



## A STUDY OF EFFECT OF PLACEMENT OF 0.5% BUPIVACAINE SOAKED SURGICEL IN GALLBLADDER BED ON PAIN RELIEF FOLLOWING LAPAROSCOPIC CHOLECYSTECTOMY

**Dr. Saurabh Purohit**

Assistant Professor, Department of Surgery, M.L.B. Medical College, Jhansi.

**Dr. Pankaj Kumar  
Saunakiya\***

Assistant Professor, Department of Surgery, M.L.B. Medical College, Jhansi.  
\*Corresponding Author

### ABSTRACT

Pain following cholecystectomy although significantly less with laparoscopic approach still remains prime concern in most patients. The aim of this double blind prospective randomized controlled study was to assess the character of pain after laparoscopic cholecystectomy and its relief following 0.5% Bupivacaine soaked surgicel placement on to the gallbladder bed, compared with port-site infiltration with 0.5% bupivacaine.

**PATIENTS AND METHODS:** Sixty symptomatic patients with uncomplicated gall stone disease of both genders, who underwent laparoscopic cholecystectomy, included in to an institutional ethic committee approved protocol from November 2016 to April 2018 for the proposed study. Patients were divided in to two groups of 30 each: test group A (0.5% Bupivacaine soaked surgicel kept in gall bladder bed) and control group B (infiltration of 0.5% bupivacaine at port-sites after wound closure). The character of pain was noted after laparoscopic cholecystectomy and its relief was assessed with Visual analog scale (VAS) scoring.

**RESULTS:** Results showed that overall 60% patients felt visceral pain, while 56.70% and 8.33% patients experienced parietal and shoulder pain respectively. After placing the Bupivacaine soaked surgicel in gallbladder bed in test group A patients, the visceral pain was significantly less than control group B and no one experienced shoulder pain. Group B patients felt significantly less parietal pain after port-site infiltration of 0.5% Bupivacaine when compared to group A, however they experienced visceral and shoulder pain more. A significant difference ( $p < 0.001$ ) in the mean VAS score found at 4hrs, 8hrs, and 24 hrs between the two groups.

**CONCLUSION:** From this study, we concluded that the overall incidence of visceral pain was more than parietal pain and 0.5% Bupivacaine soaked surgicel in gall bladder bed alone was effective in controlling both visceral and shoulder pain after laparoscopic cholecystectomy; however port-site infiltration of 0.5% Bupivacaine was effective in relieving parietal pain only.

**KEYWORDS :** Laparoscopic cholecystectomy, Bupivacaine, postoperative pain relief, visual analog scale (VAS) score.

### INTRODUCTION

Laparoscopic cholecystectomy was adopted rapidly around the world, and has subsequently been recognized as the new gold standard for the treatment of gall stone disease<sup>(1-2)</sup> with the advantages of early return of bowel function, decreased post operative pain, improved cosmesis, shorter hospital stay, early return of full activity, and decreased all over cost<sup>(3-7)</sup>.

First 24 hours of post operative period is crucial during which the patient experiences maximum pain. Pain is mainly of three types, namely, visceral, parietal and shoulder pain that have different intensities and their own time courses<sup>(8-9)</sup>. Visceral pain is more prominent than parietal pain after laparoscopic cholecystectomy<sup>(9)</sup>, which may refer to the shoulder in 35% to 60% of cases<sup>(10-11)</sup>. Visceral pain is cramping in nature, diffuse, periodic, poorly localized and having no dermatomal pattern. It accounts for most of the discomfort experienced in the early postoperative period and its intensity increases quickly after the first 24 hours of surgery<sup>(8-9)</sup> which may be attributable to greater surgical handling of the dissection area<sup>(8)</sup>. Parietal pain is tearing or crushing in character, sharp, well localized and follows a dermatomal pattern, which is less intense than visceral pain, owing to the small abdominal incisions and limited damage to the abdominal wall<sup>(8-9)</sup>. Shoulder tip pain is a referred pain from traumatized gall bladder bed area which may be due to phrenic nerve, which supplies the gall bladder, porta-hepatis, and liver, while sharing the root of nerves to the shoulder<sup>(8, 12)</sup>. It is insignificant during the first postoperative hours, increases thereafter to become the main complaint on the second day of surgery<sup>(8)</sup>. The most common location of pain is in the right upper quadrant, followed by the port site and the shoulder respectively<sup>(8)</sup>.

The visual analog scale is a simple, objective and reproducible method of quantifying pain. The beginning of ten centimetre line represents no pain (0 mark) and the end of the line represents maximum pain (100 marks). This should be done at the initial assessment and during treatment to monitor the effectiveness of the intervention.

Bupivacaine (Sensoricaine) has long duration of action, high potency, and low incidence of hypersensitivity reactions<sup>(13)</sup>. With optimal characteristics for post operative pain reduction, Bupivacaine is commonly used to infiltrate the port sites after laparoscopic procedures. The recommended dose for infiltration is a maximum of 2mg/kg<sup>(14)</sup>. It has serum half life of 3 hours, but persists for a longer time in the tissues after local infiltration, with a clinical effect lasting 7-14 hours<sup>(15)</sup>.

Surgicel (Johnson and Johnson, India) absorbs a large volume of liquid and causes vasoconstriction by low pH value. It provides enlarged matrix for platelet adhesions with advantage of fast absorption and simple handling, having bactericidal activity with less allergic potentials. It is being used widely in laparoscopic cholecystectomy for haemostasis also.

### AIMS AND OBJECTIVES

The aim of this prospective randomized study was to assess the character of post cholecystectomy pain and to evaluate the efficacy of 0.5% Bupivacaine soaked surgicel kept in the gall bladder bed as well as port site infiltration of 0.5% bupivacaine after incision closure for postoperative pain relief.

### MATERIALS AND METHOD

The proposed study conducted in the department of General surgery, Maharani Laxmibai Medical College, Jhansi from November 2016 to April 2018 after approval from institutional ethic committee.

**Selection of patient-** sixty patients of symptomatic gall stone disease admitted and evaluated for elective laparoscopic cholecystectomy. They underwent diagnostic abdominal ultrasound, routine investigations (complete blood count, random blood sugar, liver function test, kidney function test, serum electrolytes, coagulation profile, total protein and serum albumin), which were within normal limits. All the patients were classified as American society of Anaesthesiology (ASA) class one or two.

**Inclusion criteria:** sixty symptomatic patients with uncomplicated gall stone disease of both gender included after taking written and informed consent.

**Exclusion criteria:**

1. Patients age more than 60 years.
2. Patient with complication of gall stone disease viz. Pancreatitis, choledocholithiasis.
3. Obesity (BMI for male >28.5, and for female >26).
4. Patients with previous major upper abdominal surgeries.
5. Neurological disease.
6. Conversion to open cholecystectomy.

**Method:**

consent of surgery and anaesthesia was taken and the patients fulfilling the inclusion criteria, divided randomly in to two groups of 30 each. Randomization was done according to even and odd number of bed head ticket.

Group A (Test group): 0.5% Bupivacaine (2mg/kg) was instilled over the surgical and placed in gallbladder bed, after its removal.

Group B (Control group): port site infiltration of 0.5% Bupivacaine (2mg/kg) was done after incision closure.

Thiopentone-induced anaesthesia was maintained with nitrous oxide, oxygen and 0.5% Halothane. Non-invasive monitoring was done during intra- and post-operative period. Intravenous antibiotics were given intravenously just before the induction of anaesthesia.

Laparoscopic cholecystectomy was completed with the standard four port techniques and pneumoperitoneum created by carbon dioxide gas. Pressure was maintained at 12 mmHg throughout the operation. After securing haemostasis at gallbladder bed, surgical strips placed over the gallbladder bed through the epigastric port and 0.5% bupivacaine (2 mg/kg) was instilled over the surgical with the help of an aspiration needle through the mid-clavicular port. The port site infiltration of 0.5% bupivacaine (2mg/Kg) was done before its closure, with three fifths of it infiltrated at the umbilical and epigastric ports and the remaining two fifths at the mid-axillary and mid-clavicular ports. Carbon dioxide was evacuated through the ports by applying gentle pressure all over abdomen.

Rescue analgesia (intramuscular Diclofenac-sodium 75mg) or Rescue antiemetic (intravenous ondansetron 8mg) was given, if the visual analog scale score was higher than 45mm or patient had complained of vomiting.

The character of the pain was assessed postoperatively. Visceral pain was defined as deep seated pain located in right hypochondrium or referred to shoulder. Parietal pain was defined as incisional pain located at port sites that increased with greater intra abdominal pressure. The method for using the Visual analog scale had been explained to all the patients preoperatively and its score assessed at 4, 8, and 24hrs. after surgery.

**Statistical analysis:**

Statistical analysis of results were done by paired t-test, chi-square test and students t-test for character of pain, visual analog scale score and its comparison between group A and group B. The Visual Analog Scale score was expressed as mean± standard deviation. p Value <0.05 used to indicate the significant difference, with the 0.01 and 0.001 level considered highly significant and very highly significant respectively.

**RESULTS**

Of the 60 patients included in the study, 56 (93.3%) were females,

while the remaining 4 (6.7%) were male. the age of the patient ranged from 20 to 59 years. the maximum patients were in the age group 30 to 39 years (20 out of 60).the mean age of presentation was 35.48 years in both groups.

No statistical significant difference found for the symptoms, duration of disease, and duration of surgery between two groups. Biliary dyspeptic symptoms were noted in 41.7% of total patients, while symptoms of acute cholecystitis and biliary colic were observed 33.33% and 25% of patients respectively. The mean duration of surgery was 44.87minutes.

The visceral pain was more common after laparoscopic cholecystectomy in 60% patients, while incidences of parietal and shoulder pain were 56.70% and 8.33% respectively. (Table 1)

**Table 1: character of pain after laparoscopic cholecystectomy.**

	Number of patients	Visceral pain	Parietal pain	Shoulder pain
Test group A	30	12	16	0
Control group B	30	24	18	5
Total	60	36	34	5

Visceral pain was significantly less in group A patients as compared to group B. It reduced significantly from 4hrs to 24hrs in group A , however no difference was found in reduction of visceral pain in group B. (table 2)

**Table 2: Visceral pain reduction from 4hrs to 24hrs between two groups.**

Group		Visceral pain at 4hrs		Total	P-value	
		Negative	Positive			
Test group A	Visceral pain at 24hrs	Negative	18	8	26	0.008
		Positive	0	4		
Total		18	12	30		
Control group B	Visceral pain at 24hrs	Negative	6	4	10	0.125
		Positive	0	20		
Total		6	24	30		

In group B, significant relief in parietal pain was noted from 4 hrs to 24 hrs (p value= .008) whereas no difference observed in group A. (table 3)

**Table3: Parietal pain reduction from 4hrs to 24hrs between two Groups.**

Group		Parietal pain at 4hrs		Total	P-value	
		Negative	Positive			
Test group A	Parietal pain at 24hrs	Negative	14	5	19	0.063
		Positive	0	11		
	Total		14	16	30	
Control group B	Parietal pain at 24hrs	Negative	12	8	20	0.008
		Positive	0	10		
	Total		12	18	30	

None of the group A patients had shoulder pain, while five patients experienced in group B. Reduction in shoulder pain was not significant in group B. (table 4)

**Table 4: Shoulder pain reduction from 4hrs to 24hrs in Group B.**

	Negative	Positive	Total	P-value
Negative	25	1	26	1.00
Positive	0	4	4	
Total	25	5	30	

The mean Visual Analog Scale score of group A patients was

significant less than of group B. (table 5)

**Table 5: The mean VAS scores of two Groups.**

	Patient Nos.	Mean VAS score	Std. Deviation	P-value
Group A	30	22.89	6.20	<0.001
Group B	30	32.62	3.37	
Total	60	27.76	6.97	

A statistical significant difference (p-value <0.001) was noted in mean VAS score at 4, 8, and 24hrs and its reduction from 4hrs to 24 hrs between two groups. (Table 6)

**Table 6: Comparison of VAS Score at 4hrs, 8hrs, and 24hrs. between two groups.**

		Patient Nos.	Mean VAS Score	Std. Deviation	p-value
VAS Score at 4Hrs.	Group A	30	27.27	6.72	<0.001
	Group B	30	39.00	2.96	
	Total	60	33.13	7.84	
VAS Score at 8Hrs.	Group A	30	24.20	6.22	<0.001
	Group B	30	34.13	2.97	
	Total	60	29.17	7.84	
VAS Score at 24Hrs.	Group A	30	17.20	5.79	<0.001
	Group B	30	24.73	4.31	
	Total	60	20.97	6.33	

**DISCUSSION**

Singh A et al<sup>(16)</sup> conducted a study in India, on 250 patients of biliary tract disease, reported that the majority of gall stone sufferers are in their 3<sup>rd</sup> to 5<sup>th</sup> decade. Earlier study done by Verma G R et al<sup>(8)</sup> reported the median age of presentation as 41.3years. The age of presentation in our study, ranged from 20 to 59 years, with median of presentation being 35.5years.

Females were affected more than the males in our study. This is in accordance to literature, which states that women are three times more commonly affected by gall stone disease as compared to men<sup>(17)</sup>. Classical biliary dyspeptic symptom was found in 41.7% of patients, while it was present only in 31.6% of patients in the study done by Verma G R et al.

Duration of surgery in previous study was reported as 74.30±30.78 minutes; however it was only 45.53±6.34 minutes in our study.

Pain after laparoscopic cholecystectomy can be divided in to three components, namely, visceral, parietal and shoulder pain. they have different intensities and their own time courses<sup>(8,9)</sup>.we observed 60%, 56.7%, and 8.33% incidences of visceral, parietal and shoulder pain respectively in our study, while it was found 78.66%,70% and 23.33% respectively in study conducted by Verma G Ret al<sup>(8)</sup>.

Verma GR et al<sup>(8)</sup> soaked the surgicel with 0.5% Bupivacaine and kept it in the gall-bladder bed. They ensured that the drug remain in contact for a longer time, which appears to be the reason for its efficacy in their study. Ure BM et al<sup>(18)</sup> observed the peak serum level of intraperitoneal Bupivacaine 20 to 30 minutes after its application and lasts for 2 to 24 hours after surgery. Weber et al<sup>(14)</sup> noted considerable pain relief even up to 48 hours after surgery.

Chundrigar et al<sup>(19)</sup> and Gharaibeh and Jaber<sup>(20)</sup> have also reported a significant reduction in shoulder pain with intraperitoneal Bupivacaine placement after laparoscopic cholecystectomy. This finding reinforces the fact that the phrenic nerve supplies the gall-bladder bed, porta hepatis, and liver, while sharing the root of nerves to the shoulder<sup>(12)</sup>, which was consistent with findings of Verma G Ret al<sup>(8)</sup>.

In our study, we observed a significant reduction of pain after placing Bupivacaine soaked surgicel in gall-bladder bed alone. This effect is indirectly reflected by progressive reduction in both the VAS score and the visceral pain. None of the patients in the group alone experienced shoulder pain, although majority continued to have parietal pain. This suggests that progressive reduction of the VAS score was attributed to effective control of visceral pain. It seems that visceral pain is more common and more intense than parietal pain after laparoscopic cholecystectomy and contributes substantially to the VAS score reduction. This was consistent with the observation of Verma G R et al.

Parietal pain after laparoscopic cholecystectomy is less intense than visceral pain, owing to the small abdominal incisions and the limited damage to the abdominal wall<sup>(8,9)</sup>. The intensity of pain was more after port site infiltration of bupivacaine reflected by high mean VAS score at 4hrs. , 8hrs. , and 24hrs. However, pain- reduction is also noted in this group, but significantly lesser than group A. this effect is indirectly seen by reduction of the VAS score and relieve from parietal pain suggesting that parietal pain is less intense than visceral pain after laparoscopic cholecystectomy and showed the efficacy of bupivacaine infiltration at port site in relieving of pain and a significant VAS score reduction. This was similar to the experience of Sarac A M et al<sup>(21)</sup>, who concluded that the local anaesthesia (bupivacaine) during laparoscopic cholecystectomy reduces post operative pain and that infiltration of the port sites after surgery offers a better pain relief than local anaesthesia given just before the incision.

**CONCLUSION**

From the present study, it is concluded that the overall incidences of visceral, parietal and shoulder pain are 60%, 56.7% and 33% respectively after laparoscopic cholecystectomy. However the visceral pain is more prominent than parietal pain.

0.5% Bupivacaine (2mg/kg) soaked surgicel in gall-bladder bed alone is effective in controlling both visceral and shoulder pain after laparoscopic cholecystectomy. 0.5% bupivacaine (2mg/kg) infiltration at port sites after wound closure is effective in relieving of parietal pain.

**REFERENCES:**

- Soper NJ, Stockman PT, Dunnegan DL, et al. Laparoscopic cholecystectomy: the new gold standard. Arch surg 1992; 127:917-92.
- Soper NJ, Brunt LM, Kerbl K. Laparoscopic General Surgery. N Engl J Med 1994; 330: 409-419.
- Barkun JS, Barkun AN, Samplis JS, et al. Randomized controlled trial of Laparoscopic versus mini cholecystectomy. Lancet 1992; 340: 1116-1119.
- Bass EB, Pih HA, Lillemo KD. Cost effectiveness of Laparoscopic cholecystectomy versus open cholecystectomy. Am J Surg 1993; 165:466-471.
- McMahon A, Russel I, Baxter J et al. Laparoscopic versus mini laparoscopic cholecystectomy: a randomized trial. Lancet 1994; 343: 135-138.
- Soper N. Laparoscopic cholecystectomy. Curr probl surg 1991; 28: 585-655.
- Soper N, Barreau J, Clagman B, et al. Laparoscopic versus standard open cholecystectomy comparison of early results. Surg Gynecol Obstet 1992; 174: 114-118.
- Verma GR, Lyngodh TS, Kaman L, Bala I, PGI Chadigarh, India. Surg Endosc. 2006 Aug 1, 1560-1564.
- Joris J, Thyry E, Paris P, Weerts J, Lamy M (1995) pain after Laparoscopic cholecystectomy and effect of intraperitoneal Bupivacaine. Anesth Analog 81: 379-384.
- Collins KM, Docherty PIWQ, Plantivien OM (1984) postoperative morbidity following Gynecological outpatient Laparoscopy: a reappraisal of service. Anesthesia 39:819-822.
- Edwards ND, Barclay K, Catlin SJ, Martin DG, Morgan RH (1991) Day care Laparoscopy: a survey of postoperative pain and assessment of the value of Diclofenac. Anesthesia 46: 1077-1080.
- Peter LW, Roger W, Mary D, Lawrence HB (1989) Biliary duct and gallbladder. In: Gray's anatomy, 37th ed. Churchill Living stone, London p. 1394-1395.
- Yadav Ajay, Short text book of anaesthesia. 2004; 110-111.
- Weber A, Munoz J, Garteiz D, Cutoo J (1997) Use of sub diaphragmatic Bupivacaine instillation to control postoperative pain after Laparoscopic surgery. Surg laparosc Endosc PCT 7:6-8.
- Adams WJ, Avramovic J, Barraclough BH (1991) Wound infiltration with 0.25% Bupivacaine is not effective for postoperative analgesia after cholecystectomy. Aust N Z J Surg 61: 626-630.
- Singh A et al (1989) Gall bladder disease- an analytical report of 250 cases j, Indian Med Assoc 1989 Nov; 97 (11): 253-256.
- Nakeeb A, Comuzzie AG, Martin L, et al: Gall stones: Genetics Versus Environment. Ann Surg. 233:842, 2002.

18. Ure BM, Troidl H, Spangenberger W, Neugebauer E, Lefering R, Ullman K, Benede J (1993) Pre-incisional local anesthesia with Bupivacaine and pain after Laparoscopic cholecystectomy: a double blind randomized clinical trial. *Surg Endosc* 7:482-488.
19. Chundrigar T, Morris R, Hedges AR, Stamatakis JD (1993) Intraperitoneal Bupivacaine for effective pain relief after Laparoscopic cholecystectomy. *Ann R Coll Surg Engl* 75: 437-439.
20. Gharaibeh KI, Ai Jaber TM (2000) Bupivacaine instillation into gallbladder bed after Laparoscopic cholecystectomy: does it decrease shoulder pain? *J Laparoendosc Adv Surg Tech* 10: 13709.
21. Sarac AM, Aktan AO, Baykan, Yagen C, Yalin R (1996) the effect and timing of local anesthesia after Laparoscopic cholecystectomy: *Surg Lap Endosc* 6: 362-366.