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Research Paper

Outcome Analysis of Low Pressure versus Standard Pressure Pneumoperitoneum on Operative Difficulty and Complications in Laparoscopic Cholecystectomy – A non-randomized clinical study

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ABSTRACT
Background and Objective:*With the establishment of laparoscopic cholecystectomy as gold standard management of cholelithiasis, the current stress is on increasing patient safety and reducing the postoperative morbidity associated with this procedure. Hence, this study was undertaken to compare the effect of low pressure pneumoperitoneum (LPP - 9 mm Hg) versus standard pressure pneumoperitoneum (SPP - 12 mm Hg) in a prospective non randomized manner on postoperative shoulder tip pain, operative difficulty and the perioperative complications.*
Materials and Methods:*Forty patients undergoing laparoscopic cholecystectomy were divided into the LPP (9 mm Hg) group (n=20) and the SPP (14 mm Hg) group (n=20) in a prospective non randomized manner. Total duration of surgery, intra-operative gas consumption, occurrence of bile spillage during operation, shoulder tip pain in postoperative period, amount of analgesia required in postoperative period and tolerance to early oral feeding were assessed.*
Results:*There was no significant difference in terms of operative duration, consumption of CO2 gas, surgeon's operative difficulty, intraoperative bile spillage, total hospital stay and tolerance to early feeding.*
Comparing statistically the incidence of shoulder pain was higher in patients who underwent SPP laparoscopic cholecystectomy ($p<0.05$). Mean requirement of intramuscular diclofenac sodium for effective pain control was significantly lower in LPP in the 24-h postoperative period ($p<0.0.5$) however there was no statistical difference in total analgesic dosage calculated in the two groups.
Conclusion:*Low-pressure pneumoperitoneum is feasible and safe and results in reduced postoperative shoulder tip pain and near-equal operative time compared with standard-pressure pneumoperitoneum.*

I. INTRODUCTION

Adequate working space is a major requirement in every surgery and its abdomen is a closed space while performing any laparoscopic procedure, this assumes a top requisite for better ergonomics and patient safety. With the introduction of pneumoperitoneum as one of the methods to create abdominal working space, it has resulted in a big advancement in the field of minimal invasive surgery. Pneumoperitoneum for laparoscopic cholecystectomy is most often created by insufflating carbon dioxide gas into the peritoneal cavity and then holding it at constant pressure till the end of surgery when it is released at the time of withdrawal of the ports. [1] Literature is abundant that standard pressure pneumoperitoneum, employing a pressure range of 12-14 mm

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Hg, over prolonged periods has been associated with adverse effects such as decreased pulmonary compliance, altered blood gas parameters, impaired functioning of the circulatory system, raised liver enzymes and renal dysfunction and even increased intra-abdominal venous pressures. [2-6] Therefore a rising trend has been the use of low pressures for pneumoperitoneum in the range of 8-10 mm Hg 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 pneumoperitoneum appear to be lower incidence of shoulder tip pain in the postoperative period and also better quality of life in post operative 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. [7-14]

This study proposes to compare the use of the low pressure pneumoperitoneum (LPP defined as 9 mm Hg) with the use of standard pressure pneumoperitoneum (SPP defined as 14 mm Hg) in patients undergoing laparoscopic cholecystectomy in a prospective non randomized manner. The main areas of interest will be the operative duration, intraoperative gas consumption and bile spillage, postoperative course especially pain scores and amount of analgesia required.

II. METHODS

The study was carried out in the Department of General Surgery in the tertiary care hospital of one of the medical university in India, over a period of 12 months duration. All consecutive patients with uncomplicated symptomatic gallstone disease and ASA Grade I and II tagged for laparoscopic cholecystectomy were included in the study. Exclusion criteria included ASA grade > = III, BMI >30 kg/m2, history of ERCP and stent in situ, known shoulder disease, empyema gallbladder, prior history of acute cholecystitis, cholangitis and pancreatitis, history of multiple abdominal surgery, coagulopathy, significant co-morbidities like coronary artery disease, asthma, COPD, and previous malignancy, patients requiring other concomitant procedures, patients who do not give consent for participation in the study or patient with cognitive impairments and patients on chronic analgesic use or history of addiction to alcohol. Ethical clearance from the Institute Ethics Committee was taken. The details of procedure were explained and informed consent taken before enrolment.

The study was done in a nonrandomized prospective manner with a sample size of 40 patients. Patients were divided into two groups as per surgeon preference. The general anesthetic protocol was the same for both groups. One group with 20 patients underwent laparoscopic cholecystectomy with standard pressure pneumoperitoneum (SPP) at 14 mm Hg while the other group with 20 patients underwent laparoscopic cholecystectomy with low pressure pneumoperitoneum (LPP) at 9 mm Hg. A single experienced consultant surgeon performed all surgeries. During the surgery in both groups the first port was inserted at a pressure of 14 mm Hg. In the SPP group, the pressure was taken up to 14 mm Hg whilst in the LPP group the pressure was reduced to 9 mm Hg for the rest of intra-operative period. A standard laparoscopic cholecystectomy was performed according to the European 'four puncture' technique described by Dubois et al. Intra-operative monitoring was performed by monitoring heart rate and blood pressure non-invasively every 5 minutes. Closure of the rectus sheath was done at 10 mm ports at the umbilicus site and at the epigastric site using port Vicryl 2-0 suture. Skin was approximated at all the port sites using Nylon 3-0 suture.

Postoperative analgesia was administered in the form of intramuscular diclofenac sodium (1 ampule = 75mg diclofenac) 12-hour postoperative period with additional doses where necessary. Patients were encouraged for early ambulation and were allowed oral intake six hours after surgery or return of bowel sounds whichever was earlier. They were discharged on day one following surgery in postoperative period.

For comparison between groups special attention was paid on following outcomes:

1. Total duration of surgery
2. Intra-operative gas consumption
3. The occurrence of bile spillage during operation
4. The shoulder tip pain in postoperative period
5. Amount of analgesia required in postoperative period
6. Tolerance to early oral feeding

The degree of post-operative shoulder tip pain was assessed by a nurse attendant who was blinded to the operative technique by means of a visual analog scale at 1, 3, 6, 12, 24 and 48 hours thereafter. If discharge was early (i.e. before 48 hours) then the patients were consulted on phone. The timing of administering the VAS was not adjusted for patients receiving intravenous post-operative analgesics. The pain scale, with scores ranging from 0 (no pain) to 10 (unbearable) pain, was constructed without numeration, allowing patients to mark a point along the scale that best served to analyze the presence and intensity of shoulder-tip pain alone and was not a representation of generalized post operative discomfort. Analgesic requirements of all patients in the

postoperative period and length of post-operative hospital stay were also recorded.
Statistical analysis was carried out using the chi-square and independent student t tests. A p value <0.05 was taken as statistically significant.

III. RESULTS

There was no difference in patients in the two groups in term of age, sex, body weight and height (Table 1). Conversion to open surgery was none in both the groups. Laparoscopic cholecystectomy with SPP took an average of 43.25 ± 7.85 minutes (range 45-75 minutes). Laparoscopic cholecystectomy with LPP took an average of 45.75 ± 6.78 minutes (range 45-90 minutes). LPP laparoscopic cholecystectomy took on average two minutes more than SPP laparoscopic cholecystectomy but this difference was not statistically significant (p>0.05). However, mean consumption of CO2 gas was less in LPP compared to SPP laparoscopic cholecystectomy with no statistical difference (102 ± 11.5 liters v/s 108 ± 14.5 liters; p>0.05)

Comparing surgeon's operative difficulty between the two groups, there was no significant difference in terms of visualization, grasping and dissection at Calot's triangle. There was no statistical difference in terms of bile spillage and total hospital stay in between the groups.

Three patients (15%) who underwent LPP laparoscopic cholecystectomy and nine patients (45%) who underwent SPP laparoscopic cholecystectomy had postoperative shoulder tip pain at any point in time during the peri-operative period. Amongst these right-sided shoulder tip pain occurred in 10 patients and pain on both sides, moving from one shoulder to the other in 2 patients. Comparing statistically the incidence of shoulder pain was higher in patients who underwent SPP laparoscopic cholecystectomy (p<0.05). Shoulder tip pain started after a mean interval of 3 hours postoperatively and peaked in both the groups at 12 hours with significant improvement after this time. The frequency of shoulder-tip pain was significantly lower in patients with LPP laparoscopic cholecystectomy at 6, 12, 24 and 48 hours in the postoperative period. Pain scores as recorded on VAS revealed that postoperative shoulder-tip pain was significantly less intense at 12 and 24 hours in the LPP group. Mean scores approached zero in LPP laparoscopic cholecystectomy at end of postoperative period whereas in patients underwent SPP laparoscopic cholecystectomy still reported comparative higher score.

Half of the patients undergoing LPP laparoscopic cholecystectomy and one fourth of patients undergoing SPP laparoscopic cholecystectomy did not require any analgesic medication in the postoperative period. Mean requirement of intramuscular diclofenac sodium for effective pain control was significantly lower in LPP laparoscopic cholecystectomy in the 24-h postoperative period (p<0.0.5) however there was no statistical difference in total analgesic dosage calculated in the two groups. There was no significant difference between tolerance to early oral feeding except the numbers were more for patients undergoing LPP laparoscopic cholecystectomy. (p>0.05)

IV. DISCUSSION

With the establishment of laparoscopic cholecystectomy as gold standard for the management of cholelithiasis, there has been a series of untiring efforts to evolve and increase its safety. The aim has been to reduce the trauma especially during access, increasing surgeon and patient satisfaction and decreasing operative difficulty during the procedure. [1] Attention focused towards reduction of pain, improved early postoperative recovery, early return to work and better quality of life.

The traditional teaching has been to create a pneumoperitoneum with a SPP of 14-16 mm Hg by insufflating carbon dioxide into the peritoneal cavity before the insertion of ports. The added advantage was the raised abdominal wall and creating an iatrogenic space for proper visualization of gallbladder along with surrounding organs and adequate enough to manipulate laparoscopic instruments with ease. However pneumoperitoneum with carbon dioxide gas at the pressures commonly used has been shown to be associated with unique and specific side effects both in intraoperative and postoperative period. [2-6] To negate these specific problems, the idea of LPP with carbon dioxide was introduced. Research studies have indicated that the use of LPP is associated with better intra-operative tolerance (including anesthesia tolerance) and improved postoperative recovery with reduced intensity of the surgical pain. Various authors have reported that laparoscopic cholecystectomy performed with LPP resulted in a better postoperative quality of life as compared to laparoscopic cholecystectomy performed with SPP. [7-18]

Postoperative pain following laparoscopic cholecystectomy is related to a number of factors like tissue injury at port site insertion and gallbladder dissection or peritoneal stretch, diaphragmatic stretch and chemical irritation of the peritoneum by pneumoperitoneum due to carbon dioxide. Apart from generalized postoperative discomfort shoulder tip pain is a common cause of morbidity following laparoscopic cholecystectomy with a reported incidence of 30-50%. [14] Published literature has reported that the incidence and intensity of postoperative shoulder tip pain was significantly less in the patients undergoing LPP laparoscopic cholecystectomy when compared to ones undergoing SPP laparoscopic cholecystectomy. [14,18] Our study also shows significant low frequency of shoulder tip pain in LPP group. Low consumption of CO2 gas in LPP group

resulting in reduced stretching of diaphragmatic and visceral peritoneum might have helped in minimizing shoulder tip pain and generalized postoperative abdominal discomfort which needs to be substantiated by further studies.

Several researches including different intraoperative techniques like saline washing, intraperitoneal aesthetic application and perioperative analgesics combinations have been conducted to find out ways to reduce the frequency and intensity of shoulder tip pain. [19] The results of our study demonstrates the effectiveness in reducing this morbidity by simply reducing the pneumoperitoneum pressures to low values ~ 9mm Hg. Shoulder tip pain started after a mean interval of 3 hours postoperatively and peaked in both the groups at 12 hours with significant improvement after this time. Intensity as validated by calculating pain scores using VAS revealed that postoperative shoulder-tip pain was significantly less intense at 12 and 24 hours in the LPP group with all patients becoming symptom free as early as 48 hours after surgery. Various randomized trials published so far also the same observations but according to a recent Cochrane review are plagued with a high risk of bias. [20]
Although the pain scores differed between the two groups, quite a few patients who did not require any analgesic medications existed in both groups. This may point out that a large number of patients in postoperative period may require analgesics for causes other than shoulder tip pain which creates an avenue for adopting methods to further improve quality of life in postoperative period. Also patients with LPP laparoscopic cholecystectomy consumed significantly lower doses of analgesic for effective pain control. Published literature also supports that incidence and intensity of postoperative pain is significantly lower in LPP with fewer requirements of analgesics in the postoperative period. [7-18] Surgeon's satisfaction in terms of visualization, grasping and dissection at Calot's triangle matched in both groups with no statistical difference in terms of bile spillage and total hospital stay. LPP also showed improved tolerance to early oral feeding and it might be hypothesized that low gas consumption may result in less nausea due to reduced diaphragm stretching.
Small sample size forms a limitation of this study. A recent systematic review also concluded that the recommendation to use low-pressure pneumoperitoneum during laparoscopy is weak, and more studies are required. [21]

V. CONCLUSION

Low-pressure pneumoperitoneum is feasible and safe and results in reduced postoperative pain and near-equal operative time compared with standard-pressure pneumoperitoneum. More studies with a larger sample size are required to compare overall quality of life between the two groups.

Conflicts of Interest: None (of all authors)

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Table 1: Baseline characteristics of two groups

Characteristic	LPP (n=20)	SPP (n=20)	P value
Age (mean_sd) (yrs)	33.3_11.6	32.5_9.5	ns
Sex (M:F)	6:14	6:14	ns
Weight (kgs) (mean_sd)	48.5_5.2	49.6_6.1	ns
Height (cm) (mean_sd)	158.6_9.2	157.3_13.5	ns

Table 2: Comparison of outcome variables between two groups

Characteristic	LPP (n=20)	SPP (n=20)	P value
Operative Difficulty			
Visualization Good/Easy Poor/Difficult	 18(90%) 02(10%)	 19(95%) 01(5%)	ns
Grasping Good/Easy Poor/Difficult	 17(85%) 03(15%)	 18(80%) 02(20%)	ns
Dissection Good/Easy Poor/Difficult	 14(70%) 06(30%)	 12(60%) 08(40%)	ns
Bile Spillage			
Yes	03(15%)	02(10%)	ns
No	17(85%)	18(80%)	
Total Gas Consumption (in liters)			
Mean_sd	102_11.5	108_14.5	ns
Total Duration of Surgery (in minutes)			
Mean_sd	45.6_6.8	43.3_7.9	ns
Total Duration of hospital stay (in days)			
Mean_sd	1.8_0.6	1.9_0.6	ns
Shoulder Tip Pain			
Yes	03(15%)	09(45%)	<0.05
No	17(85%)	11(55%)	
Pain frequency at various time interval			
1hour	0	0	-
3 hours	3	9	<0.05
6 hours	3	9	<0.05
12 hours	3	9	<0.05
24 hours	3	9	<0.05
48 hours	0	9	-
Analgesic Consumption (mg/day)			
0 mg/day	10 (50%)	05 (25%)	ns
75-150 mg/day	07 (35%	05 (25%)	ns
>225 mg/day	03 (15%)	10 (50%)	<0.05
Mean dose (mg/day)	120_125.03	189.5_129.9	ns
Tolerance to early feeding (Postoperative day – POD)			
POD 0/1	18 (90%)	16 (80%)	ns
POD 2	02 (10%)	04 (20%)	