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A Study of Intraperitoneal Instillation of Levobupivacaine in Gall Bladder Fossa for Assessment of Postoperative Pain after Laparoscopic Cholecystectomy

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Abstract: ***Background: Even though laparoscopic cholecystectomy is associated with less discomfort following surgery, many patients still report mild shoulder and stomach pain in the first 48 hours. This prospective, controlled study aims to assess the impact of intraperitoneal levobupivacaine instillation on postoperative pain reduction following laparoscopic cholecystectomy. Methods: Patients undergoing laparoscopic cholecystectomy for symptomatic gallstones are the subjects of this prospective controlled study. Patients are randomly assigned to one of two groups: group A will not receive any intraperitoneal instillation following the procedure, and group B will receive intraperitoneal instillation of levobupivacaine (0.25%, 20ml) following the procedure. The amount of NSAIDs administered and the assessment of postoperative pain were documented at predetermined intervals in accordance with the VAS. Shoulder tip discomfort and nausea/vomiting were also assessed along with the duration of the hospital stay. Results: Mean pain scores up to 6 hours after surgery were lower in group B than in group A. The difference was statistically significant (p < 0.05). There was a substantial incidence of shoulder tip discomfort. However, pain levels at 6 hours were not substantially different between the two groups. Group A had substantially greater mean total NSAID consumption (p=<0.05) and a shorter initial dose of rescue analgesia than group B. Group B had a considerably shorter mean hospital stay than Group A (P < 0.05). We had no negative effects from administering levobupivacaine intraperitoneally. Conclusion: To conclude, levobupivacaine is effective in preventing pain up to the first 6hours after laparoscopic cholecystectomy when instilled intraperitoneally at the end of laparoscopic cholecystectomy. Levobupivacaine is better choice because of its higher efficacy and larger safety margin. This modality of treatment is cost effective in terms of patient care in post operative units, lesser NSAID and opioid requirement and helps the patient to get a better post operative recovery and early discharge.***

Keywords: Laparoscopic cholecystectomy, Post operative pain relief, Local anaesthetics.

1. Introduction

In recent years, laparoscopic operations have gained popularity due to its association with quick postoperative recovery, few postoperative complications, and early release home ([1, 2]). While prior research has shown that laparoscopy is linked to lower levels of pain compared to laparotomy, it is important to note that it is not entirely devoid of pain ([2 - 10]). A recent randomized controlled experiment has shown that pain levels may be higher and the need for pain relief medication may be greater immediately after laparoscopic surgery compared to open laparotomy.

Laparoscopic cholecystectomy has become the primary method for performing gall bladder surgery in situations of symptomatic cholelithiasis and is now widely accepted as the standard treatment. Although this treatment has resulted in a decrease in postoperative pain compared to open cholecystectomy, a notable number of patients still endure substantial discomfort during the first 48 hours. It is essential to address this problem since the need for pain relief after surgery might possibly lengthen the time spent in the hospital and postpone the patient's release.

The enhanced comprehension of the source of abdominal and shoulder discomfort after laparoscopic surgeries has resulted in the use of intra peritoneal and port site instillation of local anaesthetic to diminish postoperative pain. Levobupivacaine is a local anaesthetic that has a good safety record, lasts for a long time, and has a low risk of adverse effects such gastritis from NSAIDs or nausea, vomiting, and worries about becoming dependent on opioids. The use of long - acting local anaesthetics as an additional treatment alongside regional or local anaesthetic techniques enhances the management of postoperative pain. Moreover, when administered prior to surgery, these straightforward techniques can also reduce the amount of anaesthetic and pain - relieving medication needed during the surgery, as well as decrease the necessity for opioid - based pain medication after the operation. The use of local anaesthetic administered intraperitoneally and at the port site, in addition to general anaesthesia, has been extensively studied in many interventional studies undertaken during laparoscopic cholecystectomy. Approximately 50% of these trials have shown a significant reduction in postoperative pain.

Aims and Objectives:

To study the effect of intraperitoneal instillation of levobupivacaine in gall bladder fossa for assessment of postoperative pain after laparoscopic cholecystectomy.

To compare the post operative pain and the amount of analgesic requirement in post operative period in between test and control.

Source of Data:
The source of data is from inpatients of SARASWATHI INSTITUTE OF MEDICAL SCIENCES Hospital, Hapur who are diagnosed to have symptomatic cholelithiasis and undergo laparoscopic cholecystectomy.80 patients who are willing to participate during the study period from JULY 2022 to JUNE 2024 at Saraswathi institute of medical sciences Hospital will be taken and followed up.

Mode of Selection of Cases and Method of Analysis:
It is a Prospective controlled study of patients undergoing laparoscopic cholecystectomy for symptomatic gall stones, where the patients will be randomly selected. The study will be conducted using a pre - tested proforma meeting the objectives and the post operative pain is evaluated using Visual analogue scale for a period of 48 hours post operatively. The analysis of the study is made statistically with relevant tests.

2. Method of Data Collection

80 patients allocated into two study groups - to receive Levobupivacaine intraperitoneally after the procedure (group A), to receive no intraperitoneal instillation after the procedure (group B).

Inclusion Criteria
- All symptomatically diagnosed cases of cholelithiasis who will be scheduled to undergo conventional 4 port laparoscopic cholecystectomy.
- Age group >20 years.
- Gender - both male and female.

Exclusion Criteria
- Conversion of laparoscopic cholecystectomy into open cholecystectomy
- Patients who fail to understand the pain evaluation scale.
- Sensitivity to levobupivacaine.

- Statistical analysis: In this study the results of the two groups were compared and analyzed by using SPSS software version 22.

3. Results and Observations

In this Comparative study of **INTRAPERITONEAL INSTILLATION OF LEVOBUPIVACAINE IN GALL BLADDER FOSSA FOR ASSESSMENT OF POSTOPERATIVE PAIN AFTER LAPAROSCOPIC CHOLECYSTECTOMY**

Conducted in department of Surgery at Saraswathi institute of medical sciences, hapur. From July 2022 to July 2023. A Total of 80 Patients of symptomatic cholelithiasis who underwent Laparoscopic cholecystectomy included for this Prospective comparative study. It has been observed that patients who received levobupivacaine after laparoscopic cholecystectomy had less pain as compared to the group which had received no levobupivacaine.

A total of 80 patients participated in the study

Age wise distribution

Age group (yrs.)	Group A (N=40)		Group B (N=40)	
	Frequency	%	Frequency	%
20 - 30	4	10.00	4	10.00
31 - 40	26	65.00	21	52.50
41 - 50	10	25.00	14	35.00
>50	0	0.00	1	2.50
Total	40	100.00	40	100.00

Chi - square value=2.198
p - value= 0.532

Age wise distribution
After analysing the demographic Data obtained from the Study, we found that Cholelithiasis was prevalent in 2nd to 5th decade of life with highest propensity towards 30 - 40yrs with mean age of 50.5%. and p - value =0.532 which is statistically significant.

Sex wise distribution

Sex	Group A (N=40)		Group B (N=40)	
	Frequency	%	Frequency	%
Male	2	5.00	5	12.50
Female	38	95.00	35	87.50
Total	40	100.00	40	100.00

Chi - square value=1.40
p - value= 0.235

Group A comprised of 40 patients: 2 males and 38 females with ratio of (0.05: 1) roup B comprised of 40 patients: 5 males and 7 females with ratio of (0.14: 7)

VAS (1 HR)

VAS (1hr.)	Group A (N=40)		Group B (N=40)	
	Frequency	%	Frequency	%
0	-	-	-	-
1	-	-	36	90.00
2	-	-	2	5.00
3	-	-	2	5.00
4	-	-	-	-
5	3	7.50	-	-
6	10	25.00	-	-
7	8	20.00	-	-
8	19	47.50	-	-
9	-	-	-	-
10	-	-	-	-
Total	40	100.00	40	100.00

Chi - square value=42.46
p - value= <0.0001

VAS (1hr.)
Visual analogue score of pain at 1 hour after surgery: In our study we found that the VAS score at 1 hour post operation period was more in Group A which did signifies more pain while in Group B the VAS score was 1 - 3 in up to all patients with p value=<0.0001 which is statistically significant. Thus, the instillation of levobupivacaine reduces post operative pain

VAS (2 HR)

VAS (2 hr.)	Group A (N=40)		Group B (N=40)	
	Frequency	%	Frequency	%
0	-	-	-	-
1	-	-	-	-
2	-	-	-	-
3	1	2.50	9	22.50
4	1	2.50	15	37.50
5	1	2.50	16	40.00
6	17	42.50		
7	17	42.50		
8	3	7.50		
9	-	-	-	-
10	-	-	-	-
Total	40	100.00	40	100.00

Chi - square value=68.88
p - value= <0.0001

VAS (2hr.)

VAS 2 Hr: Visual analogue score of pain at 2hour after surgery: In our study, we found that in Group A about 42.5% patients had a VAS score of 6 at 2hrs after surgery while no patient of Group B had a score of >5. Thus, the patients of Group B are experienced no pain at 2 hrs with p value =0.0001 which was statistically significant.

VAS (4hr.)

VAS (4 hr.)	Group A (N=40)		Group B (N=40)	
	Frequency	%	Frequency	%
0				
1			9	22.50
2			10	25.00
3			2	5.00
4			7	17.50
5	23	57.50	12	30.00
6	17	42.50		
7				
8				
9				
10				
Total	40	100.00	40	100.00

Chi - square value=48.45
p - value= <0.0001

VAS (4hr.)

In our study, we found that in Group A about 42.5% patients had a VAS score of 6 at 4hrs after surgery while no patient of Group B had a score of >5. Thus, the patients of Group B are experienced no pain at 2 hrs with p value =0.0001 which was statistically significant.

VAS (6HRS)

VAS (6 hr.)	Group A (N=40)		Group B (N=40)	
	Frequency	%	Frequency	%
0	7	17.50	-	-
1	8	20.00	-	-
2	13	32.50	5	12.50
3	-	-	7	17.50
4	1	2.50	14	35.00
5	5	12.50	6	15.00
6	3	7.50	8	20.00
7	3	7.50	-	-
8	-	-	-	-
9	-	-	-	-
10	-	-	-	-
Total	40	100.00	40	100.00

Chi - square value=42.18
p - value= <0.0001

VAS (6 hr.)

In our study, we found that in Group A about 7.5% patients had a VAS score of 7 at 6hrs after surgery while no patient of Group B VAS score more than 6 with p value =0.0001 which was statistically significant.

VAS (12 hr.)

VAS (12 hr.)	Group A (N=40)		Group B (N=40)	
	Frequency	%	Frequency	%
0	1	2.50	-	-
1	7	17.50	-	-
2	3	7.50	6	15.00
3	3	7.50	11	27.50
4	5	12.50	17	42.50
5	7	17.50	6	15.00
6	8	20.00	-	-
7	6	15.00	-	-
8	-	-	-	-
9	-	-	-	-
10	-	-	-	-
Total	40	100.00	40	100.00

Chi - square value=34.19
p - value= <0.0001

VAS (12 hr.)

VAS 12 hrs: Visual analogue score of pain at 12hour after surgery: In our study, we found that 27 patients had a VAS score of >4 at 12 hrs. and 23 patients had VAS score >4 at 12 hrs with p value: <0.0001 which was statistically significant.

VAS (24 HRS)

VAS (24 hr.)	Group A (N=40)		Group B (N=40)	
	Frequency	%	Frequency	%
0	-	-	-	-
1	8	20.00	-	-
2	1	2.50	12	30.00
3	4	10.00	18	45.00
4	10	25.00	2	5.00
5	5	12.50	8	20.00
6	12	30.00	-	-
7	-	-	-	-
8	-	-	-	-
9	-	-	-	-
10	-	-	-	-
Total	40	100.00	40	100.00

Chi - square value=44.24
p - value= <0.0001

VAS (24 hr.)

In our study, we found that Group A, VAS score was6 in 12 patients while no patient in Group B with p value <0.0001 which is significantly significant.

VAS (48 hr.)

VAS (48 hr.)	Group A (N=40)		Group B (N=40)	
	Frequency	%	Frequency	%
0	15	37.50	-	-
1	16	40.00	-	-
2	6	15.00	23	57.50
3	-	-	9	22.50
4	-	-	7	17.50
5	3	7.50	1	2.50
6	-	-	-	-
7	-	-	-	-
8	-	-	-	-
9	-	-	-	-
10	-	-	-	-
Total	40	100.00	40	100.00

Chi - square value=57.96
p - value= <0.0001

VAS (48 hr.)

Visual analogue score of pain at 48 hours after surgery: In our study we found that at 48 hrs in post operative period in Group A, 3 patients had a VAS score of 5 while 1 patient has VAS of 1 with p value: 0.0001 which is statistically significant. Thus, the instillation of levobupivacaine reduces post operative pain.

1st Rescue

Analgesics (in hrs)	Group A (N=40)		Group B (N=40)	
	Frequency	%	Frequency	%
0	1	2.50	-	-
1	37	92.50	8	20.00
2	-	-	1	2.50
3	-	-	-	-
4	1	2.50	12	30.00
6	-	-	8	20.00
12	-	-	10	25.00
24	1	2.50	-	
48	-	-	1	2.50
Total	40	100.00	40	100.00

Chi - square value=49.99
p - value= <0.0001

1st Rescue

1st rescue: The average time at which the first analgesic was taken with postoperative period.

In our study among the groups, Group A which didn't receive intraperitoneal instillation of levobupivacaine had a relatively shorter span of (0 - 1) hour of 1st rescue dose of analgesic as compared to Group B. In Group A more than one dose was given in (0 - 1hr) is almost 95% as compared to Group B (0%). Therefore, the timing of first shot of rescue analgesic was significantly shorter in Group B as compared to Group A with p value: 0.00001 which was statistically significant.

Total No. of Analgesics

No. of Analgesics	Group A (N=40)		Group B (N=40)	
	Frequency	%	Frequency	%
0	-		-	-
1	1	2.50	22	55.00
2	-	-	14	35.00
3	-	-	2	5.00
4	12	30.00	2	5.00
5	18	45.00	-	
6	9	22.50	-	
Total	40	100.00	40	100.00

Chi - square value=69.31
p - value= <0.0001

Total No. of analgesics

Hospital Stay After Surgery (in days)

Hospital Stay (in days)

Hospital Stay (in days)	Group A (N=40)		Group B (N=40)	
	Frequency	%	Frequency	%
2	1	2.50	16	40.00
3	2	5.00	20	50.00
4	17	42.50	3	7.50
5	15	37.50	1	2.50
6	5	12.50	-	-
Total	40	100.00	40	100.00

Chi - square value=55.01
p - value= <0.0001
Hospital Stay (in days)

Among the Group B patients who received intraperitoneal instillation of levobupivacaine 40% of patients were discharged on day 2 and 50% on Day 3 as compared to Group A.

The duration of hospital stays of patients enrolled in Group B was significantly shorter as comparison to Group B with p value: <0.0001 which was statistically significant.

4. Discussion

In our study, after analysing the demographic Data obtained, we found that Cholelithiasis was prevalent in 2nd to 5th decade of life with highest propensity towards 30 - 40yrs with mean age of 50.5%. and p - value =0.532 which is statistically significant. [refer to fig; 7]

As per our study the prevalence is more in females as compared to males in both the groups. [refer to fig: 8]

Group A comprised of 40 patients: 2 males and 38 females with ratio of (0.05: 1)

Group B comprised of 40 patients: 5 males and 7 females with ratio of (0.14: 7)

Prior research has shown that laparoscopy is linked to reduced discomfort compared to laparotomy, however it is not entirely devoid of pain [2 - 10]. Patients who have Laparoscopic cholecystectomy often experience significant pain on the day of the operation, sometimes necessitating the use of painkillers.

There is a debate on the primary cause of discomfort after a laparoscopic surgery. Some physicians argue that the major cause of pain is the insertion of trocars through the abdominal wall, while others feel that most of the pain comes from the dissection and insufflation of CO2 inside the abdominal cavity, which leads to the distension of the abdominal wall and prolonged elevation of the diaphragm.

The early pain experienced after a laparoscopic cholecystectomy is a multifaceted process that involves various pain elements resulting from different pain

mechanisms. These mechanisms include surgical trauma to the abdominal wall, trauma within the abdomen due to the removal of the gall bladder, abdominal distention, and the use of carbon dioxide for pneumoperitoneum. Ideally, pain should be managed using many methods. Consequently, we examined the impact of administering local anaesthesia via both the intraperitoneal and port site routes to provide pain relief after laparoscopic cholecystectomy.

In prior Randomized control trial investigations, the use of incisional local anaesthetics for analgesia was shown to lower pain intensity and opioid demand, as demonstrated by Alexander et al. [72] and Sarac et al. [44]. However, Ure et al. [88] found that infiltrating local anaesthetics into the abdominal wall did not result in pain

The p - value of 0.0001 indicated a statistically significant difference between the two groups.

Therefore, the use of levobupivacaine decreases discomfort experienced after surgery.

5. Conclusion

To conclude, levobupivacaine is effective at preventing pain in the first 4 - 6 hours of post operative period after laparoscopic cholecystectomy when instilled intraperitoneally on laparoscopy. Our study showed, instillation of 20ml of levobupivacaine significantly reduced the need for diclofenac compared with saline. This technique is simple, safe, and without adverse effects. As postoperative pain is unpredictable, local anesthetics should be considered for instillation in all patients at the time of laparoscopic procedures. Levobupivacaine is better choice because of its higher efficacy and larger safety margin. A systematic instillation is likely to be cost effective, because it decreases time in the postoperative units, usage of NSAIDS or opioids, and resource utilization in the ward for treatment of postoperative pain and and helps patient get a better post operative recovery and early discharge.

References

[1] Pan dove PK, Arora N, Garg A, Pan dove L, Kumar A. Intraperitoneal instillation of bupivacaine in gallbladder fossa and at trocar sites in reduction of postoperative pain after laparoscopic cholecystectomy: a prospective randomized controlled double - blind trial. Int Surg J 2017; 4.

[2] Artemesia et al in 2009 studied Repeated intraperitoneal instillation of levobupivacaine for the management of pain after laparoscopic cholecystectomy https: //doi. org/10.1016/j. surg.2009.04.010.

[3] Wei X, Yao X. The Impact of Intraperitoneal Levobupivacaine on Pain Relief After Laparoscopic Cholecystectomy: A Meta - analysis of Randomized Controlled Studies. Surg Laparosc Endosc Percutan Tech.2020 Feb; 30 (1): 1 - 6. doi: 10.1097/SLE.0000000000000742. PMID: 31913214.

[4] Yıldırım Ar A, Erdoğan Arı D, Yiğit Kuplay Y, İşcan Y, Karadoğan F, Kırım D, Akgün FN. Bloqueio do plano abdominal transverso guiado por ultrassom em pacientes submetidos à colecistectomia laparoscópica: comparação da eficácia de bupivacaína e levobupivacaína no controle da dor pós-operatória [Ultrasound - guided transversus abdominis plane block in patients undergoing laparoscopic cholecystectomy: comparison of efficacy of bupivacaine and levobupivacaine on postoperative pain control]. Braz J Anesthesiol.2018 Sep - Oct; 68 (5): 455 - 461. doi: 10.1016/j. bjan.2018.02.004. Epub 2018 Jun 22. PMID: 29937216; PMCID: PMC9391702.

[5] Eypasch E, Sauerland S, Lefering R, Neugebauer EA. Laparoscopic versus open appendectomy: between evidence and common sense. Dig Surg 2002; 19: 518 - 522.

[6] Ekstein P, Szold A, Sagie B, Werbin N, Klausner JM, Weinbroum AA. Laparoscopic surgery may be associated with severe pain and high analgesia requirements in the immediate post - operative period. Ann Surg 2006; 243: 41 - 46.

[7] Slim K. Pain after laparoscopic cholecystectomy. Br J Surg 2000; 87: 1249

[8] Alexander JI. Pain after laparoscopy. BrJ Anaesth 1997; 79: 369 - 378.

[9] Cunniffe MG, McAnena OJ, Dar MA, Calleary J, Flynn N. A prospective randomized trial of intra operative bupivacaine irrigation for management of shoulder - tip pain following laparoscopy. Am J Surg 1998; 176: 258 - 261.

[10] Joris J, Thiry E, Paris P, Weerts J, Lamy M. Pain after laparoscopic cholecystectomy: characteristics and effect of intraperitoneal bupivacaine. Anesth Analg.1995 Aug; 81 (2): 379 - 84. doi: 10.1097/00000539 - 199508000 - 00029. PMID: 7618731.

[11] Loizides S, Gurusamy KS, Nagendran M, Rossi M, Guerrini GP, Davidson BR. Wound infiltration with local anaesthetic agents for laparoscopic cholecystectomy. Cochrane Database Syst Rev.2014 Mar 12; (3): CD007049. doi: 10.1002/14651858. CD007049. pub2. PMID: 24619479.

[12] Heppolette CAA, Brunnen D, Bampoe S, Odor PM. Clinical Pharmacokinetics and Pharmacodynamics of Levobupivacaine. Clin Pharmacokinet.2020 Jun; 59 (6): 715 - 745. doi: 10.1007/s40262 - 020 - 00868 - 0. PMID: 32034727.

[13] Ismail MT, Hassanin MZ, Elshmaa NS. Preincisional infiltration and intraperitoneal instillation of levobupivacaine 0.25% for management of early postoperative pain following laparoscopic ovarian drilling. J Obstet Gynaecol Res.2013 Feb; 39 (2): 543 - 8. doi: 10.1111/j.1447 - 0756.2012.01989. x. Epub 2012 Aug 26. PMID: 22925421.

[14] Alexander JI. Pain after laparoscopy. British Journal of Anaesthesia.1997 Sep; 79 (3): 369–78.

[15] Mitra S, Khandelwal P, Roberts K, Kumar S, Vadivelu N. Pain Relief in Laparoscopic Cholecystectomy - A Review of the Current Options. Pain Practice.2011 Oct 19; 12 (6): 485–96.