COMPARATIVE STUDY OF CLINICAL OUTCOME OF LOW PRESSURE VERSUS STANDARD PRESSURE PNEUMOPERITONEUM IN LAPAROSCOPIC CHOLECYSTECTOMY AT BIRAT MEDICAL COLLEGE TEACHING HOSPITAL (BMCTH)

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ABSTRACT

Laparoscopic cholecystectomy at standard pressure pneumoperitoneum (12-15 mmHg of Co2) is standard of practice among surgeons. The increase in intraabdominal pressure by insufflation of carbon dioxide during laparoscopy brings certain changes in function of cardiopulmonary systems and also leads to postoperative pain due to stretching of the diaphragm. To minimise this impact on human physiology there is increasing effort of performing laparoscopic cholecystectomy at low pressure pneumoperitoneum (8mm Hg) however its safety has not been established. This study aims to compare outcomes of laparoscopic cholecystectomy at low pressure pneumoperitoneum versus standard pressure pneumoperitoneum in people undergoing laparoscopic cholecystectomy in terms of intraoperative time, postoperative pain including shoulder tip pain and length of hospital stay.

Methodology

This descriptive randomised prospective study was conducted from Feb 2023 to Aug 2023 in the department of general surgery, BMCTH in patients diagnosed with symptomatic gallstone disease meeting inclusion criteria and willing for laparoscopic cholecystectomy. All patients were prospectively randomized into two groups randomly by the lottery method. A convenient sampling method was used. Group A odd number patients underwent surgery under low pressure (LPPLC group), Group B patients at standard pressure pneumoperitoneum (SPPLC).

Result

A total of 145 patients (114 female and 31 male) with mean age 44.99 years of presentation. 73 patients underwent surgery under LPPLC group and 72 under SPPLC group. Mean pain recorded as per VAS score at 6, 12, 24 and 36 hours postoperatively showed no significant difference in pain among two groups with p value 0.972,0.121, 0.212,0.072 respectively. Shoulder tip pain and additional need of analgesia was significantly less in LPPLC group, p value 0.002 and 0.015 respectively. No significant difference was observed in terms of operating time p value 0.151.Conversion between two groups p value 0.494 suggested no significant difference between two group.

Conclusion

LPPLC is feasible, safe and can be considered over SPPLC. LPPLC is non inferior to SPPLC in terms of postoperative pain including shoulder tip pain and additional need of analgesia.

KEYWORDS

Laparoscopic cholecystectomy; low pressure pneumoperitoneum; standard pressure pneumoperitoneum; shoulder tip pain

INTRODUCTION

Laparoscopic cholecystectomy is the gold standard surgical procedure for symptomatic cholelithiasis.[1] Creation of pneumoperitoneum is essential for laparoscopic procedures to achieve adequate exposure by distention of abdominal wall. Carbon dioxide gas (Co2) insufflation has been established safe and effective in creating pneumoperitoneum.[2] Widely across globe, laparoscopic cholecystectomy is being performed at pressure of 12-16mm Hg of Co2 gas and this has been termed as standard pressure pneumoperitoneum. Pneumoperitoneum maintained at 8 or low (=< 8) mm Hg is considered as low pressure pneumoperitoneum.[3] Co2 insufflation causes stretching of intraperitoneal diaphragm and this causes physiological changes in blood circulation, cardiovascular and respiratory system.[3] Increased intra-abdominal pressure due to the pneumoperitoneum causes several functional cardiopulmonary changes and also leads to postoperative pain. The increased intra-abdominal pressure increases the absorption of CO2, causing hypercapnia and acidosis. It also pushes the diaphragm upwards, decreasing pulmonary compliance, and increases the peak airway pressure. Increased intra-abdominal pressure increases the venous return due to blood compressed out of the splanchnic vasculature.[4] Co2 pneumoperitoneum predisposes to cardiac arrhythmias by decreasing venous return. Co2 insufflation is linked to peritoneal irritation, diaphragm stretching and shoulder tip pain. This uncomfortable pain incidence from 35 to 63 percent and intensity is often strong requiring additional analgesia.[5]

Various efforts are made to lower these effects of Co2 insufflation and very few studies have been on use of low pressure pneumoperitoneum. This study aims to evaluate the outcome of laparoscopic cholecystectomy at low pressure in terms of intraoperative time, postoperative pain including shoulder tip pain and length of hospital stay.

METHODOLOGY

Between Jan 2023 to July 2023, randomized prospective descriptive, cross sectional observational comparative study was conducted in the department of general surgery, BMCTH in patients with diagnosis of symptomatic cholelithiasis who presented in OPD. All patients with symptomatic cholelithiasis willing for surgery and having normal common bile duct on preoperative ultrasound were included in this study. Patients of age group less than 18 years, pregnant and lactating women, having acute inflammation or any other complications of symptomatic cholelithiasis, choledocholithiasis, coexisting liver disease like chronic liver disease, previous abdominal surgery, concomitant significant portal hypertension, uncontrolled coagulopathies, suspected gallbladder carcinoma, cirrhosis, generalized peritonitis and who did not give consent for study were excluded from study.

Patients demographic data, detailed history and clinical examination were recorded at the time of diagnosis. Patients who consented for the study were divided into two groups (Group A and Group B). Patients who were in group A underwent laparoscopic cholecystectomy at low pressure pneumoperitoneum (LPPLC group) and patients under group B underwent laparoscopic cholecystectomy at standard pressure pneumoperitoneum (SPPLC group). Group division was done randomly by the lottery method. A convenient sampling method was used. Study patients were equally divided into two groups and compared. Ethical clearance was taken from the institutional review committee of BMCTH (Ref: IRC-PA-282/2078-79)

All procedures were performed by trained laparoscopic surgeons. Surgeons were aware of the study being done and pressure maintained for pneumoperitoneum. Intraoperative data and finding was noted by resident doctors in a predesigned performa. Patients in both the groups received similar preoperative antibiotics and anesthetic agents for induction and maintenance. In all the patients intraperitoneal access was achieved using trocars and standard four working ports were made. In LPPLC group pressure was maintained at 8 mm Hg and flow rate of 10 mm Hg. In SPPLC group pressure was maintained at 12-15 mm Hg and flow rate of 10-12 mm Hg. After port placement all patients were placed in a moderate 30 degree reverse trendelenburg position. Similar intraoperative and postoperative protocols were followed in both groups including sterilization, instruments handling and suture material. Post operative care and analgesia (intravenous paracetamol 1 gram Q6H) was similar. Inj Ketorol 30 mg iv was given for documented additional requirement of analgesia. Post operative pain was assessed by using visual analog scale (VAS) with the evaluation done at 6, 12, 18, 24 and 48 hours postoperatively. Postoperative ward sisters and patients were not aware of study design.

Data collected were checked thoroughly for completion and error. Data was entered manually in windows excel sheet and coded and recorded digitally using an IBM Statistical Package for the Social Sciences (IBM SPSS Statistics; Armonk, NY, USA) on Windows version 22.0. The chi-square, Fisher's exact tests and cross tabulation were used to compare qualitative data. A p value of < 0.05 was considered statistically significant.

RESULT

A total 145 patients were included in this study of which 114 (78.6%) were female and 31 (21.4%) were male. Mean age of presentation was 44.99 years, lowest being 20 years and elder 81 years. 73 patient in LPPLC group and 72 patients in SPPLC group. Mean operating time in LPPLC group was 54.55 minutes compared to 52.54 minutes in SPPLC with p value 0.151. Overall average operating time was 53.55 minutes. 8 patients in LPPLC group had change of intraoperative pressure to standard pressure due to difficulty in surgery because of intraoperative bleeding, adhesion or both. 3 patients among those (1 female, 2 male) had to be converted to open cholecystectomy patient. In SPPLC group 3 female patients had adhesion and 2 male patient had bleeding intraoperatively resulting in conversion to open cholecystectomy. Conversion to open cholecystectomy was seen in both the groups due to adhesion and bleeding, p value 0.494. Mean pain recorded as per VAS score at 6, 12, 24 and 36 hours postoperatively showed no significant difference in pain among two groups with p value 0.972,0.121,0.212,0.072 respectively.. A total of 18 patients in both group (3 in LPPLC and 15 in SPPLC group) experienced shoulder tip pain, of which 15 (3 and 12 respectively) required additional analgesia. Mean hospital stay in LPPLC

group 3.42 days and SPPLC group was 3.61 days with p value of 0.842 showing no significant difference in hospital stay between two groups.

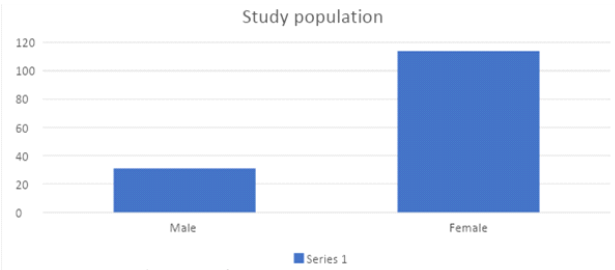

Figure 1: Study population

Table 2 : Co-morbidities and pressure group

Comorbidities	LPPLC group	SPPLC group
Hypertension	11	3
Diabetes Mellitus	5	5
Hypothyroidism	1	4
Coronary artery disease CAD	4	0
COPD	1	1
Hypertension & Diabetes Mellitus	0	2

Table 3 : Intraoperative change of pressure and conversion in LPPLC group

Intraoperative change of pressure from Low pressure group to standard pressure		
Reason	Male	Female
Bleeding	-	4
Adhesion	4 (2*)	1
Bleeding and adhesion both	-	2*

(*) Represents final conversion to open cholecystectomy

Table 4: Conversion to open in both groups

Conversion to open cholecystectomy				
LPPLC group		SPPLC group		P value
Male	Female	Male	Female	0.494
2	1	2	3	

Table 5: Comparison of pain as per VAS score among two groups

Interval	LPPLC group (mean pain as per VAS)	SPPLC group	P value
Pain at 6 hours	6.47	6.69	0.972
Pain at 12 hours	5.11	5.06	0.121
Pain at 24 hours	3.11	3.17	0.212
Pain at 36 hours	2.0	2.04	0.072

Table 6 : Comparison of Shoulder tip pain and need of additional analgesia among two groups

	LPPLC group	SPPLC group	P value
Shoulder tip pain Present	3	15	0.002 *
Additional Analgesia	3	12	0.015*

* p value <0.05 is considered significant

Table 7 : Comparison of hospital stay among both groups

LPPLC group	SPPLC group	P value
3.42 days	3.61 days	0.842

DISCUSSION

Minimal invasive laparoscopic cholecystectomy has revolutionized the treatment for gallstone disease and has been established as gold standard surgery. It allows adequate and appropriate exposure of the surgical field, reduces trauma during access and minimal tissue handling.[6] Postoperative reduction of pain, lesser need of analgesia and early return to work are proven advantages. Traditionally and till date most commonly pneumoperitoneum is created at 14-15mm Hg by insufflation of Co2 gas, as it provides better exposure of surgical field and manipulation of instruments are easier and hence has been a mental comfort to all laparoscopic surgeons, despite knowing facts that pneumoperitoneum at this pressure using Co2 gas has various specific side effects like decreased cardiopulmonary and renal perfusion, decreased stroke volume resulting in increased mean arterial pressure. There has been much less study in regard to breaking this myth and adaptation to low pressure pneumoperitoneum needs more extensive research.

In our study 73 patients subjected to LPPLC group, 8 had intraoperative pressure change to standard pressure. Need to change to standard pressure was due to bleeding and adhesion. 3 patients out of 8 in LPPLC had to be converted to open cholecystectomy despite change to standard pressure due to bleeding and adhesion. These were difficult laparoscopic surgery. In SPPLC group 5 patients were converted to open cholecystectomy because of adhesion and bleeding. No statistical difference was observed between two groups in terms of conversion, p value 0.494. Similar study was done by Yasir M *et al* (2012)[7], Sandhu T *et al* (2008)[8] , Barczynski M (2003)[9] and no statistically significant difference was found between two groups in terms of conversion. There was no comment on intraoperative change of pressure from low pressure to standard pressure in above studies. Intraoperative bleeding and adhesion are important intraoperative reasons for conversion in laparoscopic surgery especially in laparoscopic cholecystectomy.[10] Thapa et al in 2021 conducted similar study and experienced that conversion rate were insignificant (p= 0.64) among both groups, adhesions, bleeding and intraoperative organ injury were reasons for conversion.[11] Decision to convert to open must not be delayed and conversion shouldn't be taken as failure.

In our study mean operating time in LPPLC group was 54.55 minutes compared to 52.54 minutes in SPPLC with p value 0.151 showing no difference. Overall average operating time was 53.55 minutes. Ghosh BC et al in 2021 in their similar study observed no significant difference in operating time among both group.[12] Gohil et al (2018) in his study observed that laparoscopic cholecystectomy at low pressure took on an average 10 minutes longer than standard pressure pneumoperitoneum.[13] Sandhu *et al* and Yasir *et al* observed no significant difference in operating time p value 0.739 and 0. 396 respectively which is consistent with our result.[7,8]

Mean pain recorded as per VAS score at 6, 12, 24 and 36 hours postoperatively showed no significant difference in pain among two groups. A total of 18 patients experienced shoulder tip pain (3 in LPPLC and 15 in SPPLC group) of which 15 required additional analgesia. Shoulder tip pain and need of additional analgesia was comparatively lesser in LPPLC group which was statistically significant p value 0.002 and 0.015 respectively. Sandhu et al also observed no significant difference in mean intensity of postoperative period assessed by similar VAS scale between two groups, p value 0.070. Shoulder tip pain or back pain was also lesser in low pressure pneumoperitoneum group.[8] Yasir *et al* accessed shoulder tip pain on VAS scale and concluded significant reduction of pain in low pneumoperitoneum group p = 0.001, however his study didn't assessed postoperative pain at intervals.[7] Thapa *et al* in their study observed significant reduction in severity and intensity of post operative shoulder tip pain in low pressure pneumoperitoneum group.[11] Our study results are comparable and consistent with Gohil *et al*[13], Ghosh *et al*[12], Sarli L *et al*[14], Barczynski M *et al*.[15] Reduced shoulder tip pain allows adequate postoperative patient ventilation, prevents pulmonary complication leading to early mobilization, shorter hospital stay leading to enhanced functional recovery. Mean hospital stay in LPPLC group 3.42 days and SPPLC group was 3.61 days with p value of 0.842 showing no significant difference in hospital stay between two groups. Sandhu et al, Yasir et al, Thapa et al, Gohil et al, Sarli L et al, Barczybski all showed similar results.

Ortenzi M *et al* in 2022 in their meta analyses and systematic review of low pressure versus standard pressure laparoscopic cholecystectomy included 44 research articles which showed no statistically significant difference between two groups in terms of conversion. Operating time in the standard pressure group was found to be comparatively shorter. Post operative pain at all intervals and shoulder tip pain and need of analgesia was lesser in the low pneumoperitoneum group and this was statistically significant.[16] Our study result complies with meta analysis. Our result is also consistent with similar meta analysis and systematic review by Hua *et al* 2014.[17] Hua et al also concluded that LPPLC is feasible and safe. Postoperative pain including shoulder tip pain and additional need of analgesia are less compared to SPPLC. Both groups have near equal operative time and no significant difference in surgical complications or conversion to open cholecystectomy.

CONCLUSION

From our study we conclude that LPPLC is non inferior to SPPLC and implies significant patient related advantage in terms of postoperative pain including shoulder tip pain and additional need of analgesia. Both have near equal operative time and hospital stay. Conversion to open cholecystectomy in both the groups was similar.

RECOMMENDATIONS

Based on our findings and conclusion we recommend clinical practice of low pressure pneumoperitoneum to be employed to the majority of patients undergoing laparoscopic cholecystectomy until adequate exposure of surgical field is not compromised. Patient related benefits are more with use of low pressure pneumoperitoneum.

LIMITATIONS OF THE STUDY

We have limited sample size due to time bound duration of the study so we encourage further study into this . Also this study is single centre study and different surgeons for the procedure were also our limitations.

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CONFLICT OF INTEREST

We have no conflict of interest to declare for this research work.

FINANCIAL DISCLOSURE

We disclose no financial support for this research work.

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