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## Effectiveness of 0.5% bupivacaine - soaked sheet of regenerated oxidized cellulose in the gallbladder bed and port - site infiltration of bupivacaine for pain relief after laparoscopic cholecystectomy

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### Abstract

**Background:** Laparoscopic Cholecystectomy [LC] has become the gold standard for treatment of benign gall bladder disease. Pain after laparoscopic cholecystectomy though primarily visceral, often affecting sub diaphragmatic region and often referred to the right shoulder region, also has a parietal component which occurs at the trocar site.

**Aim:** This study was conducted to compare postoperative pain control with use of 0.5 %bupivacaine-soaked sheet of regenerated oxidized cellulose in the gallbladder bed versus port site infiltration of 0.5 % bupivacaine after laparoscopic cholecystectomy.

**Material and Method:** Total patients were 75, which were divided in three groups - Group A (n=25) bupivacaine- soaked sheet of regenerated oxidized cellulose was placed in the gall bladder bed, Group B (n=25) bupivacaine was infiltrated at trocar site before skin suturing, Group C (n=25) was the control group. Nature of pain - visceral, parietal or shoulder was assessed on VAS at 3,6 & 24hrs after surgery.

**Results:** All patients demonstrated different intensities of visceral and parietal pain in all groups. No patient had shoulder pain. Visceral pain at 3, 6 & 24hr was significantly less in group A ( $2.04 \pm 1.71$ ,  $1.56 \pm 1.68$  &  $0.40 \pm 0.57$ ) as compare to group B ( $3.08 \pm 0.70$ ,  $2.56 \pm 1.29$  &  $1.28 \pm 0.54$ ) & group C ( $4.32 \pm 0.62$ ,  $3.84 \pm 0.85$  &  $3.08 \pm 0.91$ ) ( $p < 0.05$ ). Parietal pain at 3,6 & 24hrs for group B ( $2.28 \pm 1.45$ ,  $1.36 \pm 1.22$  &  $0.60 \pm 0.50$ ) was less than group A ( $2.76 \pm 0.66$ ,  $2.28 \pm 0.54$  &  $1.12 \pm 0.44$ ) & group C ( $4.64 \pm 0.86$ ,  $3.68 \pm 0.90$  &  $3.16 \pm 0.80$ ) ( $p < 0.05$ ). Postoperative analgesic requirement was 16% in Group A, 20% in Group B and 100% in Group C.

**Conclusion:** Bupivacaine (0.5%) soaked sheet of regenerated oxidized cellulose (ROC) in the gall bladder bed is safe, increases postoperative comfort and decreases postoperative analgesics requirement after laparoscopic cholecystectomy as compare to trocar site infiltration.

**Keywords:** laparoscopic cholecystectomy, regenerated oxidized cellulose (ROC), Visual analogue scale (VAS)

### Introduction

Laparoscopic cholecystectomy [LC] has become the gold standard for treatment of benign gall bladder disease. Though laparoscopic surgery has a number of advantages over conventional open surgery, it is not a completely pain free procedure. After open cholecystectomy pain is usually because of large incision of surgery, and is of parietal type. Pain after laparoscopic cholecystectomy though primarily visceral, often affecting sub diaphragmatic region and often referred to the right shoulder region, also has a parietal component which occurs at the trocar site.

Many factors such as humidity and temperature of gas, pressure of pneumo-peritoneum during surgery, residual intra-peritoneal gas at the end of surgery, duration of surgery and length of trocar incision, trauma caused by cholecystectomy itself play an important role in causation of pain. Post-operative pain in turns affects postoperative morbidity, hospital stay, increased financial burden on the patient.

A number of studies have been done till date to try to assess the effectiveness of different measures to alleviate the postoperative pain after laparoscopic cholecystectomy [1-13].

Pain management has not been standardized at mass medical centers in India and Abroad and this is reflected in the number of different pain studies after LC available in literature<sup>[1-13]</sup>. Till date many different methods have been used, they include low pressure pneumoperitoneum, gasless technique of LC, use of warm carbon dioxide. Peritoneal wash with normal saline. Strict surgical technique, perfect hemostasis, trocar site infiltration of anesthetic drugs, use of non-steroidal anti-inflammatory drugs or dexamethasone<sup>[1-9]</sup>.

To gain major insight into the effectiveness of intra-peritoneal use of 0.5% Bupivacaine soaked sheet of regenerated oxidized cellulose and port site infiltration of Bupivacaine in postoperative pain relief after laparoscopic cholecystectomy, the present study was carried out in the Department of General Surgery, JLN Medical College & Hospital, Ajmer in the year May 2017 to December 2018.

## Material and Methods

A prospective randomized study of 75 patients of benign gallbladder disease in whom laparoscopic cholecystectomy was conducted in Department of General Surgery at JLN Medical College & Hospital, Ajmer during the period of May 2017 to December 2018.

## Aims and objective of the study

### Primary objectives

1. To assess the effectiveness of 0.5% bupivacaine for pain control after laparoscopic cholecystectomy (LC) at its optimal dose (2mg/kg) by bupivacaine- soaked sheet of regenerated oxidized cellulose placed in the gall bladder bed after LC.
2. To assess the effectiveness of 0.5% bupivacaine for pain control after LC at its optimal dose after infiltration of 0.5% bupivacaine in muscular fasciae of trocar site after LC.

### Secondary objectives

To define the nature of pain – visceral, parietal or shoulder tip pain after LC.

To assess the efficacy of 0.5% bupivacaine at its optimal dose and timing of first request for analgesic drugs.

### Inclusion criteria

- Age > 18 years
- ASA grade 1 or 2.
- Gallbladder calculi or polyp with no evidence of acute cholecystitis at the time of surgery

### Exclusion criteria

- Age < 18 years
- ASA grade > 2
- Pregnancy
- Acute cholecystitis
- Choledocholithiasis
- Conversion of laparoscopic cholecystectomy to open cholecystectomy.

After taking informed and written consent, patients were randomized into three groups.

### Randomization

Randomization was done with prepared enveloped. The day before operation an independent hospital staff randomly opened an envelope with a card inside. Patients were randomized to their respective card group, either A, B or C.

**Group A:** Bupivacaine – soaked sheet of regenerated oxidized

cellulose positioned in the gallbladder bed after removal of G.B. and before evacuation of pneumoperitoneum. (Figure 1).

**Group B:** Bupivacaine infiltrated in the muscular fasciae of the trocars before skin suturing.

**Group C:** Control group.

Patients were blinded, they did not know into which group they were being allotted. For the patients undergoing Laparoscopic Cholecystectomy, ultrasonography, X-ray chest, ECG, complete blood count, liver function test, random blood sugar, blood urea, serum creatinine, physician and preanesthetic checkup for fitness of surgery was done and inj. Cefotaxime was given preoperatively just before induction of anesthesia.

**Procedure:** Laparoscopic Cholecystectomy was performed by creating pneumoperitoneum with the veress needle at the rate of 2L/min with conventional four ports. first umbilical 10 mm camera port created, other 10 mm in epigastrium, one 5 mm in right subcostal region, one 5 mm in anterior axillary line several centimeters below fundus of gall bladder to grasp the gall bladder. Calot's triangle dissection started, firstly posterior window was created at the GB and cystic duct and cystic artery cleared. Cystic duct clipped and cut. Cystic artery clipped and cauterized. GB was dissected out from liver bed. Gallbladder extracted out, homeostasis achieved. Wash with normal saline done. In Group A after removal of gallbladder, 0.5% bupivacaine- soaked regenerated oxidized cellulose was placed in GB bed (Figure.1). In Group B, before skin suturing 0.5% bupivacaine infiltrated into muscular fasciae at trocar sites. In Group C no local anesthetic drug was used. Analgesic inj. Tramadol 1mg/kg was given for pain relief on patient demand.

### Patient Assessment

Assessment of the nature of pain [{visceral: Deep seated abdominal pain felt by patient in the right hypochondrium.} {parietal: Incisional pain at the trocar sites that increased with greater intra-abdominal pressure} or {shoulder pain: Referred pain to shoulder.}] was done and its intensity was recorded on VAS [visual analogue scale {The VAS is a 100mm horizontal scale representing varying intensities of pain, with end points labeled as "no pain" and "worst possible pain".}] after 3 hrs, 6 hrs & 24 hrs of surgery.

### Following data were also recorded

- Time of First request for analgesics
- Vomiting
- Duration of surgery
- Intraperitoneal drain was kept or not
- Length of hospital stay
- Any other postoperative complication.

**Statistical analysis:** Comparison of three groups was done using Kruskal – Wallis Test. For mean between two groups Mann Whitney I test was used. The data for all the patients was entered into specifically designed computer software SPSS-PC-17 version, p-value < 0.05 was considered statistically significant.

### Results

A prospective, randomized study of 75 patients of benign gall bladder disease in whom laparoscopic cholecystectomy was conducted in the department of General surgery at J L N Medical College and Hospital Ajmer during May 2017 to December 2018.

Out of the 75 patients 60 were female (80%) and 15 were male

(20%). In Group A 20 females and 5 males, in Group B 22 females and 3 males, in Group C 18 females and 7 males. The mean age of the 75 patients was  $45.41 \text{ years} \pm 13.27 \text{ SD}$ .

There was no significant difference in age, duration of surgery, ASA, weight, hospital stay, number of ports. [Table 1] In Group A 2 patients out of 25 required Intra – peritoneal drain placement, in Group B it was 1 out of 25 and in Group C it was 2 out of 25 [ Table 4].

Visceral pain at 3, 6 & 24hr was significantly less in group A  $2.04 \pm 1.71$ ,  $1.56 \pm 1.68$  &  $0.40 \pm 0.57$  (as compare to group C  $4.32 \pm 0.62$ ,  $3.84 \pm 0.85$  &  $3.08 \pm 0.91$ ) ( $p < 0.05$ ) [ Table 2]. Parietal pain at 3,6 & 24hrs for group B  $2.28 \pm 1.45$ ,  $1.36 \pm 1.22$  &  $0.60 \pm 0.50$  (was significantly less than group C  $4.64 \pm 0.86$ ,  $3.68 \pm 0.90$  &  $3.16 \pm 0.80$ ) ( $p < 0.05$ ) [Table 3].

### Postoperative analgesic requirement

**Group A:** four patients out of 25 required postoperative analgesic injection Tramadol postoperatively. Mean time was 10 hrs for first request and 24 hrs for second request. 2 patients out of these 4 patients had intra-peritoneal drain. Rest of 21 patients never asked for analgesics in postoperative period [Table 4].

**Group B:** five patients out of 25 required postoperative analgesics. Mean time was 8 hrs for first request and 24 hrs for second request. 1 patient out of these 5 patients had intra-peritoneal drain. Rest of 20 patients never asked for analgesics in postoperative period.

**Group C:** All 25 patients required postoperative analgesic Tramadol injection. Postoperative analgesic requirement was 16% in Group A, 20% in Group B and 100% in Group C.

### Discussion

Post-operative pain control after laparoscopic cholecystectomy (LC) remains a major cause of concern for laparoscopic surgeon and anesthesiologists. The fact that in many hospitals LC is now performed as a day care procedure emphasizes the need for early and appropriate post operative pain relief so that the patient has painless discharge post operatively.

Postoperative pain after LC is considered to arise from three main sources:

1. Incision sites on the abdominal wall causing parietal pain.
2. Pneumoperitoneum associated with local and systemic changes resulting in shoulder pain.
3. Post cholecystectomy wound in the liver bed causing visceral pain.

There was increased predominance of female patients in all the studies including the present study which is natural because of high incidence of gallstone disease in female patients. Determining the sex incidence in any pain study is important

because women report more pain than men [3].

In present study none of the patients had shoulder pain in postoperative period. This was at odds with results of other studies by Feroci F *et al.* [3] 44%, Verma G R *et al.* [4] 14% and Chundrigar T *et al.* [8] 12%. It is difficult to attribute any particular cause to the absence of shoulder pain the study. It is postulated that shoulder pain is due to CO<sub>2</sub> gas trapped beneath the right hemidiaphragm after deflation of abdomen. We were meticulous in postoperative deflation after LC. This may partly explain low incidence.

Visceral and parietal pain accounted for most of the pain in early post-operative period [3 & 6 hrs] in this study. Visceral pain score (55.58%, 54.08%) and parietal pain score (59.60%, 58.04%) were highest at 3 hrs and 6 hrs assessment in control Group C. (Table 5) Though Joris *et al.* [11] and Verma G R [4] have concluded this study that visceral pain is predominant, we were unable to concur with them as both the scores were almost similar.

We used Bupivacaine soaked in regenerated oxidized cellulose at the optimal dose 2mg/kg to increase the contact time of Bupivacaine at the gallbladder bed so as to increase absorption and get maximum postoperative pain relief. The peak serum level of bupivacaine was reached 20-30 minutes after application and lasts for 2-24 hours after surgery. It was evident that the methods in this study significantly reduced visceral pain when compare to control group as was seen in trials by Feroci F [3] and Verma G R *et al.* [4] Visceral pain was significantly low in Group A (24, 20%, 24.52%) as compared to Group B (33.92%, 35, 40%) and Group C (55.88%, 54.08%) at 3 hrs and 6 hrs assessment. (Table 5).

In Group B when bupivacaine was infiltrated to the trocar site it significantly reduces the parietal pain (24.86%, 24.42%) as compared to Group C (59.60%, 58.04%) and Group A (29.54%, 35.54%) in early post-operative period at 3 & 6 hrs ( $p \text{ value} < 0.05$ ). [Table 5] Parietal pain comes near to the baseline within 24 hrs in Group B while in other two groups they remain above the baseline. These findings support the findings of two previous studies where local infiltration of bupivacaine at its optimal dosage at trocar sites reduced parietal pain [3, 4].

Bupivacaine in either form of administration at its optimal dose reduces post-operative analgesic requirement as compare to control group. All patients in control Group C required analgesics within 8 hrs as compared to 16 % for Group A and 20% for Group B. There was clinically decrease in the mean analgesic requirement in Group A and Group B as compared to control Group C. These findings are comparable to the study by Feroci F *et al.* [3]

**Table 1:** Demographic and operative details of analyzed data

	Group A (n=25)	Group B (n=25)	Group C (n=25)	P-value
Sex (M/F)	5/20	3/22	7/18	0.36
Age (in years)	$48.84 \pm 11.67$	$44.28 \pm 13.91$	$43.12 \pm 14.01$	0.27
Duration of surgery (min)	$66.40 \pm 13.50$	$66.40 \pm 13.50$	$68.47 \pm 15.17$	0.25
ASA (I/II)	23/2	23/2	22/3	0.85
Port	4	4	4	-
Weight (kgs)	$58.56 \pm 8.01$	$63.96 \pm 9.78$	$63.96 \pm 9.78$	0.06
Post-op Hospital Stay	$2.08 \pm 0.27$	$2.04 \pm 0.20$	$2.12 \pm 0.33$	0.59

**Table 2:** Comparison of VAS Score between Group A & C

	Group A (n=25)	Group C (n=25)	P-value
Visceral pain at 3 hrs	$2.04 \pm 1.71$	$4.32 \pm 0.62$	$< 0.001$
Visceral pain at 6 hrs	$1.56 \pm 1.68$	$3.84 \pm 0.85$	$< 0.001$
Visceral pain at 24 hrs	$0.40 \pm 0.57$	$3.08 \pm 0.91$	$< 0.001$

**Table 3:** Comparison of VAS Score between Group B & C

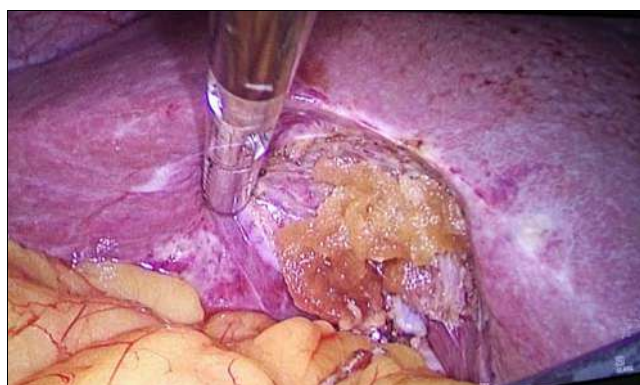
	Group B (n=25)	Group C (n=25)	P-value
Parietal pain at 3 hrs	2.28±1.45	4.64±0.86	<0.001
Parietal pain at 6 hrs	1.36±1.22	3.68±0.90	<0.001
Parietal pain at 24 hrs	0.60±0.50	3.16±0.80	<0.001

**Table 4:** Analgesic, Antiemetic and drain requirement in study groups.

	Group A (n=25)	Group B (n=25)	Group C (n=25)	P-value
No. of patients who need analgesics	4	5	25	<0.001
No. of patients who need antiemetic	2	1	1	0.58
Drain kept	2	1	2	0.80

**Table 5:** Mean rank in all groups

	Group A (n=25)	Group B (n=25)	Group C (n=25)
Visceral pain at 3 hrs	24.20	33.92	55.88
Parietal pain at 3 hrs	29.54	24.86	59.60
Visceral pain at 6 hrs	24.52	35.40	54.08
Parietal pain at 6 hrs	35.54	24.42	58.04
Visceral pain at 24 hrs	17.34	35.40	61.26
Parietal pain at 24 hrs	31.68	19.80	62.52

**Fig 1:** Bupivacaine soaked ROC in Gall Bladder fossa (Group A)

### Conclusion

Use of 0.5% Bupivacaine soaked sheet of Regenerated Oxidized Cellulose (ROC) placed in gallbladder bed after laparoscopic cholecystectomy was found to be more effective than 0.5% Bupivacaine infiltration at trocar site to control post-operative pain and reduces postoperative analgesics requirement. However this was not statistically significant. When used at its optimal dose (2 mg/kg) bupivacaine was found safe and easy to use without any adverse effects.

Visceral pain and Parietal pain were predominant in postoperative period after laparoscopic cholecystectomy caused by surgical trauma at gallbladder bed and abdominal incision. Prevalence of shoulder tip pain in this study was not observed which could be attributable to meticulous deflation of pneumoperitoneum after laparoscopic cholecystectomy.

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