

Original Research Article

Role of intraperitoneal instillation of bupivacaine after laparoscopic cholecystectomy for post-operative pain management: a randomized controlled trial

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ABSTRACT

Background: Intra peritoneal (IP) local anaesthesia (LA) is a simple, cheap and safest method of providing post-operative (post-op) analgesia after laparoscopic cholecystectomy (LC). In this research, the role of intraperitoneal (IP) instillation of bupivacaine on post-op pain was studied. Post-op pain at 6, 12 and 24 hours was assessed using numeric rating scale. The degree of ambulation postoperatively at 6 and 24 hours and the requirement of analgesics was taken into account. The length of hospital stay was also a factor.

Methods: A total of 76 patients during January 2018 to December 2018, undergoing LC, fitting the inclusion criteria were included randomly and divided in to two groups, bupivacaine group (B) and control group (A) based on a pre-generated random number sequence by the principal investigator. The surgical outcome was compared based on multiple parameters and the primary outcome measures were the post-op pain and analgesic requirement.

Results: Degree of ambulation at 6 hours was significantly better in group B, compared to group A ($p=0.008$). The requirement of first dose of rescue analgesia was found to be within 6 hours (post-op) in 34 patients of group A (89.47%) as compared to 13 patients of group B (34.21%), was found to be statistically significant ($p<0.001$). There was statistically significant ($p=0.002$) difference with respect to length of hospital stay between the two groups.

Conclusions: In our study we found that IP bupivacaine (0.5%) is an effective, economical, safe method of post-op pain management with better post-op recovery.

Keywords: Peritonitis, Peritoneal lavage, Solutions, Normal saline, Infection

INTRODUCTION

Laparoscopic cholecystectomy (LC) is a gold standard surgical procedure for treatment of gall stone disease.¹ LC is a widely performed surgical procedure that achieves superior outcomes in post-operative (post-op) pain, recovery time, cosmetic issues, and morbidity.² Though LC is associated with lesser post-op pain than open cholecystectomy, but patients still experience some amount of pain. Pain from incision sites is of somatic origin, whereas pain from gall bladder bed is mainly visceral, also many patients complain of pain radiating to

right shoulder, which is due to residual carbon dioxide (CO₂) post-pneumoperitoneum irritating the diaphragm. Intra-abdominal dull pain that cannot exactly be located is considered as visceral pain, while the sharp pain felt in the abdominal wall is deemed as parietal pain.

Pain relief is an important goal of any surgery. Administration of intraperitoneal (IP) local anesthetic (LA), either during surgery, is used by many surgeons as a method of reducing post-op pain. This technique was first evaluated in patients undergoing laparoscopic gynecological surgery by Narchi et al.³ Its application in

LC was initially examined in a randomized trial in 1993 by Chundrigar et al.⁴ Since then, several trials evaluating the efficacy of IP LA in LC have been published worldwide. Any amount of reduction in the pain is beneficial, when the treatment is not associated with any side effects. Post-op pain control is one of the most important factors in determining the length of hospital stay and post-op recovery and day to day activities.⁵

Early post-op pain management will lead to early ambulation, early recovery and also it helps in decreased incidence of deep vein thrombosis. To reduce post-op pain, laparoscopy has evolved over the laparotomy as a major alternative due to its equal or better outcomes.⁶ IP LA is a simple, cheap and safest method of providing post-op analgesia.

Bupivacaine belongs to amide group of local anaesthetic, with a half-life of three hours, acts by inhibiting depolarization of nerves by blocking (visceral nociceptors) the voltage gated sodium channels and preventing impulse conduction. It is also has anti-inflammatory action and prevents peritonitis and bowel adhesion. The mean duration of action of bupivacaine hydrochloride is 8.07 hours which is 2-3 times longer than lignocaine.^{7,8} Bupivacaine is 90% protein bound in plasma, thus is a very safe drug as the active component is the unbound form.⁹

Objectives of the study were to compare post-op pain at 6, 12 and 24 hours using numeric rating scale, to study and assess post-op analgesia requirement, to assess the degree of ambulation post-op at 6 and 24 hours and to study the length of hospital stay. This study was undertaken to assess the efficacy and effectiveness of IP instillation of bupivacaine for post-op analgesia following LC.

Aim of the study was to study the role of IP bupivacaine instillation for post-op pain in patients undergoing LC.

Objectives of the study were: to compare post-op pain using numeric rating scale, to study and assess the post-op analgesia requirement, to assess the degree of ambulation post-operatively, and to study the length of hospital stay (fit for discharge).

METHODS

The prospective randomized controlled trial was conducted at KPC Medical College and Hospital from 01 January 2018 to 31 December 2018 (a period of one year). The sample size was 76.

Sample size calculation

The sample size was calculated to be 76.

Assuming p value <0.05 to be significant and considering effect to be two sided we get,

$$Z\alpha = 1.96$$

Assuming power of study to be 90% we get,

$$Z1 - \beta = 1.28$$

Considering an effect size (difference in visual analogue scale-VAS score between the 2 drugs) of 0.75 to be statistically significant we get,

$$n > 2(Z\alpha + Z1 - \beta)^2 \times SD^2 / d^2$$

n=38 in each group. Hence 38 patients were taken in each group.

The source of data for the study were 76 patients, 18 years and above, both males and females requiring LC admitted during the period of 12 months commencing from 01 January 2018, in the Department of General Surgery at KPC Medical College and Hospital, Kolkata. A written informed consent was obtained from all the patients prior to the day of surgery.

All patients less than 18 years of age were excluded from the study as were patients with history of hypersensitivity to bupivacaine. Those with history of chronic use of analgesics were not included. Pregnant patients and patients requiring conversion to open surgery were also excluded. Other criteria for exclusion were those who underwent combined procedures with laparoscopic cholecystectomy and patients who refused consent to participate in the study.

Patients meeting the inclusion criteria were randomized for the study by the use of random number generator. The study was carried out as a prospective, double blind, randomized and controlled trial. Patients undergoing LC and who gave written informed consent to participate in the trial were allocated into two groups (A and B) of 38 patients each using computer generated random numbers. Group A (n=38) patients were assigned as control group, who did not receive IP instillation of bupivacaine after gall bladder extraction and patients in group B were assigned to receive intervention in the form of 20 ml of 0.5% bupivacaine IP after achieving haemostasis after extraction of gall bladder.

In the pre-op ward, all patients were instructed regarding the proper use of numerical rating scale (NRS) for assessing pain. Premedication in all cases was omitted and uniform anaesthesia technique was used for all the patients conforming to the institutional anaesthetic protocol. Standard four port LC was done. The procedure followed the sequence of creation of pneumoperitoneum using veress needle, port placement, separation of all adhesions to the gall bladder and the surrounding liver with the exposure of the peritoneal fold in which the cystic artery and duct are situated, dissection and skeletonisation of the cystic duct and cystic artery (demonstration of critical view of safety), occlusion of cystic artery with clips and division of cystic artery, followed by occlusion of cystic duct with clips and division of the cystic duct and

dissection of gall bladder from its fossa in the liver and extraction of the gall bladder from the infraumbilical/supraumbilical port under vision using a 10 mm 30 degree telescope during specimen extraction. This was followed by IP instillation of 20 ml of 0.5% injection. Bupivacaine in the study group B. No instillation in patients of control group. Deflation of pneumoperitoneum and closure of infraumbilical/supraumbilical port sheath was done using number 1 braided coated polyglactin 910 violet (vicryl). Skin over all the port sites was opposed using 3-0 monofilament poliglecaprone 25 (monocryl), undyed with subcuticular sutures.

All patients were extubated and shifted to the post-op ward where patient were kept overnight. The post-op ward nursing staff, who were not aware of the patients group recorded NRS at fixed intervals, that is at 6, 12 and 24 hours and whenever the patient complaints of pain for all measurements the time of extubation is considered as "0". The patients were assessed for pain, post-op nausea and vomiting (PONV) and any other complications. For any pain complaints (NRS >3), a dose of paracetamol intravenous (IV) 1 gm was given SOS (if necessary) with minimum interval of 6 hours between each dose. Patients were prescribed oral analgesic tab. Paracetamol (650 mg) 1 tablet, thrice daily, starting 6 hours post-surgery for 2 days then SOS. If the patients complained of pain in between the paracetamol dose, injection pethidine 50 mg intramuscular (IM) was administered as rescue analgesia.

Acute post-op pain was assessed using the 11-point NRS score on which 0 indicates "no pain" and 10 represents "worst imaginable pain" (Figure 1). The scores were provided by the patients themselves after the NRS of pain was explained to them.

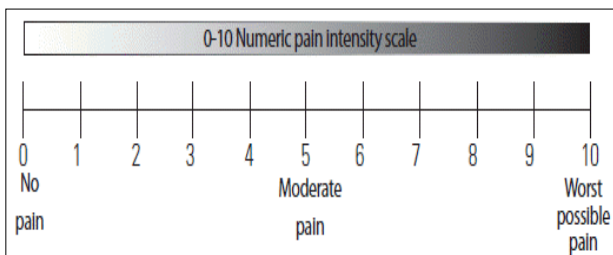


Figure 1: Numerical rating scale (NRS).

The severity of PONV were assessed by four-point scale on which: 1 indicates no PONV, 2 indicates mild PONV, 3 indicates moderate PONV, and 4 indicates severe PONV.

Degree of ambulation was assessed at 6 and 24 hours post-op in terms of ability to sit up unassisted, ability to get out of bed unassisted and ability to perform routine activity (i.e. going to toilet).¹⁰

The study variables that included the comparative outcome of severity of post-op pain in terms of NRS score, first analgesic requirement in post-op period, and total post-op

analgesic dose requirement in 24 hours were statistically evaluated. Other outcomes that included opioid requirement, degree of ambulation, hospital stay and the comparison of the incidence of side-effects of the two groups was statistically defined.

Patients who were unable to understand and report NRS score, required drain placement, converted to open cholecystectomy, or where surgery was combined with other procedure were considered as drop out.

Statistical methods

Categorical variables will be expressed as number of patients and percentage of patients and compared across the 2 groups using Pearson's chi square test for independence of attributes.

Continuous variables will be expressed as mean±standard deviation (SD) and compared across the 2 groups using unpaired t test if the data follows normal distribution and Mann-Whitney U test if the data does not follow normal distribution.

The statistical software Statistical Package for the Social Sciences (SPSS) version 20 will be used for the analysis.

An alpha level of 5% has been taken, i.e. if any p value is less than 0.05 it will be considered as significant.

RESULTS

The study was conducted at Department of General Surgery, KPC Medical College and Hospital from 01 January 2018 to 31 December 2018. After obtaining approval from institutional ethics committee, 76 patients planned for LC, satisfying the inclusion criteria were selected for the study. The patients were randomized into 2 groups, group A and group B. Patients randomly allocated to group A (n=38) (50%) were control group and rest 38 (50%) patients allocated to group B were given 0.5%, 20 ml IP bupivacaine after extraction of gallbladder. To ensure the blindness, the identity of the drug administered among the 2 groups was not disclosed to the investigator till the end of the study.

Following parameters were recorded and evaluated statistically: age of the patient; gender of the patient; PONV score of the patient; NRS (pain score) of the patient at 6, 12 and 24 hours post-op; ambulation of the patient at 6 and 24 hours post-op; rescue analgesia-injection paracetamol requirement at 6 hours post-surgery, total paracetamol requirement in 24 hours post-surgery and injection pethidine requirement; and fit to discharge.

The mean age (mean±SD) of the patients in group A was 42.71±13.15 years and the median age was 43 years. The mean age (mean±SD) of the patients in group B was 41.37±13.08 years and the median age was 43 years. There was no significant difference between the two groups in

terms of age distribution (p=0.600) (Table 1). In group A, 27 (71.05%) out of 38 were female. In group B, 28 (73.68%) out of 38 were female. There was no significant difference in sex distribution in between the two groups (p=0.798). Thus cholelithiasis was mostly prevalent among the female patients as compared to male patients (Table 2). PONV score in majority of patients of both group was PONV “1” [group A- 28 (73.68%) and group B- 29 (76.32)] that is no nausea and vomiting. However, the difference in PONV score between the two groups at any point of observation was statistically not significant (p=0.913) (Table 3). At 6 and 12 hours post operation, mean NRS score of group A (4.08±1.46) and (2.87±1.23) was found to be higher than that of group B (1.87±1.76) and (2.11±1.13). These differences of mean NRS of group A (p<0.001) were found to be significantly higher than that of group B (p=0.009) statistically (Table 4).

Table 1: Age distribution.

Group		Age in years
Group A	Mean	42.71
	Median	43.00
	Standard deviation	13.15
Group B	Mean	41.37
	Median	43.00
	Standard deviation	13.08
P value		0.600
Significant		Not significant

Statistically there was significant difference between the two groups A and B with respect to degree of ambulation at 6 hours following surgery (p=0.008). 28 (73.68%) out of 38 patients in group A were able to sit up unassisted. As compared to group A, 16 (42.11%) out of 38 patients in group B at 6 hours following surgery. Therefore, less number of patients in group A, 9 (23.68%) out of 38 patients as compared to 14 (36.84%) out of 38 patients in group B had some limitation in ambulation and were able to get out of bed unassisted but not able to perform routine activities. One (2.63%) out of 38 patients in group A were able to perform routine activities (i.e. going to toilet) as compared to 8 (21.05%) out of 38 patients in group B at 6 hours following surgery had statistically significant

Table 2: Gender distribution.

Variables	Group		Total (%)	P value	Significance
	Group A (%)	Group B (%)			
Gender	Male	27 (71.05)	28 (73.68)	0.798	Not significant
	Female	11 (28.95)	10 (26.32)		
Total	38 (100)	38 (100)	76 (100)		

Table 3: Post-op nausea and vomiting (PONV).

Variables	Group		Total (%)	P value	Significance
	Group A (%)	Group B (%)			
PONV	1	28 (73.68)	29 (76.32)	0.193	Not significant
	2	4 (10.53)	5 (13.16)		
		57 (75)	9 (11.84)		

difference. Statistically significant number of patients in group B were able to get out of bed unassisted and able to perform routine activity as compared to group A. Overall, the degree of ambulation among patients in group B was better than the patients in group A at 6 hours following surgery were found to be higher than that of group B at 24 hour post-op (1.21±0.70 versus 0.89±0.69) however these differences were statistically not significant (p=0.060) (Table 5).

Rescue analgesia was required in 34 (89.47%) out of 38 patients in group A and 13 (34.21%) out of 38 patients in group B. Requirement of first dose of rescue analgesia was earlier in patients of group A as compared to group B. There was statistically significant difference between the two groups A and B with respect to SOS dose of injection paracetamol received or not at 6 hours following surgery (p<0.001). Analgesia requirement was significantly higher (p<0.001) in group A (1.45±0.60 gm) compared to group B (0.76±0.71 gm). Most number of patients received single dose of injection. Paracetamol in group-B as compared to most patients in group-A, who required 2 doses of injection paracetamol in 24 hours following surgery.

Injection pethidine as rescue analgesia was required in 10 (26.32%) patients in group A whereas 4 (10.53%) patients in group B. The difference in requirement of injection pethidine in patients of the two groups was not found to be statistically significant (p=0.076) (Table 6).

3 (7.89%) out of 38 patients were fit for discharge in the same post-op day. 7 (18.42%) out of 38 patients in group A and 19 (50%) out of 38 patients in group B were fit for discharge in the 1st post-op day. 29 (76.32%) out of 38 patients in group A and 15 (39.47%) out of 38 patients in group B were fit for discharge by 2nd post-op day. Two out of 38 patients, in group A and one out of 38 in group B, who had delayed recovery, were fit for discharge by te 3rd post-op day. More than 50% of the patients in group B were dischargeable in the 1st post-op day. There was statistically significant difference between the two groups A and B in terms for post-op recovery (p=0.002). All the patients, once fit were discharged on the same day (Table 7).

Continued.

Variables	Group		Total (%)	P value	Significance
	Group A (%)	Group B (%)			
3	3 (7.89)	2 (5.26)	5 (6.58)		
4	3 (7.89)	2 (5.26)	5 (6.58)		
Total	38 (100)	38 (100)	76 (100)		

Table 4: Pain score at 6 hours, 12 hours and 24 hours following surgery- numerical rating scale (NRS).

Group		Pain score post-op 6 hours	Pain score post-op 12 hours	Pain score post-op 24 hours
Group A	Mean	4.08	2.87	1.21
	Median	4.00	3.00	1.00
	Standard deviation	1.46	1.23	0.70
Group B	Mean	1.87	2.11	0.89
	Median	1.00	2.00	1.00
	Standard deviation	1.76	1.13	0.69
	p value	<0.001	0.009	0.060
	Significance	Significant	Significant	Not significant

Table 5: Ambulation 6 hours after surgery.

Variables	Group		Total (%)	P value	Significance	
	Group A (%)	Group B (%)				
Ambulation at 6 hours	Able to sit up unassisted	28 (73.68)	16 (42.11)	44 (57.89)	0.008	Significant
	Able to get out of bed unassisted	9 (23.68)	14 (36.84)	23 (30.26)		
	Able to perform routine activity	1 (2.63)	8 (21.05)	9 (11.84)		
Total	38 (100)	38 (100)	76 (100)			

Table 6: Rescue analgesia 6 hours post-surgery.

Variables	Group		Total (%)	P value	Significance	
	Group A (%)	Group B (%)				
IV paracetamol	No	4 (10.53)	25 (65.79)	29 (38.16)	<0.001	Significant
	Yes	34 (89.47)	13 (34.21)	47 (61.84)		
Total	38 (100)	38 (100)	76 (100)			

Table 7: Fit to discharge.

Variables	Group		Total	P value	Significance	
	Group A (%)	Group B (%)				
Fit to discharge	POD 0	0 (0)	3 (7.89)	3 (3.95)	0.002	Significant
	POD 1	7 (18.42)	19 (50)	26 (34.21)		
	POD 2	28 (76.32)	15 (39.47)	44 (57.89)		
	POD 3	2 (5.26)	1 (2.63)	3 (3.95)		
Total	38 (100)	38 (100)	76 (100)			

DISCUSSION

Recent advances in the pathophysiology of pain have suggested that it is possible to prevent or to attenuate the neuronal hyper-excitability that contributes to enhanced post-op pain.¹¹ Adequate pain relief post-op is important as it may reduce post-surgery length of hospital stay. The choice of such analgesic is guided by factors such as efficacy, convenience of administration, cost-effectiveness

and safety profile. Post-op pain is the main factor delaying discharge of patients undergoing day care procedure including laparoscopic procedures and hence adding to hospital cost.

LA can have an analgesic effect lasting few hours. They have minimal sedative effects that can expedite the discharge of the patient. LA agents can have an opioid sparing effect. They reduce the nausea and vomiting,

commonly encountered during GA. In this way, they may be able to reach the criteria for early discharge from hospital.

Early pain after LC is multifactorial. It is a combination of parietal pain is caused by abdominal wall penetration by trocar; visceral pain is due to dissection of gall bladder, traction on nerves and peritoneal inflammation are caused by raised IP pressure secondary to CO₂ insufflations. While referred pain in the shoulder tip is due to diaphragmatic irritation by residual CO₂. Visceral pain is the main contributory factor for abdominal pain after LC, pain following LC is maximum on the first post-op day and declines over next 3 to 4 days.

We observed that patients in group A had more pain abdomen as compared to the patients in group B throughout the post-op period.

The pain scores at 6 hours ($p < 0.001$) and at 12 hours (0.009) following surgery were significantly better among patients in group B, compared to patients in group A. But at 24 hours ($p = 0.060$) it was not significant. In terms of the degree of ambulation at 6 hours, patients in group B did better than group A ($p = 0.008$). However, when the degree of ambulation was assessed at 24 hours following surgery, there was no significant difference between the two groups ($p = 0.297$). This gives confidence to the patient for returning back to his routine activity soon, when you manage immediate post-op pain adequately. PONV as a side effect was compared between the two group and the scores were comparable with no statistical difference ($p = 0.913$) at all instances of observation, and very less number of patients experienced nausea and vomiting and the anti-emetic requirement equal in both groups.

The requirement of first dose of rescue analgesia was found to be within 6 hours (post op) in 34 patients of group A (89.47%) as compared to 13 patients of group B (34.21%), was found to be statistically significant ($p < 0.001$). In a likewise manner the total dose of paracetamol required by patients of group A (1.45 ± 0.60 g) was found to be 50% higher than that of group B (0.76 ± 0.71 g) the difference was found to be statistically significant ($p < 0.001$).

In our study, 3 out of 76 patients were discharged in the same post-op day. 26 of remaining 73 patients were discharged on 1st post-op day. 44 of remaining 47 patients were discharged on 2nd post-op day; remaining 3 patients were discharged on 3rd post-op day. Three patients, who got discharged on same post-op day, are from group B. Seven out of 26 patients are from group A was discharged on 1st post-op day. 15 out of 47 patients from group B were discharged on 2nd post-op day, in which 6 patients had pain score 5 and above at 6 hours post-op. Two out of 15 patients required anti emetic who were discharged on 2nd post-op day in group B. Only three patients were discharged on 3rd post-op day. 2 patients had post-op

nausea and vomiting requiring anti emetic, and one patient had pain score 7 at 6 hours post-op.

The study of Chundrigar et al used 20 ml 0.25% bupivacaine and 20 ml of saline for IP instillation for post-op laparoscopic surgery.⁴ They concluded bupivacaine group had less pain in the early post-op period but they noted pain relief only up to 2 hours with IP administration of 0.25% bupivacaine.

Chakravarty et al performed a randomized controlled study on 66 ASA grade 1 patients with 20 ml 0.5% IP instillation and concluded IP bupivacaine provides a simple technique to be used as a part of multimodal approach and the above findings are in complete agreement with the findings of our study.¹²

One randomized controlled study had assessed 40 patients. In conclusion, IP bupivacaine for LC reduces pain in the initial post-op period, it is easy to administer with no adverse effects and may become a routine practice for this procedure.¹³

Limitations of the study

Pain is a subjective parameter and perception may vary from person to person.

In our study, requirement of stretching of infraumbilical/supraumbilical port was not noted during gall bladder extraction. This factor may have had an impact on the post-op pain score.

In this study we had assessed acute calculus cholecystitis patients, these are the patients who required more analgesia postoperatively and noted more pain scores, and this may have impact on postoperative pain scores and analgesia requirement assessment.

The difficulty of surgery performed not assessed in this study. The assessment of this parameter seems to be confounded by factors like level of training and skill of the individual who performed it. This also means that, the operation time could have been lesser, if all the procedures were performed by the same surgeon or surgeons with similar skills in laparoscopy.

CONCLUSION

In conclusion, IP bupivacaine for LC reduces pain in the initial post-op period, it is easy to administer with no adverse effects and may become a routine practice for this procedure. This simple, safe, inexpensive, effective technique thus improves the post-op in-hospital course and expedites early discharge. We advocate its use in all elective LC.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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