperative.Test applied is chi-square . p< 0.05 is statistically significant

Intra-peritoneal local anaesthetic instillation, removal of residual CO_2 before closure, peritoneal washout with saline, ultrasound guided transverse abdominis plane block with local anaesthetic are the various techniques that have been studied [8,11]. Many post-operative analgesics eg. diclofenac sodium, Fentanyl, Morphine, Ketoprofen,

Ibuprofen have been studied but none of them showed sufficiently positive results for complete analgesia. Pain after laparoscopic cholecystectomy needs multimodal analgesia for complete pain relief.

Studies have been done to compare the effect of different intra-abdominal pressures on post-laparoscopic cholecystectomy pain [12,13]. It has been shown that low insufflation pressure reduces pain frequency, as well as, pain intensity after laparoscopic cholecystectomy [5]. Analgesic requirement is also less in low pressure technique. There are other advantages of low pressure technique, such as less hemodynamic variation, which is specially beneficial in patients having cardiac disease [12,14]. The increased intra-abdominal pressure due to the pneumoperitoneum causes several cardiopulmonary changes. The increased intra-abdom inal pressure increases the absorption of CO_2, causing hypercapnia and acidosis, which has to be avoided by hyperventilation. It pushes the diaphragm upwards decreasing the pulmonary compliance and increases the peak airway pressure. Pneumoperitoneum increases the systemic vascular resistance and pulmonary vascular resistance. Carbon-dioxide pneumoperitoneum also predisposes to cardiac arrhythmias. During the early phase of pneumoperitoneum, there is a reduction in the cardiac output by decreasing the venous return. While these cardio-respiratory changes may be tolerated by healthy adults with adequate cardiopulmonary reserve, people with cardiopulmonary diseases may not tolerate these cardiopulmonary changes. About 17% of patients undergoing laparoscopic cholecystectomy have an American Society of Anesthesiologists (ASA) status of III or IV. Low insufflation pressure may be beneficial for these patients.

Results of our study have shown that post-operative pain after laparoscopic cholecystectomy is less both in frequency and intensity in low pressure group. 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 data are in agreement with those of other authors [5]. In majority of the patients post-operative pain could be managed by injection Diclofenac sodium 75 mg i.v given 8 hourly. But, 4 patients in Group A and 16 patients in Group B required additional analgesia in the form of injection Fentanyl 20mcg i.v bolus at various intervals. Total consumption of injection 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. Incidence of complications like bile leak and bleeding post-operative nausea and vomiting were similar in both the Groups.The same was observed by Wallace et al., T Sandhu et al., L Sarli et al., [2,4,5].

Duration of surgery was also comparable between two Groups. This indicates that the exposure is adequate with low pressure technique and the surgery could be performed in the same duration and without compromising the safety and efficacy of surgical procedure. But this may depend upon experience of surgeon. Many patient factors may also interfere eg. obese patients, previous surgery and presence of adhesions etc. So, further studies are needed to compare with different surgical teams and in obese patients.

Guruswamy KS, Samraj K searched cochrane central register of trials and collected data from fifteen randomised 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 [5]. All studies were done in ASA grade 1 & 2. To study the cardiovascular stability by low pressure pneumoperitoneum, further studies are needed in patients having cardiac disease or ASA grade 3 & 4 patients with other problems.Ingelmo PM et al., showed that Ropivacaine (1%) intraperitoneal nebulisation before and after (3ml) surgery reduced post-operative pain after laparoscopic cholecystectomy. It also reduced Morphine consumption and allowed early mobility [15].

Analysing the results of our study, we opine that low pressure pneumoperitoneum results in decrease in intensity and frequency of post-operative pain and fewer requirement of analgesics as compared to standard pressure. Further studies can be planned by combining low pressure techniques with other techniques like local anaesthetic infiltration of wounds and intraperitoneal instillation of Ropivacaine or Bupivacaine to decrease analgesic requirement. There is, thus, a need for further research into ways to improve the quality of the post-operative care of these patients.

CONCLUSION

This study demonstrates that the use of simple expedient of reducing the pressure of pneumoperitoneum to 8 mm of Hg results in reduction in both intensity and frequency of post-operative pain and hence, early recovery and better outcome. This will promote day case laparoscopic cholecystectomy and hence, leads to cost saving. Further studies can be planned for assessing possibility of day case surgery and early return to work.

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