IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)
e-ISSN: 2279-0853, p-ISSN: 2279-0861.Volume 18, Issue 11 Ser.7 (November. 2019), PP 05-12
www.iosrjournals.org

A Prospective Comparative Study Between Outcome Of Bupivacaine Soaked Surgicel Application Over Gall Bladder Bed With Intraperitoneal Instillation Of Bupivacaine With Control Group In Laparoscopic Cholecystectomy

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Abstract:*This study is regarding to determine postoperative pain relief after laparoscopic Cholecystectomy by using bupivacaine soaked surgicel application over gallbladder bed (Group-A) with intraperitoneal bupivacaine instillation (Group-B) with a control group (Group-C). Our study aims to compare post-operative pain relief after application of bupivacaine soaked surgicel over gallbladder bed with intraperitoneal instillation of bupivacaine with control group in laparoscopic cholecystectomy. We encountered75 cases of calculous cholecystitis operated by laparoscopic Cholecystectomy, 25 cases in each Group A, B & C, during a period of 2 years, between September 2017 to august 2019, at P.D.U. medical college. Visceral pain at right hypochondrium& Epigastrium was assessed on Visual Analogue scale (0-10) at 1,4,8,12,18,24,48 & 72 hours post-operatively.*

Hence study showed that after laparoscopic cholecystectomy, visceral pain at right hypochondrium& epigastrium is common & can be effectively decreased by application of 0.25% Bupivacaine soaked Surgicel at gallbladder bed after removal of gallbladder and minimally decreased by intraperitoneal instillation of 0.25% Bupivacaine as compared with control group of intraperitoneal instillation of Normal Saline.

Date of Submission: 02-11-2019 Date of Acceptance: 18-11-2019

I. Introduction

Laparoscopic cholecystectomy is the procedure of choice for symptomatic gall bladder diseases, laparoscopic cholecystectomy has resulted in reduced postoperative pain, decreased infection rates, decreased length of hospital stay and early recovery to functional status. Although significant reduction in postoperative pain and infection has occurred with the advent of laparoscopic cholecystectomy, it still remains a major problem in the first few days post-surgery. Proper management of postoperative pain results in early mobilization, decreased hospital stay and increased patient satisfaction. Although postoperative pain is less intense after laparoscopic cholecystectomy than an open surgery, it is not a total pain-free procedure. Post-operative pain following laparoscopic cholecystectomy is most predominant in the first 24 hours and can persist for about 3 days. Pain following laparoscopic cholecystectomy is multifactorial in etiology with visceral pain predominating the abdominal wall pain and shoulder pain.

Pain can increase morbidity and is the primary reason for prolonged hospitalization after laparoscopic cholecystectomy. Patient frequently complaint of pain over right hypochondrium, epigastric region, back, shoulder region and sub-diaphragmatic region occurs in about 12% to 60% of patients. Peak of pain is during the first few postoperative hours and usually declines after 2 to 3 days.

Various modalities proposed to relieve pain after laparoscopic cholecystectomy are intraperitoneal instillation of bupivacaine, bupivacaine soaked surgicel application at Gall Bladder bed in laparoscopic cholecystectomy, intraperitoneal instillation of ketamine, etc. Here aim of our study was to compare post-operative pain relief after application of bupivacaine soaked surgicel over gallbladder bed with intraperitoneal instillation of bupivacaine with control group in laparoscopic cholecystectomy.

II. Material and methods

We have used 75 patients of either sex between the age of 18 to 65 years scheduled for laparoscopic cholecystectomy under general anaesthesia, which was conducted in patients with chronic calculous cholecystitis admitted to generalsurgery department in Pandit Dindayal Upadhyay Medical College & Civil Hospital, Rajkot, Gujarat.

Study design: Prospective comparative study

Study location:PDU Medical College & Civil Hospital, Rajkot, Gujarat, India

Study duration:2 years
Sample size:75 patients
Sample size calculation:we have done this study on total of 75 patients of chronic calculous cholecystitis. Each group of our study was containing 25 patients.
Subjects and selection method: The study population was drawn from consecutive patients of benign gallbladder disease like chronic calculous cholecystitis, who presented to Pandit Dindayal Upadhyay Medical College & Civil Hospital, Rajkot, Gujarat, who underwent laparoscopic cholecystectomy between September,2017 to August,2019.
All the patients of one group have received the similar type of standardized anaesthetic regimen. In our prospective comparative study, we have used 3 groups of 25 patients. After removal of gall bladder by laparoscopic cholecystectomy,
Group A (N=25 patients) - (0.25%) Bupivacaine soaked surgicel was kept at gall bladder bed.
Group B (N= 25 patients) - Intraperitoneal instillation of 40 ml of (0.25%) bupivacaine was done
Group C (N= 25 patients) - Intraperitoneal instillation of 40 ml of normal saline (0.9%).

Inclusion criteria:
- All patients between age of 18 to 65 years.
- All patients who were giving consent for prospective study.

Exclusion criteria:
- All patients below age of 18 years and above age of 65 years.
- All patients of gall bladder disease in whom laparoscopic cholecystectomy was converted into open cholecystectomy.
- All patients with chronic pain disorders or those who were already taking analgesics for other reasons.
- Patients with choledocholithiasis, empyema and mucocele of gall bladder or placement of drain intra-operatively.

Procedure methodology:
After obtaining institutional ethical committee approval and written informed consent, 75 patients of either sex between the age of 18 to 65 years scheduled for laparoscopic cholecystectomy under general anaesthesia were enrolled in this Prospective comparative study, which was conducted in patients with chronic calculous cholecystitis.

In our study, during laparoscopic cholecystectomy, after removal of gallbladder, we have applied bupivacaine soaked surgicel over gallbladder bed in group A, we have instilled bupivacaine intraperitoneally in group B & we have instilled normal saline in group C (control group).

The prescribed doses of bupivacaine and normal saline in PDUMC in laparoscopic cholecystectomy for post-operative pain relief were as follows:

GROUP A:0.25% bupivacaine soaked surgicel
GROUP B:intraperitoneal instillation of 0.25% bupivacaine
GROUP C:intraperitoneal instillation of 0.9% normal saline

Intraperitoneal instillationwas done under both hemi-diaphragms and in the gall bladder bed. The method used for pain intensity assessment is Visual Analogue Scale (VAS) of 0-10. This was explained to all the patients preoperatively. Pain was assessed at 1,4,8,12,18 and 24,48 & 72 hours post surgery. Shifting of patient from recovery room to ward was considered as zero hours. All the patients were allowed to receive analgesic medications as needed.

Statistical analysis:
Analyses were performed on the data by using the student t-test for continuous quantitative variables. Numerical values were expressed as Mean± Standard Deviation (SD) and Kruskal Wallis test (One-way ANOVA test) to test the ability of Bupivacaine(0.25%) to predict pain intensity after laparoscopic cholecystectomy. A p-value less than 0.05 were considered statistically significant for all analyses.

III. Result

A total of 75 (59 female & 16 male) patients of chronic calculous cholecystitis in whom Laparoscopic Cholecystectomy was conducted in the department of General Surgery at the PDU Medical college, Rajkot during a period of 2 years from September, 2017 to August, 2019 were enrolled. Patients were divided in 3

groups (A=25, B=25 & C=25). There was no significant difference in age, duration of surgery, ASA, weight, hospital stay, number of trocars. All patients demonstrated different intensities of visceral pain. However, none of the patients developed shoulder pain in post- operative period in either group due to effective deflation of pneumoperitoneum. Duration of surgery was not affected by our study.

Table no 1 shows pain score (MEAN ± SD) of all three groups (A,B & C) at different time intervals post surgery after laparoscopic cholecystectomy. According to this table, postoperative pain score (MEAN ± SD) of group A at different time intervals is least than other groups & group C has highest postoperative pain score.

Table 1: Pain score (MEAN ± SD) by VAS scale

Time	**Group**	**Total patients**	**Pain score (Mean± SD)**
1 hour	A	25	2.04±1.46
	B	25	2.32±1.14
	C	25	4.24±1.48
4 hours	A	25	1.04±1.31
	B	25	1.76±0.83
	C	25	3.92±1.5
8 hours	A	25	0.52±1.05
	B	25	1.32±0.99
	C	25	3.16±1.46
12 hours	A	25	0.36±0.76
	B	25	0.8±0.76
	C	25	2.28±1.49
18 hours	A	25	0.48±1
	B	25	0.4±0.6
	C	25	1.88±1.33
24 hours	A	25	0.28±0.61
	B	25	0.4±0.6
	C	25	1.36±1.04
48 hours	A	25	0.04±0.2
	B	25	0.08±0.4
	C	25	0.92±0.9
72 hours	A	25	0
	B	25	0.04±0.2
	C	25	0.28±0.46

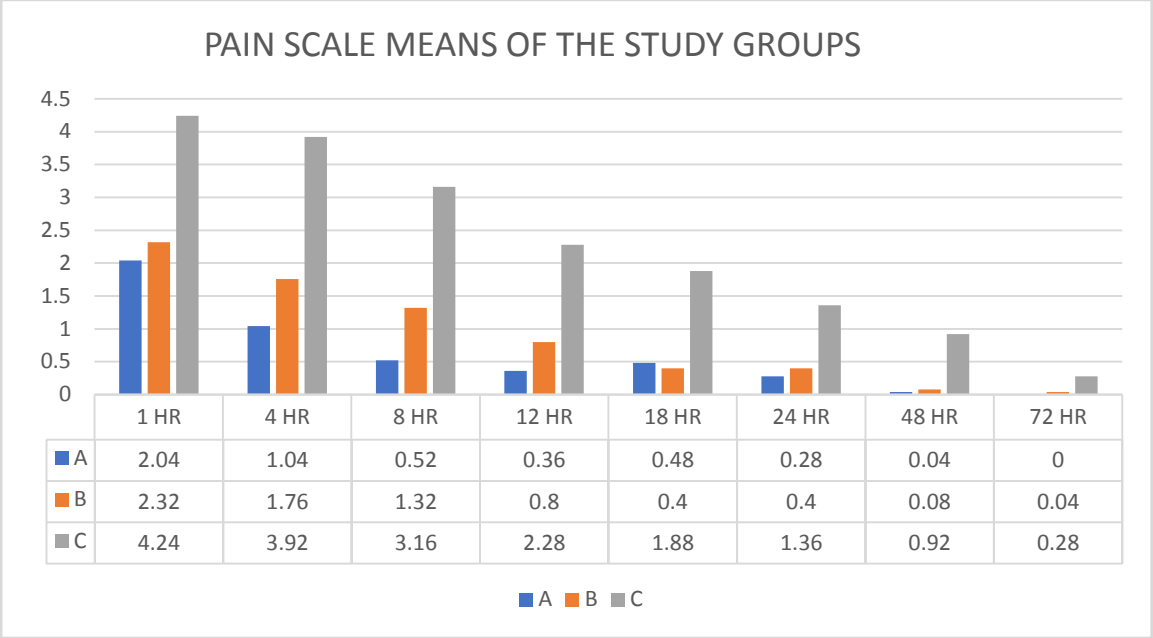


Table 2: statistical analysis of post-operative VAS-score (MEAN ± SD) by Kruskal Wallis H test

Time	**Surgicel Group (N = 25)**	**Bupivacaine Group (N = 25)**	**Saline Group(Control) (N = 25)**
1 Hour	2.04±1.46	2.32±1.14	4.24±1.48
12 Hours	0.36±0.76	0.8±0.76	2.28±1.49
24 Hours	0.52±1.2	0.4±0.6	1.36±1.04
48 Hours	0.04±0.2	0.08±0.4	0.92±0.9
72 Hours	0	0.04±0.2	0.04±0.2
p-value	< .00001	< .00001	< .00001

According to this table no 2,which suggest decrease in pain over the period of time is statistically significant in one single group, so for all groups A, B & C, Kruskal-Wallis test is statistically significant. Significant Kruskal-Wallis test indicates that at least one sample stochastically dominates one other sample.Kruskal Wallis test is one-way ANALYSIS OF VARIANCE (ANOVA test).

- **Group A:**

The H statistic is 38.8873. (n= 25).
The p-value is <0.00001. The result is significant as p is <0.05.

- **Group B:**

The H statistic is 59.0846. (n= 25).
The p-value is <0.00001. The result is significant as p is <0.05.

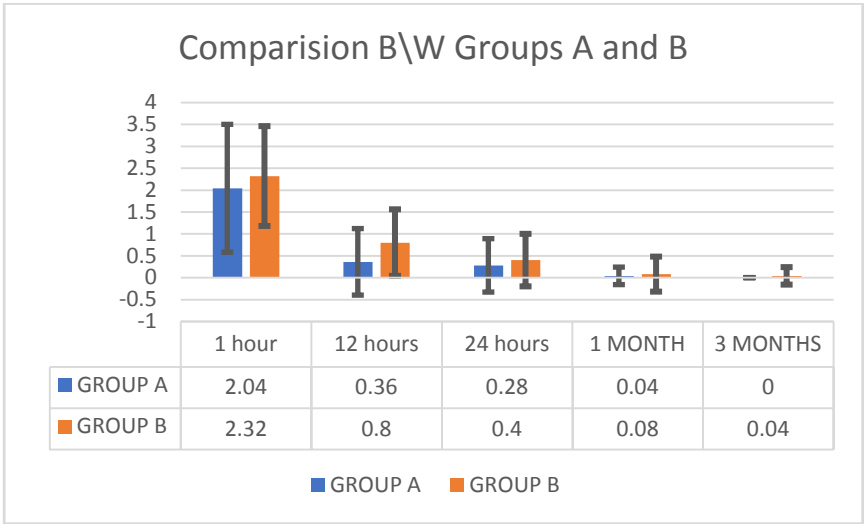
- **Group C:**

The H statistic is 72.5343. (n= 25).
The p-value is <0.00001. The result is significant as p is <0.05.

Table 3:'p' Value between group A & B (By Quantitative t-Test)

	Group A	**Group B**	**t test**	**Percentage change**	**p value**
1 hour	2.04±1.46	2.32±1.14	0.76	12.07%	0.4535
12 hours	0.36±0.76	0.8±0.76	2.05	55%	0.0462
24 hours	0.28±0.61	0.4±0.6	0.7	30.1%	0.6567

48 hours	0.04±0.2	0.08±0.4	0.44	50%	0.6567
72 hours	0	0.04±0.2	1	100%	0.3223



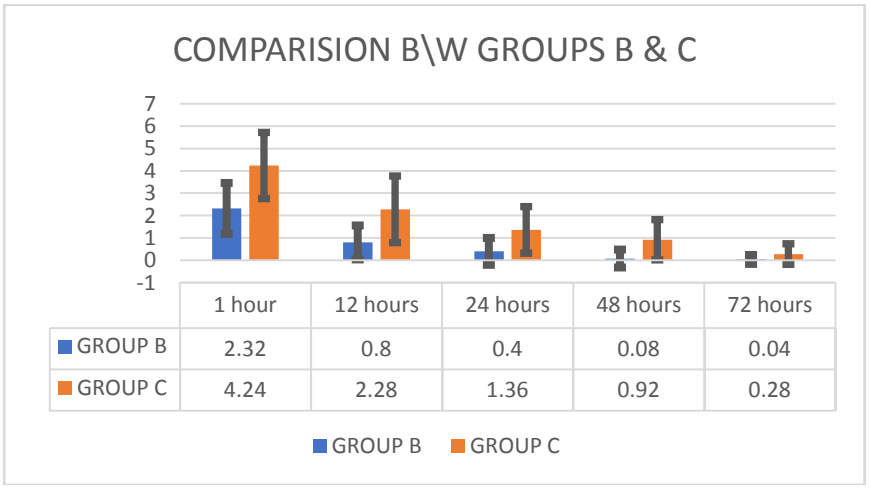
✓ **Statistical analysis between group A and B:**

Table no 3 shows percentage change of postoperative pain in between group A and group B. as per table, postoperative pain was 12.07%, 55%, 30.1%, 50%, 100% lesser in group A as compared to group B at 1,12,24,48 & 72 hours postoperatively.

Overall p-value of group A & B by quantitative t-test is not < 0.05, so it is considered to be not statistically significant. It is suggestive of there is no significant difference in post-operative pain relief after laparoscopic cholecystectomy in group A and group B.

Table 4:'p' value between group B & C (by quantitative t-test)

	Group B	**Group C**	**t test**	**Percentage change**	**p value**
1 hour	2.32±1.14	4.24±1.48	5.14	45.29%	0.0001
12 hours	0.8±0.76	2.28±1.49	4.4	64.9%	0.0001
24 hours	0.4±0.6	1.36±1.04	4	70.59%	0.0002
48 hours	0.08±0.4	0.92±0.9	4.3	91.31%	0.0001
72 hours	0.04±0.2	0.28±0.46	2.4	85.72%	0.021



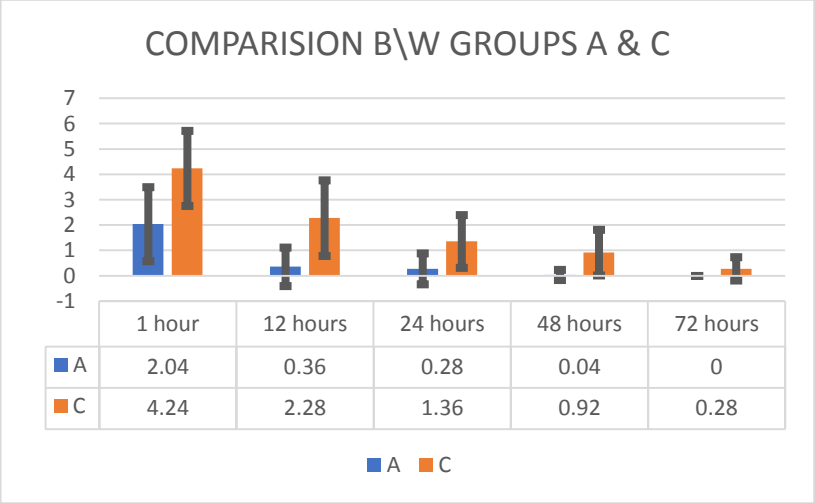
✓ **statistical analysis between group B and C:**

Table no 4 shows percentage change of postoperative pain in between group B and group C. as per table, postoperative pain was 45.29%, 64.9%, 70.59%, 91.31%, 85.72% lesser in group B as compared to group C at 1,12,24,48 & 72 hours postoperatively.

Overall p-value of group B & C by quantitative t-test is < 0.05, so it is considered to be statistically significant. It is suggestive of there is significant difference in post-operative pain relief after laparoscopic cholecystectomy in group B and group C. Post-operative Pain in patients of group B is lesser than group C.

Table 5:'p' value between group A & C (by quantitative t-test)

	Group A	Group C	t test	Percentage change	p value
1 hour	2.04±1.46	4.24±1.48	5.3	51.89%	0.0001
12 hours	0.36±0.76	2.28±1.49	5.7	84.22%	0.0001
24 hours	0.28±0.61	1.36±1.04	4.5	79.42%	0.0110
48 hours	0.04±0.2	0.92±0.9	4.8	95.66%	0.0001
72 hours	0	0.28±0.46	3.04	100%	0.0038



✓ **statistical analysis between group A and C:**

Table no 5 shows percentage change of postoperative pain in between group A and group C. as per table, postoperative pain was 51.89%, 84.22%, 79.42%, 95.66%, 100% lesser in group A as compared to group C at 1,12,24,48 & 72 hours postoperatively.

Overall p-value of group A & C by quantitative t-test is < 0.05, so it is considered to be statisticallysignificant. It is suggestive of there is significant difference in post-operative pain relief after laparoscopic cholecystectomy in group A and group C. Post-operative Pain in patients of group A is much lesser than group C.

IV. Discussion

Postoperative pain control after laparoscopic cholecystectomy remains a major cause of concern for the laparoscopic surgeon and anesthesiologist. The fact that in many hospitals laparoscopic cholecystectomy is now performed as a day care procedure emphasizes the need for early and appropriate postoperative pain relief, so that the patient has a painless discharge Post operatively.

Instillation of a local anaesthetics agent over the gallbladder bed as a method of pain control has been evaluated in many trials. some series reported a benefit in terms of reduced postoperative pain. Some authors believe that failure of adequate pain relief may be attributed to a short contact time of the drug with the surgical site due to the intraperitoneal influx. Using a sheet of regenerated oxidized cellulose (surgicel) soaked in bupivacaine, at gallbladder bed is thought to increase the contact time of the drug, leading to better pain relief. In our study, we used a 3 inches*2 inches size strip of surgicel soaked in bupivacaine in one group.

In the present study, none of the patients had shoulder pain in post-operative period. It is difficult to attribute any particular cause to the absence of shoulder pain in the present study. It is postulated that shoulder tip pain is due to CO_2 gas trapped beneath the right hemidiaphragm after deflation of the abdomen. We were

meticulous in Post-operative deflation after laparoscopic cholecystectomy. This may partly explain the low incidence of shoulder pain.

In our study, visceral pain at right hypochondrium and epigastrium accounted for most of the pain in early post-operative period (1 hour & 12 hours) in this study and postoperative pain was highest at 1 hour and 12 hours assessment in control Group C. Joris J et al[35] and Verma GR[32] had concluded from their study that visceral pain is predominant in early postoperative period and pain was highest in control group.

In the present study, we used 0.25% Bupivacaine soaked SURGICEL (regenerated oxidized cellulose) at the optimal dose to increase the contact time of Bupivacaine at the Gall Bladder bed, so as to increase absorption and get maximum post-operative pain relief. The peak serum level of intraperitoneal Bupivacaine is reached 20 to 30 min after application and lasts for 2 to 24 hours after surgery. It was evident that post-operative visceral pain at right hypochondrium& epigastric region was significantly reduced in group A in comparison to the control group C.Visceral pain at right hypochondrium& epigastric region was also significantly decreased in Group B as compared to Group C at 1 hour and 12 hours and 24 hours assessment (Table). On comparison to trials by Feroci F[31] and Verma GR et al[32]. There was no such difference in postoperative pain between group A & group B. Intra-peritoneal use of this drug without using regenerated oxidized cellulose leads to reduced contact of this drug to gall bladder bed (surgical trauma site)and decreased absorption time of Bupivacaine, leading to increased post-operative analgesia demand by patients.

It is also important to point out that a dose response relationship to the use of intra-peritoneal anaesthetics has been observed as can be seen from the results of one of the groups in the study by Verma GR et al[32]. In our study we have used 0.25% bupivacaine in Group A and B.

Use of Intra-peritoneal drain postoperatively after laparoscopic cholecystectomy leads to drainage of Bupivacaine through the drain. If intraperitoneal drain is required after laparoscopic cholecystectomy, use of intraperitoneal bupivacaine must be avoided.

Visceral pain at right hypochondrium& epigastric region comes near to the baseline (0) within 24 hours in Group A & B, while in control group C, they remain above the baseline.

Bupivacaine in either form of administration at its optimal dose reduces the postoperative analgesia requirement as compared to the control group. Almost all patients in the control Group (Group C) was having different intensities of pain in postoperative period after laparoscopic cholecystectomy. There was a clinically significant decrease postoperative visceral pain at right hypochondrium& epigastric region in Group A & B as compared to the control group C.

V. Conclusion

After laparoscopic cholecystectomy, postoperative visceral pain at right hypochondrium& epigastrium is common, rather incidence and intensity of this pain assessed by Visual AnalogueScore, can be effectively decreased by application of 0.25% Bupivacaine soaked Surgicel at gallbladder bed after removal of gallbladder and minimally decreased by intraperitoneal instillation of 0.25% Bupivacaine as compared with control group of intraperitoneal instillation of Normal Saline. Meticulous deflation of pneumoperitoneum (CO_2) after laparoscopic cholecystectomy can prevent post-operative shoulder pain.

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Dr. Bhavesh Vaishnani. "A Prospective Comparative Study Between Outcome Of Bupivacaine Soaked Surgicel Application Over Gall Bladder Bed With Intraperitoneal Instillation Of Bupivacaine With Control Group In Laparoscopic Cholecystectomy". IOSR Journal of Dental and Medical Sciences (IOSR-JDMS), vol. 18, no. 11, 2019, pp 05-12.