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Use of low pressure verses standard pressure pneumo peritoneum in patients undergoing laparoscopic cholecystectomy: A prospective clinical study

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Abstract
Aim: to compare the use of the low pressure with the standard pressure pneum operitoneum in patients undergoing laparoscopic cholecystectomy.
Materials and Methods: This randomized prospective study was carried out in the Government Hospital Sarwal, Jammu, India among 50 patients. Patients were randomized into two groups; one group with 25 patients was undergone lapro scopic cholcystectomy with standard pressure Pneumo Peritoneun (SPLC) while the other group with 25 patients was undergone lapro scopic cholecystectomy with low pressure Pneum operitoneum at (LPLC).
Results: majority of the patients (N=28) belong to 30-40 years of age group. 48 (96%) were females while 2 (4%) were males. Mean operative time in Group A (88.08 minutes) and Group B (71.60 minutes). Mean number of days of hospital stay in Group A (2.60 days) than Group B (1.59 days).
Conclusion: uncomplicated gall stone disease can be treated by low pressure laparoscopic cholecystectomy with reasonable safety. Though surgeon experience operative time is quite high but it is significantly advantageous in terms hospital stay.

Keywords: gall stone, hospital stay, laparoscopic cholecystectomy

1. Introduction
Laparoscopic cholecystectomy is a procedure in which the gall bladder is removed by laparoscopic techniques, also known as minimal invasive surgery. Now laparoscopic cholecystectomy is the procedure of choice in all gall bladder disease & acceptable surgical alternative for high risk patents requiring cholecystectomy [1-3].
Professor Erich Muhe of Germany performed the first laparoscopic cholecystectomy on 12 sept, 1985. Pneum operitoneum is the crucial element in laparoscopic surgery. Controlled intra-abdominal pressure within the abdominal cavity is tasked to facilitate the smooth operation of the surgeon. George kellings first in 1991th described technique of establishing pneum operitoneum & first did a review of the method of abdomen which was named after him. Celiloscopy, now known as laparoscopy [4, 5]. Zollikofer in 1924, first described the use of carbon dioxide for establishing pneum operitoneum. Carbon dioxide is most suitable gas for insufflations into the abdominal cavity because it is non inflammable, possible to use electro coagulations, very soluble in blood and tissues. It is easily eliminated through the lungs, is non toxic and is in expensive [6, 7]. The standard pressure pneum operitoneum employing a pressure range of 12-14mm of Hg, over prolonged periods has been associated with adverse effects such as decreased pulmonary compliance, altered blood gas parameters, impaired functioning of circulatory system, raised liver enzymes, renal dysfunction and increased intra-abdominal vascular pressure [8, 9].
Therefore a rising trend has been the use of low pressures for pneum operitoneum in the range of 8-10 mmHg in an attempt not to alter the human physiology and also providing adequate working space at the same time. One important advantage reported of low pressures during pneum operitoneum appear to be lower incidence of shoulder tip pain in the postoperative period and also better quality of life in postoperative period. However the lower pressures have also been linked less than adequate exposure of the operating field resulting in longer than usual operating time, higher rate of intraoperative complications and also possibly higher frequency of conversion to open cholecystectomy [10-12]. Hence, the present study was conducted to compare the use of the low pressure with the standard pressure pneum operitoneum in patients undergoing laparoscopic cholecystectomy.

Material and Methods
Study Design
A Prospective clinical study was conducted among 50 consecutive patients with symptomatic gallstones who attended Surgery OPD of Government Hospital Sarwal, Jammu, India.

Ethical approval and informed consent
The study protocol was reviewed by the Ethical Committee of the Hospital and granted ethical clearance. After explaining the purpose and details of the study, a written informed consent was obtained.

Inclusion Criteria

- Patients willing to participate in study.
- Patients 30-70 years of age.
- Only normotensive patients with symptomatic cholelithiasis.

Exclusion Criteria

- Patients with Acute Cholecystitis.
- Patients with contraindication of laparoscopic cholecystectomy like previous abdominal surgery, coagulation disorders, pregnancy, malignancy, chronic obstructive pulmonary diseases, coronary artery disease and cerebrovascular accident.

Sample selection

The sample size was calculated using a prior type of power analysis by G* Power Software Version 3.0.1.0 (Franz Faul, Universitat Kiel, Germany). The minimum sample size of each group was calculated, following these input conditions: power of 0.80 and $P \leq 0.05$ and sample size arrived were 50 patients i.e 25 per group.

Group: A

Patients undergoing laparoscopic cholecystectomy at Low pressure pneum operitoneum (8-10mmHg).

Group: B

Patients undergoing laparoscopic cholecystectomy at Standard pressure pneum operitoneum (12-14mmHg).

Pre: Operative

Patients will be subjected to all routine investigations including Liver function test, ECG, Chest x-ray, Ultrasound abdomen and medical fitness for laparoscopic cholecystectomy. Random allocation of patients will be done in Group A, (Low pressure pneum operitoneum) and Group B (Standard pressure pneum operitoneum).

Operative

Procedure will be conducted under general anaesthesia by standard four port technique. Primary port will be inserted at umbilicus by Hassen's technique and after slow insufflations by carbon dioxide. Patients will be kept in Reverse Trend elenburg position 15º with right shoulder up. Pressure of pneum operitoneum will be set at 8-10mm Hg in Group A and 12-14mm Hg in Group B using 30 º telescopes. Rest of the three secondary ports will be inserted under telescopic vision using 30º elescope. Titanium liga clips will be used to secure cystic duct and artery. Gall bladder will be separated from gall bladder fossa using electro cautery and shall be extracted through epigastric port. A 14 Fr vacuum drain will be inserted in the right sub hepatic space and at the end of procedure port incision will be closed by applying Prolene suture. Any change in vital of patient beyond normal range will be recorded during the procedure. Procedure may be converted into open cholecystectomy in case of technical difficulty.

Post Operative

During the post operative stay patient will be observed and monitored for vitals, post-operative pain, drain output, any other unusual symptoms and complication will be recorded as per Performa. In uncomplicated cases abdominal drain will be removed after 24 hours of surgery and patient will be allowed oral sips, liquid diet after return of bowel sounds. Patient will be advised for follow up visits as per post-operative recovery course.

Statistical Analysis

The recorded data was compiled and entered in a spreadsheet Computer program (Microsoft Excel 2010) and then exported to data editor page of SPSS version 19 (SPSS Inc., Chicago, Illinois, USA). Descriptive statistics included computation of percentages. The statistical tests applied for the analysis were Pearson's chi-square test (χ^2) and student t-test. For both the tests, confidence interval and p-value were set at 95% and ≤ 0.05 respectively.

Results

Table 1: age distribution of study subjects

Age (Years)	Group		Total
	A	B	
30-40	13	15	28
	52.0%	60.0%	56.0%
40-50	6	7	13
	24.0%	28.0%	26.0%
50-60	6	2	8
	24.0%	8.0%	16.0%
>60	0	1	1
	.0%	4.0%	2.0%
Total	25	25	50
	100.0%	100.0%	100.0%

On analysis it was observed that majority of the patients (N=28) belong to 30-40 years of age group followed by (N=13) patients in 40-50 years, (N=8) patients in 50-60 years of age and only (n=1) patient above 60 years was observed.

Table 2: gender distribution of study subjects

Gender	Group		Total
	A	B	
Female	25	23	48
	100.0%	92.0%	96.0%
Male	0	2	2
	.0%	8.0%	4.0%
Total	25	25	50
	100.0%	100.0%	100.0%

On analysis it was observed the gender distribution among total 50 study participants, 48 (96%) were females while 2 (4%) were males.

Table 3: comparison of mean operative time

Operative time (Minutes)	Group A		Group B	
	Mean	Std. Deviation	Mean	Std. Deviation
	88.0800	5.55218	71.6000	5.51513
p-value	0.001 (Sig.)			

On analysis it was observed that mean operative time in Group A (88.08 minutes) and Group B (71.60 minutes). t-test analysis revealed the mean difference between the groups was statistically significant (p<0.05).

Table 4: comparison of mean duration of hospital stay

Hospital Stay (Days)	Group A		Group B	
	Mean	Std. Deviation	Mean	Std. Deviation
	1.59	0.11	2.60	0.23
p-value	0.047 (Sig.)			

On analysis it was observed that mean number of days of hospital stay in Group A (1.59) than Group B (2.60). t-test analysis revealed the mean difference between the groups was statistically non-significant (p<0.05).

Discussion

The advent of laparoscopic cholecystectomy is a milestone achieved in both the treatment of gallstones and in the evolution of minimal access surgery [13, 14]. The aim was to reduce the trauma during access and maintain appropriate exposure of the surgical field during surgery [13, 14]. To achieve this surgeons have traditionally relied on creating a pneum operitoneum of up to 14-15 mm Hg by insufflating carbon dioxide gas into the peritoneal cavity at the time of insertion of ports. This has the desired effect of raising the abdominal wall away from the viscera giving room to visualise the gall bladder and surrounding organs, allowing manipulation of instruments and also allowing the intestine to fall away from the sub-hepatic space when the patient is positioned properly [14].

However pneum operitoneum with carbon dioxide gas at the pressures commonly used has been shown to be associated with unique and specific side effects. [15, 16]. To negate these specific problems, the concept of low pressure pneum operitoneum with carbon dioxide has been introduced.

Initial studies have indicated that the use of low pressure during pneum operitoneum is associated with better intra-operative tolerance (including anaesthesia tolerance) and improved postoperative recovery with reduced intensity of the surgical pain [17]. Many centres have reported that laparoscopic cholecystectomy performed with low pressure pneum operitoneum resulted in a better postoperative quality of life as compared to laparoscopic cholecystectomy performed with standard pressure pneum operitoneum. [17, 18].

In the present study majority of patients in our study belongs to age group 30- 40 years. 48 (96%) were females while 2 (4%) were males (F>M). As it is seen that gall stones diseases are more common in female population. Similar age and sex distribution seen in other studies like Kanwer, *et al*. and Haribhakti SP, *et al*. [19, 20].

Operating time in low pressure pneum operitoneum is also a concern to the surgeon as more the operating time, more consumption of carbon dioxide and hence higher incidence of shoulder tip pain. Studies have reported longer operating time in low pressure group than the standard group [21, 22]. Similar results were observed in the present study.

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. 2.60 vs. 1.59 days. Studies from meta-analysis also reported the hospital stay to be less in low pressure pneum operitoneum group [23-24].

Conclusion

The present study concluded that an uncomplicated gall stone disease can be treated by low pressure laparoscopic cholecystectomy with reasonable safety. Though surgeon experience operative time is quite high, it is significantly advantageous in terms of post-operative pain, use of analgesics and hospital stay. It is feasible and safe.

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