Randomized Controlled Trial of lower pressure pneumoperitoneum in reducing shoulder tip pain after elective laparoscopic cholecystectomy

Dr. Sandeep Yeleti, DNB General Surgery, senior resident
Dr. Jayanta K.Das, MS, Senior consultant, Department of general surgery.
Dr. Gordon Rangad, MS Senior consultant and head of the department, Department of general surgery.
Nazareth Hospital, Shillong. Meghalaya, India

Abstract: Laparoscopic cholecystectomy is commonly used for cholelithiasis but Post-operative shoulder pain is one of the most frequent complaints, leading to delayed recovery. The shoulder pain may be derived from multiple sources including the pressure created by the pneumoperitoneum, Several studies have explored the concept of using lower pressures but the findings varied .A randomized double blind controlled clinical trial was done at Nazareth hospital, Shillong, Meghalaya state during 2015 comparing the superiority and advantages of using low-pressure pneumoperitoneum with standard(normal) pressure pneumoperitoneum. Based on specific criteria for inclusion and exclusion all eligible patients of 18-65 years of age, of ASA physical status I and II, with a diagnosis of chronic calculus Cholecystitis or Cholelithiasis and scheduled to undergo elective laparoscopic cholecystectomy were screened and included after informed consent . 122 Patients were randomly allocated based on a confidential list, 62 in the standard(normal) pressure group(12-14 mmHg) and 60 in the low pressure group(7-10 mmHg).CONSORT guidelines for randomized controlled trials were strictly followed. Acute postoperative shoulder tip pain both at rest and during movement were assessed using Visual Analogue Scale(VAS)at 0, 1, 2, 4, 6 and 24 hours postoperatively. Using a lower pressure of the pneumoperitoneum(7-10 mmHg) resulted in a significant reduction in both the frequency and the severity of postoperative shoulder tip pain as compared to standard(normal) pressures of 12-14 mmHg. Decreased the analgesic demand, reduced the hospital stay and improved the quality of life in the early stage of postoperative rehabilitation(246 words)

Keywords: Laparoscopic Cholecystectomy, Shoulder pain, pneumoperitoneum
Short running title: Laparoscopic Cholecystectomy and Shoulder Pain

Introduction

Laparoscopic cholecystectomy is most commonly used treatment modality for cholelithiasis(Holohan,199). Post-operative shoulder pain after laparoscopic cholecystec-tomy is one of the most frequent complaints which leads to delayed recovery of the patient(Bisguard et al, 2001). The painmay be derived from multiple sources such as incision pain (somatic), deep intra-abdominal pain (visceral), and shoulder pain (visceral pain due to phrenic nerve irritation)(Jorgensen et al, 1995). Other factors may influence the degree of pain after pressure created by the pneumoperitoneum, and the temperature of insufflated gas(Slim et al,1999), including.the pressure of carbondioxide used for creating pneumoperitoneum for a laparoscopic procedure(Berberoglu et al, 1998).

Standard pressure pneumoperitoneum for laparoscopic cholecystectomy employs a pressure range of 12-14 mm Hg (Yasiret, 2012). An emerging trend has been the use of low-pressure pneumoperitoneum in the range of 7-10 mm Hg in an attempt to lower the impact of pneumoperitoneum on the human physiology while providing adequate working space(Jorgensen et al,1995).Several studies have explored this concept but the findings varied (Sarli et al,2000;Barczynski,2003;Kanwer et al, 2009;Yasir et, 2012). In order to confirm the superiority of using low pressures in reducing shoulder tip pain, arandomized double blind controlled clinical trial(Moher et al, 2001)was carried out at a tertiary hospital in Meghalaya state in northeastern India during 2015 comparing the use of low-pressure pneumoperitoneum with standard pressure pneumoperitoneumIt was also proposed to compare the duration of surgery between the two groups, . the percentage of laparoscopic cholecystectomies that are converted to open cholecystectomy in both the groups, incidence of. Intraoperative or postoperative complications, and. the satisfaction of operating surgeon while performing laparoscopic cholecystectomy.

Material and Methods

The setting for the study was theGeneral Surgery department of Nazareth hospital, Shillong,Meghalaya state in northeastern India, established in 1959
Annually over 5000 surgeries are done.The hospital treats about 150,000 outpatients each year and admits nearly 20,000 inpatients. There are 10 medical specialists including8 surgeons, 100 nurses and over550 allied health personnel. The hospital is fully equipped with state of the art diagnostic and therapeutic equipment,awell organized ICU and laboratories.
The target population for this trial included all patients of 18-65 years of age, of ASA physical status I and II, admitted to hospital with a diagnosis of chronic calculus Cholecystitis or Cholelithiasis and who are scheduled to undergo elective laparoscopic cholecystectomy . Patients with known sensitivity to study drugs, any history of severe cardiac, renal, hepatic and respiratory disease,Patients on chronic pain medication, anticonvulsant or antidepressant were excluded. Further, those with acute Cholecystitis and acute pain.common bile duct stone or Body mass index >30 kg/m2.were also excluded. Informed written consent was taken after explaining the need and importance of the study prior to filling of the patient's Proforma. A general and systemic examination

and Visual analogue scale for shoulder pain done. Ethical approval was obtained from the Institutional Ethical Committee of Nazareth Hospital, Shillong.
Assuming the low pressure group will reduce the shoulder tip pain by at least 50% in the normal pressure group, with type 1 error of 5%,power of 80% and precision of 20%, the minimum sample size in each group was estimated as 60 patients.

The eligible patients were assigned into two groups based on a confidential list of random allocation:
Group 1: Laparoscopic cholecystectomy done at an intra-abdominal pressure
of 7-10 mmHg(Low).
Group 2: Laparoscopic cholecystectomy done at intra-abdominal pressure
of 12-14 mmHg (Normal)
One doctor or a nurse who is not a part of the study monitored and maintained intra-abdominal pressure. The operating surgeon was unaware of the intra-abdominal pressure. The patient, investigator and outcome assessor were also not aware of the pressures used.
All patients underwent USG of the abdomen and were diagnosed as chronic calculus cholecystitis/cholelithiasis. Preoperative anesthetic check up was done and patients were assigned ASA status. And all patients who were ASA status I and II were included in this study.
In the preoperative ward, all patients were instructed on the proper use of Visual analogue scale (VAS) on a 10cm scale. General anesthesia was induced as per the standard anesthesia protocol of the hospital. Injection Ondansetron 4 mg and injection Ranitidine 50 mg IV were given at induction of anesthesia to prevent post-operative nausea and vomiting.
The surgeries were performed by four experienced consultant surgeons. During the surgery, the ports were inserted at a pressure of 14 mm Hg. In the conventional pressure group, the pressure was maintained at 12-14 mm Hg whilst in the low-pressure group, the pressure was reduced to 7-10 mm Hg for the remaining duration of surgery. Standard laparoscopic cholecystectomies were performed with the insertion of four ports at the start of surgery. Intra-operative monitoring was performed by monitoring heart rate, non-invasive blood pressure, end tidal carbon dioxide, oxygen saturation, ECG and peak inspiratory pressure. Closure of the rectus sheath was done at 10 mm ports using coated polyglactin sutures. Skin was approximated at all the port sites using non-absorbable suture. In the case of difficulty, operating surgeon converted to open cholecystectomy at his own discretion. At the end of surgery, the surgeon was asked to grade his level of satisfaction in following scale where 1= disappointed, 2= not very satisfied, 3= satisfied, 4= very satisfied.
Injection Ketorolac 30 mg IM were given before extubation. After adequate recovery, the trachea was extubated and patients were shifted to the post-operative care unit (POCU).

Acute postoperative shoulder tip pain both at rest and during movement were assessed using VAS on which 0 indicates “no pain” and 10 represents “worst imaginable pain”. The patient was instructed to move side way for pain assessment during movement. Pain score was recorded at 0, 1, 2, 4, 6 and 24 hours postoperatively, where 0 indicates arrival at POCU. Injection Diclofenac aqueous form 75 mg IV at 8 hours after the surgery was given as post-operative analgesia. For any patient who asks for more analgesic, injection Tramadol 100 mg was given as a rescue analgesic. Injection tramadol was diluted with 10 ml of normal saline and administered IV over 2 minutes.
The primary outcome was the severity of shoulder tip pain at rest in terms of VAS and postoperative VAS at rest and during deep breathing or coughing or movement. Duration of surgery, the rate of conversion to open cholecystectomy, the level of surgeon satisfaction and incidence of any operating complications were secondary outcomes.
All data were entered on the Research proforma, transferred to Microsoft excel sheets and analysedusing SPSS software

Results
A total of 122 patients were included in the present study. 62 patients(4 male,58 female) randomly allocated to low-pressure group and 60 patients(7 male, 53 female) to normal pressure group
Baseline characteristics
As shown in Table 1, the two groups were similar with regard to major baseline characteristics

TABLE 1

Comparison of the other parameters between the two groups are now presented
Duration of surgery
The mean duration of laparoscopic cholecystectomy in our hospital was 61.92 ± 8.249 minutes, with most of the surgeries taking 60 minutes. There is no significant difference between the duration of surgery in both the groups (*p*-value 0.85).
Satisfaction of Surgeon
Surgeon\s satisfaction was not significantly different between the 2 groups; 2 cases (3.2%) in low pressure group and 1 case (1.7%)in the normal group was not satisfied;
Operating complications
Only 3.2% in low pressure group and 3.3% in normal group(2 cases in each) were converted to open surgery, the difference not statistically significant(p=0.97)
There were no operating complications in 90% of normal and 91.9% of low pressure group, the difference not statistically significant(p=0.97). The main complication was bleeding and lack of anatomical clarity
Postoperative Shoulder tip pain:

The shoulder pain scores assessed through Visual Analogue Scale (VAS) postoperatively for patients in low and normal pressure groups at rest {(mean (SD)} are presented in Table 2.

TABLE 2
The mean VAS was significantly less in low pressure group when assessed at rest at 2,4,6 hours postoperatively (p-value was 0.014 at 2 hours, p-value was <0.001 at 4 and 6 hours postoperatively).
The shoulder pain scores assessed through Visual Analogue Scale (VAS) postoperatively for patients in low and normal pressure groups at movement {(mean (SD)} are given in Table 3
TABLE 3
As at rest, the mean VAS was significantly less in low pressure group when assessed at movement at 2, 4, 6 hours postoperatively (p-value was 0.035 at 2 hours and p-value was <0.001 at 4, 6 hours postoperatively). Thus, the shoulder tip pain was not significantly different between low pressure group and normal pressure group when assessed both at rest and at movement at 0,1,24 hours postoperatively, but at 2, 4 and 6 hours the shoulder tip pain was significantly higher both in frequency and intensity in normal(standard) pressure group compared low pressure group.

Discussion

Laparoscopic cholecystectomy is the gold standard in the management of symptomatic gallstone disease(Holohan,1991). Insufflation of carbon dioxide during laparoscopic cholecystectomy is presumed to postoperative shoulder tip pain and causes delay in recovery of patients undergoing laparoscopic cholecystectomy(Atak et al, 2011). The origin of shoulder pain is commonly assumed to be due to overstretching of the diaphragmatic muscle fibers owing to a high carbon dioxide pressure6.Globally several trials were conducted to test the superiority of low pressure pneumoperitoneum in reducing or preventing shoulder tip pain(Suginami et al ,2009;Sandoz-JIminez et al, 2009;Sandhu et al, 2009;). While most of these studies confirmed the benefits of low pressures, the findings varied and were not consistent. Other methods for reducing postoperative shoulder pain by using intraoperative magnesium sulphateinfusion(Mentes et al, 2008),or bupivacaine irrigation(Cunniffe et al,1998) were tried with limited success. Esmat et al (2006) combined low pressure pneumoperitoneum with intraperitoneal infusion of normal saline to reduce shoulder tip pain. In the present trial , the methodology was kept simple using low pressures compared to standard (normal) pressures and strictly following the consort guidelines(Moher et al2001) ensuring objective assessments using standardized tools and blinding of patients, surgeons and all investigators involved in measuring various parameters. However it was not possible to control other parameters such as surgical procedures, or patient profiles and postoperative care, which may require larger numbers. The trial was designed to make the low pressure group and standard(normal) pressure group as comparable as possible(Table 1) and the double blinding ensured reasonable objectivity of the measurements, especially the incidence, timing and severity of shoulder tip pain.(Tables 2& 3)Both the patients as well as the surgeons were satisfied with the procedures and recovery with minimal complications. Futureresearch may be useful to further reduce the incidence or even comp0letely eliminate this complication apart from lowering pressures.

Conclusions
Using a lower pressure of the pneumoperitoneum(7-10 mmHg) results in a significant reduction in both the frequency and the severity of postoperative shoulder tip pain as compared to standard(normal) pressures of 12-14 mmHg. Although the debate is going on whether the low pressure is safe, in this present study the operating complications like bleeding and difficult anatomy were extremely low and almost equally distributed in both the groups. Surgeon's satisfaction level and duration of surgery were almost similar in both the groups. The small number of cases converted to open surgery were mainly due to difficult anatomy and not due to the pressures itself. Using low pressure pneumoperitoneum decreases the analgesic demand, reduces the hospital stay and hence improves the quality of life in the early stage of postoperative rehabilitation.

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Table 1: Baseline Characteristics In The Two Groups

CHARACTERISTIC		Low(n=62)	Normal(n=60)	p
Gender:	Female (%)	58(93.5%)	53(88.3%)	0.359
	Male (%)	4(6.5%)	7(11.7%)	
Age:	Mean(SD) years	45.21 (9.98)	44.57(10.62)	0.732
Mean BMI (SD) in Kg/m2		23.21(2.65)	22.81(2.72)	0.412
Preoperative BP in mmHg:Systolic(SD)		121.66(12.13)	119.95(11.55)	0.42
	Diastolic(SD)	80.77(8.649)	80.45(9.736)	0.84
Preoperative H.R(SD)in beats/min		83.00(11.839)	80.68(11.266)	0.26
Preoperative respiratory rate (SD) in breaths/min		18.55(2.109)	18.22(2.210)	0.39

Table 2: Visual Analogue Scale (VAS) shoulder pain scores at rest {mean(SD)} in low and normal pressure groups

Postoperative assessment time in hours	Low pressure	Normal pressure
	m±SD	m±SD
0	0.33±0.475	0.40±0.493
1	0.47±0.503	0.52±0.504
2	0.45±0.502	0.67±0.473
4	0.50±0.504	1.29±0.496
6	0.47±0.503	1.10±0.360
24	0.15±0.360	0.21±0.409

TABLE 3: Visual Analogue Scale (VAS) shoulder pain scores at movement {(mean (SD)} in low and normal pressure groups

Postoperative assessment time in hours	Low pressure	Normal pressure
	m±SD	m±SD
0	0.28±0.454	0.29±0.459
1	0.52±0.504	0.67±0.473
2	0.48±0.504	0.67±0.473
4	0.70±0.497	1.66±0.762
6	0.55±0.502	1.16±0.644
24	0.12±0.324	0.22±0.421