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ORIGINAL RESEARCH

Efficacy of local infiltration of bupivacaine in controlling post-operative port site pain vs. conventional analgesics following laparoscopic cholecystectomy

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ABSTRACT
With the invention of the modern advanced telescopes, cold xenon light source, multiple dual-trocars, automatic gas insufflators and various instruments, especially the development of the chip cameras which helped in monitoring the procedure on a monitor in 1986, Laparoscopy has become more widely accepted. The study was conducted on total of 150 patients who underwent Laparoscopic cholecystectomy. The study assigned to study the efficacy of local infiltration of bupivacaine in controlling postoperative port site pain vs. conventional analgesics following laparoscopic cholecystectomy. Out of the total 75 patients who received port site Bupivacaine (test) 67 of them (87%) reported only a mild pain and 5 of them reported moderate pain and only 3(9.7%) of them reported severe pain when compared to non-bupivacaine group (control) in which 10 of them reported mild pain and 37 patients reported moderate pain and 28 (90.3%) reported severe post-operative pain,. The Visual Analogue scale at 24 hours showed that those received port site Bupivacaine reported statistically significant ($p<0.001$) lower pain.

Key words: Bupivacaine, conventional analgesics, laparoscopic cholecystectomy

INTRODUCTION

Laparoscopy is defined as the telescopic visualization of the abdomino pelvic cavity through small incisions made on the abdominal wall with various instruments [1]. This instrumentation technique was developed as a science at the turn of this century [2]. This technique was primarily used for the diagnostic purposes of the intra-abdominal pathology.

Although Laparoscopy has been used over many years by the Gynecologists to evaluate the pelvic pathology, most General Surgeons did not recognize its importance [2]. With the invention of the modern advanced telescopes, cold xenon light source, multiple dual-trocars, automatic gas insufflators and various instruments, especially the development of the chip cameras which helped in monitoring the procedure on a monitor in 1986, Laparoscopy has become more widely accepted. The developments in Laparoscopic surgery have generally been greeted enthusiastically by both the surgeons and the patients.

In 1987, the first Laparoscopic cholecystectomy was performed by Philip mouretin France [3, 4]. Almost simultaneously McKernan and Saye performed Laparoscopic cholecystectomy in the United States in 1988 [5, 6]. Mr Reddick and Osten are credited with the first report of Laparoscopic cholecystectomy in the English literature. Over these last several years, this minimally invasive procedure has emerged world-wide as the preferred treatment of choice for patients with uncomplicated cholelithiasis and cholecystitis. Laparoscopic technique has largely replaced the traditional method of performing open cholecystectomy except in some complicated cases[7, 8].

The most common indication for surgical removal of gall bladder is recurrent biliary colic. There has been no established criteria for how many episodes are tolerated before cholecystectomy should be recommended and this decision is generally decided by both the symptoms of the patient and the experience of the surgeon. The benefits of Laparoscopic cholecystectomy include shorter hospital stay, reduced cost, decreased post-operative pain, avoidance of a large incision with improved

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cosmetic outcome and reduced postoperative recovery period and quicker return to normal routine work.

Diminished surgical trauma and associated morbidity have made Laparoscopic cholecystectomy a standard technique for removal of diseased gall bladder. However, post-operative port site pain, nausea and vomiting still remain and may delay the patients return to normal activities. The patients usually suffer from post-operative pain, especially aggravated with coughing, respiratory movements and mobilisation during the initial hours after surgery. Patients may also complain of shoulder pain secondary to peritoneal insufflations after the early post-operative hours and during the night after surgery. This can delay the patient's recovery; lengthen the duration of hospital stay and hence increase the morbidity and costs. Their optimal management has a potential for shortening of hospital stay and hastening recovery and reducing the cost. Opioids and non-steroidal anti-inflammatory drugs (NSAIDs) are generally used for the management of postoperative pain after Laparoscopic cholecystectomy. Many researchers have suggested that the combination of somatovisceral local anaesthetic treatment reduces incisional site, intra-abdominal and shoulder pain which occurs in Laparoscopic cholecystectomy. These local agents induce antinociception by acting on the nerve membranes. They reversibly decrease the rate of depolarisation and repolarisation of excitable membranes (like nociceptors) [9, 10]. There are different routes to administrate the local anaesthetic drug; such as infiltration at port site after surgery, pre incisional etc. Some researchers have shown that local parietal anaesthesia is effective in controlling post-operative pain [11, 12], while others have shown that it is not effective.Various methods have been investigated for reducing postoperative pain such as port site infiltration of local anesthesia, intraperitoneal infiltration of local anesthesia, pre op administration of anti-inflammatory etc. Studies have shown that infiltrating local anesthesia after surgery through the port site reduced the intensity of pain, the number of patients requiring postoperative analgesics and the number of doses required and hence the duration of hospital stay.

METHODOLOGY

STUDY DESIGN

A prospective controlled randomized trial to study the efficacy of local infiltration of bupivacaine in controlling postoperative port site pain vs conventional analgesics following laparoscopic cholecystectomy.

INCLUSION CRITERIA

All patients undergoing laparoscopic cholecystectomy between age 20-65years.

EXCLUSION CRITERIA

1. Laparoscopic procedure converted into open surgery.
2. Patients having undergone Laparoscopic cholecystectomy within 6 months of chemotherapy or radiotherapy.
3. Patients on immunosuppressive drugs.

STUDY PROCEDURE

The study was conducted on total of 150 patients who underwent Laparoscopic cholecystectomy. The study assigned to study the efficacy of local infiltration of bupivacaine in controlling postoperative port site pain vs. conventional analgesics following laparoscopic cholecystectomy.

All patients undergoing Laparoscopic cholecystectomy were invited to participate in the study and written informed consent was taken. All patients underwent a standard clinical and laboratory evaluation that includes briefly information about age, sex, address, and routine investigations including ultrasound abdomen, which are done pre operatively.

Pre-operative investigations include liver function tests, complete blood count, and renal function test and coagulation profile. The subjects satisfying inclusion criteria were included in the study. All such patients underwent Laparoscopic cholecystectomy.

Patients were selected and divided into 2 groups using appropriate statistical methods.

Informed written consent for infiltration of Bupivacaine at the port site was obtained from all the patients in the study group.

Test dose of Bupivacaine was given for all the patients in the study group prior to the surgery.

Group 1 1-75 were given Bupivacaine at port site following Laparoscopic cholecystectomy.

Group 2 76-150 will be given conventional analgesics (control) tramadol. TID No conventional analgesics were given to the patients in the study group.

Results

Table 1: Age Group

Age groups	Frequency	Percentage (%)
<15	2	1.3
15-29	15	10.0
30-44	53	35.3
45-59	50	33.3
60-74	27	18.0
>75	3	2.0
Total	150	100.0

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The mean age is 45.35 years with standard deviation of 14.132. Majority (28%) were between the age of 36 to 45 years followed by 23% were between 46 to 55yrs, 22% were between 26 to 35 yrs, 14% were between 56 to 65 yrs, 7% were below 25 yrs and 6% were above 66 yrs.

The commonest presenting symptoms (84%) being abdominal pain in the right upper quadrant (biliary colic) associated with jaundice most of the time (69%). Fever (48%) and vomiting (29%) were not observed frequently.

Table 2: VAS at the end of 1 hour VAS 1 * group

		Group		Total
		1	2	
VAS 1	1	46	2	48
		95.8%	4.2%	100.0%
	2	24	20	44
		54.5%	45.5%	100.0%
	3	5	53	58
		8.6%	91.4%	100.0%
Total		75	75	150
		50.0%	50.0%	100.0%

X^2=86.737 df = 2 p<0.001

Out of the total 75 patients who received port site Bupivacaine (test) 46 of them (95.8%) reported only a mild pain and 24 of them reported moderate pain and only 5(8.6%) of them reported severe pain when compared to non-bupivacaine group (control) in which only 2 (4.2%) reported mild post-operative pain, 20 patients reported moderate pain and 53(91.4%) had severe pain. The Visual Analogue scale at 1 hours showed that those received port site Bupivacaine reported statistically significant (p<0.001) lower pain.

Table 2: Vas at the end of 6 hours VAS 6 * group

		Group		Total
		1	2	
VAS 6	1	59	6	65
		90.8%	9.2%	100.0%
	2	13	34	47
		27.7%	72.3%	100.0%
	3	3	35	38
		7.9%	92.1%	100.0%
Total		75	75	150
		50.0%	50.0%	100.0%

X^2=79.546 df = 2 p<0.001

Out of the total 75 patients who received port site Bupivacaine (test) 59 of them (90.8%) reported only a mild pain and 13 of them reported moderate pain and only 3(7.9%) of them reported severe pain when compared to non-bupivacaine group (control) in which pain, only 6(9.2%) of them reported mild pain. 34 patients reported moderate pain and 35 (92.1%) reported severe-post operative pain. The Visual Analogue scale at 6 hours showed that those received port site Bupivacaine reported statistically significant (p<0.001) lower pain.

Table 3: VAS at 24 hrs VAS 24 * group

		Group		Total
		1	2	
VAS 24	1	67	10	77
		87.0%	13.0%	100.0%
	2	5	37	42
		11.9%	88.1%	100.0%
	3	3	28	31
		9.7%	90.3%	100.0%
Total		75	75	150
		50.0%	50.0%	100.0%

X^2=80.421 df = 2 p<0.001

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Out of the total 75 patients who received port site Bupivacaine (test) 67 of them (87%) reported only a mild pain and 5 of them reported moderate pain and only 3(9.7%) of them reported severe pain when compared to non-bupivacaine group (control) in which 10 of them reported mild pain and 37 patients reported moderate pain and 28 (90.3%) reported severe-post operative pain. The Visual Analogue scale at 24 hours showed that those received port site Bupivacaine reported statistically significant ($p<0.001$) lower pain.

Table 4: Hospital Stay

		Hospital stay range			
		1-3days	4-7days	8 or more	Total
group	1	63	10	0	73
		86.3%	13.7%	.0%	100.0%
	2	2	55	20	77
		2.6%	71.4%	26.0%	100.0%
Total		65	65	20	150
		43.3%	43.3%	13.3%	100.0%

1-Bupivacaine group 2-control group.

HOSPITAL STAYS

In the study group: out of total 75 patients 63(86.3%) were discharged within 3 days post-surgery, 13% within a week and none more than a week.

In the control group only 2 patients (2.6%) were discharged within 3 days, and 71% were discharged within a week and more than 26% were discharged after a week.

DISCUSSION

Our study was undertaken to evaluate the efficacy of port site infiltration of Bupivacaine in controlling postoperative pain in patients undergoing Laparoscopic cholecystectomy.

Bupivacaine is long-acting local anaesthetic that was developed. The agent is a pure left-isomer and, based on its three-dimensional structure; it has less toxic potential on the central nervous system and the heart.

In our study there was a female preponderance and majority of the patients were in the age group of 30-45 years. The demographic data was comparable to the literature. The Laparoscopic procedure was completed successfully in all cases without any intraoperative complications or need of conversion to an open operation.

A total of 150 patients were included of which 75 were included in the study group and received Bupivacaine at the port site and the remaining 75 were included in the control group who received conventional analgesics.

Our observation showed that the VAS score at the end of I hour, in the study group majority of the patients nearly 95.85 had only mild pain and only 8.6% had severe pain and required rescue analgesics. However, in the control group only 4.2% had mild pain and majority of the patients that is nearly 91.4% had severe pain and required rescue analgesics. The Visual Analogue scale at 1 hours showed that those received port site Bupivacaine reported statistically significant ($p<0.001$) lower pain.

VAS at the end of 6 hours showed that in the study group, out of the 75 patients 90.8% reported only mild pain and 7.9% had severe port site pain and required rescue analgesics. However, in the control group 9.2% had mild pain but majority 92% had severe pain and required rescue analgesics. The Visual Analogue scale at 6 hours showed that those received port site Bupivacaine reported statistically significant ($p<0.001$) lower pain.

VAS at the end of 24 hours showed that in the study group, 87% had only minimal pain and 9.7% had severe pain. However, in the control group only 13% had minimal pain and nearly 90% had severe pain. The Visual Analogue scale at 24 hours showed that those received port site Bupivacaine reported statistically significant ($p<0.001$) lower pain.

Our study also showed that the in the study group: out of total 75 patients 63(86.3%) were discharged within 3 days post-surgery, 13% within a week and none more than a week. In the control group only 2 patients (2.6%) were discharged within 3 days, and 71% were discharged within a week and more than 26% were discharged after a week. Hence the duration of hospital stay in the study group was significantly lesser than in the control group and was also statistically significant.

In a study conducted by Liu YY, Yeh CN *et al*. on port site Bupivacaine infiltration following Laparoscopic cholecystectomy. Seventy-two patients were Included in the study and randomized into a control or local anaesthesia with Bupivacaine (LA) group. All 72 patients received general anaesthesia

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with the same protocol by one of the authors (Lin CC, anaesthesiologist). The Local anaesthesia group had a significantly shorter hospital stay than the control group (1.1 ± 0.3 d vs. 2.8 ± 2.7 d, P = 0.001). The Local anaesthesia group experienced significantly less pain at 1 and 24 h after surgery and at discharge when compared with the control group. Furthermore, the Local anaesthesia group had less meperidine use at 1h and total meperidine use after Laparoscopic cholecystectomy. They have concluded that local anaesthesia with Bupivacaine infusion at the port site in laparoscopic cholecystectomy patients at the end of surgery significantly decreased postoperative pain immediately. This short term benefit explains the lower parentral analgesic use and earlier discharge in patients with local anaesthesia.

In a meta-analysis conducted by Alexander P. Boddy, Samir Mehta, Michael Rhodes [4], on The Effect of Intraperitoneal Local Anesthesia in Laparoscopic Cholecystectomy. Twenty-four studies were incorporated in this systematic review. Anesthetic drugs that were evaluated included Bupivacaine, Levobupivacaine, Lidocaine. Twelve of the 24 studies reported a significant improvement in pain during the early postoperative period. VAS scores for Subcategory improved pain relief in 7 of 13 trials and a meta-analysis of 10 trials found an overall WMDin VAS of 13 mm in favor of the treatment groups. The technique seems to be safe and results in a statistically significant reduction in early postoperative abdominal pain. It may be of particular benefit when the operation is planned as an ambulatory procedure to improve same-day discharge rates.

In another study conducted by Ceyhun*et al*., [5] Comparison of Analgesic Effects of IntraperitonealLornoxicam and Bupivacaine Administration in Laparoscopic Cholecystectomy was done. Patients were randomized into three groups and received 150 mg (80 mL) Bupivacaine or 16 mg lornoxicam (80 mL) or placebo (80 mL saline) via multi-regional intraperitoneal instillation and port sites infiltration. At 24 h, VAS scores at rest and while coughing were found significantly lower in Bupivacaine and lornoxicam group when compared with control group (p=0.047). The percentage of patients needing tramadol was also significantly lower with the Bupivacaine and lornoxicam compared with control (p<0.001, p=0.018). They have concluded stating that multi-regional, intraperitoneal instillation and port site infiltration of Bupivacaine and lornoxicam during Laparoscopic cholecystectomy reduces the postoperative pain significantly.

This present study confirms earlier evidence that, in patients with gallbladder lesion undergoing Laparoscopic cholecystectomy, local anaesthesia infusion is more effective when applied at the end of an operation than at the start. Local anaesthesia with Bupivacaine infusion at the port site in Laparoscopic cholecystectomy patients at the end of surgery significantly decreased postoperative pain immediately.

Any reduction in such pain is relevant, particularly if it is statistically significant, whether the lower pain score translated into increased patient's comfort and compliance is questionable. However, at whatever level they functioned, they did so more comfortably. Thus, this simple, inexpensive, effective technique improves the postoperative period in-hospital course and can be practiced routinely in all elective Laparoscopic cholecystectomies.

CONCLUSION

In conclusion, our study showed that the port sites infiltration of Bupivacaine following Laparoscopic cholecystectomy is an effective, safe and simple analgesic technique that reduces the post-operative pain and hence the hospital stays and cost.

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