

Comparison of Pain and Requirement of Injectable Anti-Inflammatory Drugs with and without Port Site Infiltration of Injection Bupivacaine in Laparoscopic Surgeries

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ABSTRACT

Background: Laparoscopic surgery is associated with shorter hospital stay, less post-operative pain and excellent cosmesis. Post-operative pain is lesser in laparoscopic procedures but in some cases, it is not absolutely painless. The aim of different methods to reduce the post-operative pain is to avoid the use of opioids by using anti-inflammatory drugs and infiltration of local anesthesia either intra-peritoneal or in the wound. Theoretically peripheral blockage of pain stimuli with local anesthetic agent is more effective than treating pain. For this purpose, Bupivacaine has been recently used to be injected at port sites. **Objective:** To evaluate the pain and requirement of injectable anti-inflammatory drug (inj. Ketorolac 30mg) after port site infiltration of inj. bupivacaine in laparoscopic cases. **Study Design:** Prospective randomized study of elective laparoscopic procedures. **Settings:** Surgical Unit-IV, DHQ Teaching Hospital Faisalabad, Medical University Faisalabad Pakistan. **Duration:** November 2015 to May 2017. **Methodology:** Two hundred and sixty patients included in the study were divided into two groups with equal number in each group. **Results:** In the study group(A), 103(79.3%) patients were females of 27(20.7%) patients were males. All female patients in the study group underwent LC and among males, 26(96.3%) patients underwent TAPP and 1(3.7%) patient underwent LC. In the control group(B) 97(74.6%) patients were females, 33(25.4%) patients were male. All female patients (100%) underwent LC and among the males, 30 patients (90.9%) underwent TAPP, 3(9.1%) patients underwent LC. In the study group, the mean VAS in the study group at 2 hours, 6 hours, 12 hours after surgery was 1.6, 1.7, 1.6 with standard deviation 1.6, 1.7, 1.8 respectively while in the control group VAS was 2.9, 3.1, 2.6 with standard deviation 2.1, 1.8, 1.9 respectively. In the study group the mean of anti-inflammatory drug injections (Ketorolac) needed was 1.0000 with standard deviation 0.7 and in control group, the same was 1.3 with standard deviation 70.8. The previous was less than 0.05. **Conclusion:** Infiltration of local anesthetic agent i.e., Bupivacaine results in almost total painless procedure in laparoscopic surgery, the timing and anatomical site of injection should be investigated further.

Keywords: Pain, Anti-Inflammatory Drugs, Port-site, Bupivacaine.

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INTRODUCTION

For a long time, only the gynecologists had been using laparoscopy to diagnose the pelvic pathologies and to perform minor surgeries like tubal ligation. When Phylip Mouret in 1987 and in 1988 Francois Dubios and Jacques

Parisant performed successful laparoscopic cholecystectomies, only then the value of laparoscopy was recognized by the general surgeons.¹

Later on, because of this procedure being associated with lesser post-operative pain plus patient discomfort,

shorter stay at hospital and excellent cosmesis, it has been adopted and accepted all over the world warmly and has resulted in revolution in the management of cholelithiasis, and now many other surgical procedures are also being performed laparoscopically.²

If compared with open procedures, Post-operative pain is lesser in laparoscopic procedures, but in some cases, it is not painless and is still an issue. The proposed mechanism of pain is that it is multifactorial in nature and severity and varies among individuals and aims of different methods to treat the post-operative pain are to avoid the use of opioids, by the use of anti-inflammatory drugs and infiltration of local anesthesia either intraperitoneal or in the wounds.³

Post-operative pain is the main cause of delayed mobility and extended hospital stay of patients. Therefore, surgeons are very keen to minimize the post-operative pain.⁴

Post-operatively, anti-inflammatory drugs or opioids are mostly used for pain relief, but they have many side effects and many a times are not fully affective. Many surgeons have been practicing injection of local anesthetic agent at port sites to combat the post-operative pain, after laparoscopic procedures. It is advantageous because it is easy to inject, is safe and cost effective.⁵ Theoretically, speaking, peripheral blockage of pain stimuli with local anesthetic agent is more effective than treating the pain. For this purpose, bupivacaine has been recently used and is injected at port sites.⁶

The purpose of this study was to evaluate the pain and requirement of injectable anti-inflammatory drug (inj. Ketorolac 30mg) after port site infiltration of injection bupivacaine in laparoscopic cases.

METHODOLOGY

Study Design: Prospective randomized study of elective laparoscopic procedures.

Settings: Surgical Unit 4, DHQ hospital, Faisalabad, Faisalabad Medical University, Faisalabad.

Duration: November 2015 to May 2017.

Sample Technique: Non-probability consecutive sampling.

Sample Size: 260 patients, 130 in each group.

Inclusion Criteria: All the patients with clinical diagnosis of symptomatic gallstones and inguinal hernia above the age of 18 years.

Exclusion Criteria: Patients with gangrenous gall bladder or empyema gall bladder, patients with strangulated hernias, Patients younger than 18 years, patients with previous open pelvic surgery and patients not fit for general anesthesia were excluded from the study.

Data Collection: Informed consent was taken from all the patients, who were included in the study for the study and type of surgery. Same consultant surgeon performed all the surgeries under general anesthesia. After obtaining informed consent from the patients, demographic details

of the patient like name, age, sex, occupation and address were noted on a specific proforma. Patients were randomly allocated into two groups, study group and control group, based on computer generated table of random numbers. History and complete physical examination of the patient was done by a Senior Registrar.

Laparoscopic cholecystectomy was done by standard 4-ports method. For inguinal hernias, all the procedures were standard TAPP. After the completion of the procedure, in study group, 6cc of Inj. Bupivacaine (5mg/ml) was injected in all 10mm ports and 4cc in all 5mm ports and no injections given in control groups. Post-operatively, same IV anti-inflammatory drug was given to all the patients as per their need. The pain score was recorded on a visual analog score (VAS) index at an interval of 2 hours, 6 hours and 12 hours after the surgery, between 0 to 10, according to the severity of pain. Number of anti-inflammatory drug (Ketorolac 30mg) injections required by each patient was also recorded. All the information was recorded on proforma.

Data Analysis: The data was analyzed by statistical program of social sciences version 20. Descriptive statistics were used to summarize the data. Mean and standard deviation were calculated for quantitative data like age, VAS, number of anti-inflammatory injections given in first 12 hours after the surgery. Frequency and percentage were calculated for qualitative data like, gender. Independent sample t-test was used to compare the VAS and number of anti-inflammatory drug injection given. p-value of less than 0.05 was considered significant.

RESULTS

260 patients were included in the study. 130 patients were there in each group. In the study group(A), 103 (79.2%) patients were females and 27 (20.7%) patients were male. Among the females, all the patients (100%) underwent LC and among the males, 26 (96.3%) patients underwent TAPP and 1(3.7%) patient underwent LC. Minimum age in study group was 18 years and maximum age was 85 years with mean age of 39.57 with Std. Deviation 10.4. In the control group, 97 (74.6%) patients were females and 33 (25.4%) patients were male. Among the females, all the patients (100%) underwent LC and among the males, 30 patients (90.9%) underwent TAPP and 3 (9.1%) patients underwent LC. Minimum age in control group was 18 years and maximum age was 65 years with mean age of 37.3 and Std. Deviation 9.8. In the study group the mean VAS at 2 hours, 6 hours and 12 hours after the surgery was 1.6, 1.7 and 1.6 with Std. Deviations 1.6, 1.7 and 1.8 respectively while in control group the VAS was 2.9, 3.1 and 2.6 with Std. Deviations 2.1, 1.8 and 1.9 respectively. In study group, the total number of injections (Ketorolac) required by all the patients were 132 with an average of 1.01 and in control group, the same were 312 with an

average of 2.4. In the study group, the mean of anti-inflammatory drug injections needed was 1.0000 with std. Deviation of 0.7 and in control group; the same was 1.3 with Std. Deviation of .88235. The p-value was less than 0.05.

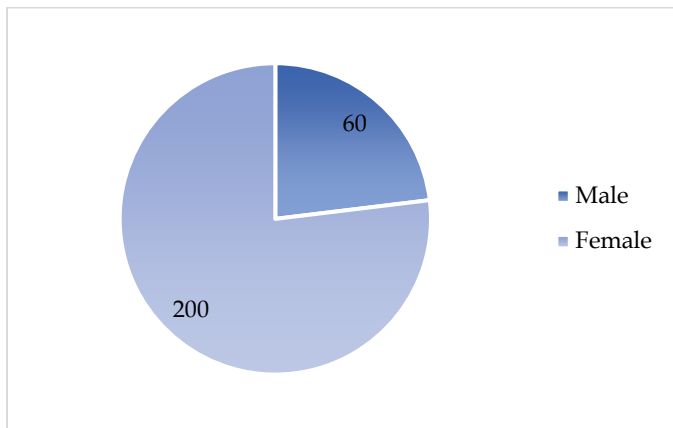


Figure 1: Gender distribution

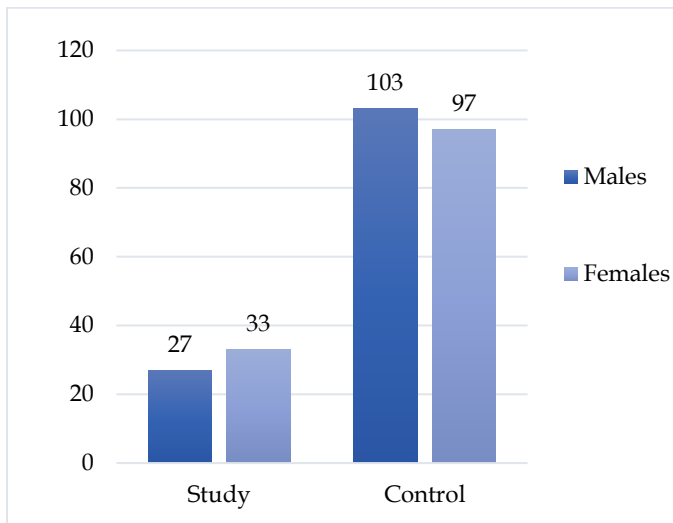


Figure 2: Gender distribution in both groups

Table 1: Demographic details

	Study group of patients	N	Mean	Std. Deviation
Age	Group A	130	39.6	10.4
	Group B	130	37.3	9.8

Table 2: Gender percentage in groups

Gender	Group		Total
	Study Group	Control Group	
Male	27 (20.77%)	33 (25.39%)	60
Female	103 (79.23%)	97 (74.61%)	200
Total	130	130	260

Table 3: VAS & Anti-inflammatory (injection Ketorolac) stats (n=130)

	Group	Mean	Std. Deviation	Std. Error Mean
VAS at 2 hours Postoperatively	Group A	1.6	1.6	0.14
	Group B	2.9	2.1	0.18
VAS at 6hrs Postoperatively	Group A	1.7	1.7	0.15
	Group B	3.1	1.8	0.16
VAS at 12 hours Postoperatively	Group A	1.6	1.8	0.16
	Group B	2.6	1.9	0.16
No of anti-inflammatory inj. given in first 12 hours	Group A	1.0	0.7	0.06
	Group B	1.3	0.8	0.07

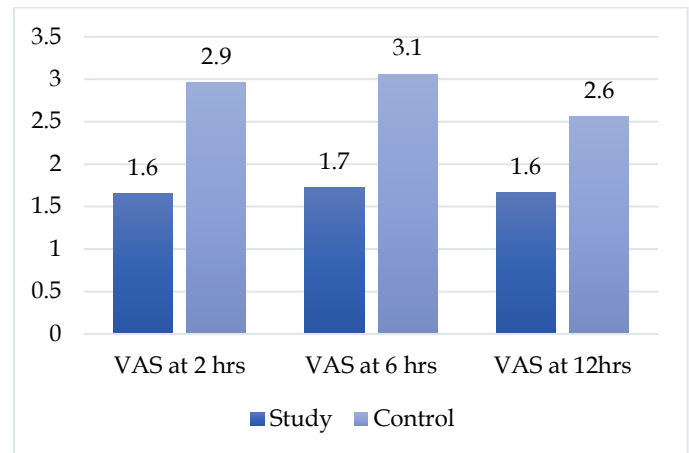


Figure 3: Mean VAS

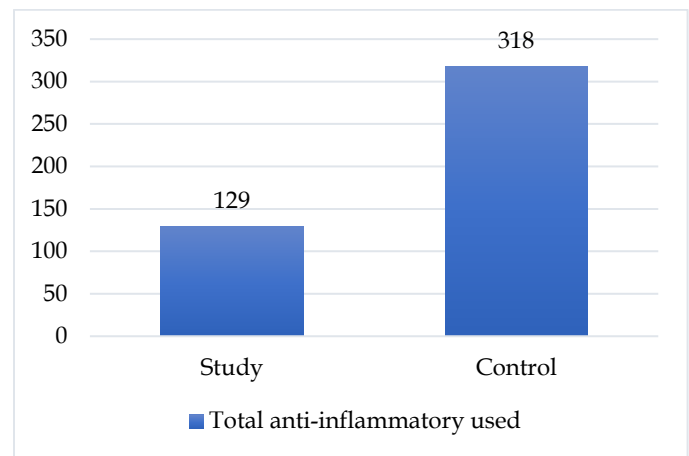


Figure 4: Total number of anti-inflammatory drugs used in both groups

DISCUSSION

Post-operative pain is a major problem of surgical practice and planning for its control should be born in

mind of the surgeon preoperatively. In this regard, counseling of the patient about the degree of post-operative pain and different methods of its management is the most important. It helps in reducing the anxiety of the patient when they are explained about possible post-operative problems.⁷ Clinically, the importance of reduction of post-operative pain and nausea has become significant ever since the laparoscopic procedures especially, laparoscopic cholecystectomy has been considered as day case procedure. Early post-operative pain after laparoscopy is quite complex with different components, and is incisional, visceral, and shoulder tip pain. In early post-operative phase, the most important of all these three types of pain is incisional one because according to the reports, it is more intense than visceral pain.⁸

There have been many trials to evaluate the efficacy of subcutaneous infiltration of local anesthetic agents at incision sites in laparoscopic procedures. Report from the work of Liu *et al*³ showed that use of ropivacaine infiltrated at port sites in patients undergoing laparoscopic cholecystectomy clearly reduces the magnitude of early post-operative pain. While Papagiananopoulou *et al*⁹ conducted a randomized double-blind study and their conclusion was that levobupivacaine is better in reducing the early post-operative pain compared with ropivacaine, when both infiltrated locally at port site. In our study we infiltrated bupivacaine locally at port sites, post-operatively and found that it significantly reduced the post-operative pain and hence the need of anti-inflammatory injectable in patients undergoing laparoscopic procedures.

There are some other studies concluding the clear advantages of the use of local anesthetic agents at port sites in laparoscopic procedure by reducing the early post-operative pain. Although considered to be associated with less pain due to being minimally invasive, in laparoscopic procedures, the pain originating from the skin is still a problem and prospective data shows favorable results for the use of local anesthetic agent at port sites.^{10,11} The result of the study from the work of M. Upadya, S.H. Pushpavathi and Kaushik Rao Seetharam showed that intracincisional infiltration of 20ml of 0.5% bupivacaine results in lower VAS and VRS in early post-operative phase.⁷ A thorough literature review has many evidences to show that the intra-incisional use of local anesthetic at port sites for pain relief is very effective and is quite long lasting.¹²

Bupivacaine is a good choice as local anesthetics in these laparoscopic cases because of its easy administration and being cheaper with an acceptable toxic effect profile but duration of its analgesia is questionable. The safety range of dose is up to 150mg as reported in many trials and pain reduction is there from 1 to 8 hours post-operatively and in studies where the dose used was less i.e., 90mg, the analgesic effects were for half an hour post-operatively

which shows that the duration may be dose dependent.^{5,13,14} In our study, the dose used was 100mg. In our study, we infiltrated the bupivacaine subcutaneously, post-operatively. The anatomical layer of infiltration of local anesthetic agent and timing of injection has been evaluated by many studies and is thought to be significant. Reports from the study^{10,19} show that local anesthetic was more effective when instilled in all the layers of anterior abdominal wall and work of Yangaard and colleagues showed that if the lidocaine is applied subfascially, it is more effective, compared to when it is applied subcutaneously in laparoscopic inguinal hernia repairs while some other studies show that infiltration of parietal peritoneum which is most pain sensitive results in best outcomes in patients undergoing appendectomy and cholecystectomies, laparoscopically, as far as reduction in severity of pain is concerned.¹⁵ This was lacking in our study.

In our study, we used Injection Ketorolac 30mg I/V (an NSAID), post-operatively for pain relief as per need of the patients in both groups and found that the need for anti-inflammatory drug is greatly reduced if the port sites are infiltrated with injection bupivacaine. A study reviewing different choices for pain relief after laparoscopic cholecystectomy concludes that a combination of local anesthetic agent and an NSAID is quite effective modality and a choice for pain relief.¹⁶ While a study by Ziauddin A. Kashmiri¹⁷ and coworkers states that NSAIDs used for pain relief post-operatively in patients after laparoscopic cholecystectomy are not always fully effective rather because pneumoperitoneum results in the pathophysiological changes of renal blood flow, the use of NSAIDs can even be dangerous. Work of Jhonson *et al*¹⁸ shows that when local anesthetic agent is used for pain relief, the use of anti-inflammatory agent has not got much role in reducing the post-operative pain and Hernandez-Palazon *et al*¹⁹ concluded that in patients with laparoscopic cholecystectomy, if bupivacaine is used for local pain relief, intra-peritoneally, it significantly reduces the need for pain killers in the first six hours, post-operatively.

The timing of local anesthetic agent infiltration whether given pre or post-operatively is not that much significant as shown by Sarac *et al*²⁰ concluded that pre-operative injection is not effective compared to the one given post-operatively. Therefore, this is a debatable issue.

CONCLUSION

To make the laparoscopic surgery almost totally pain free, infiltration of local anesthetic agent at port site is a very good, easy and advantageous technique. It proves to be harmless as well and is associated with early return to routine daily activities in patients. Bupivacaine is the best available choice at the moment. The timing of injection

and exact anatomical plain to be injected needs to be evaluated more.

LIMITATIONS

Non availability of injection bupivacaine

SUGGESTIONS / RECOMMENDATIONS

We recommend use of injection bupivacaine at port site in laparoscopic procedures.

CONFLICT OF INTEREST / DISCLOSURE

None.

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