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COMPARISON OF INTRAPERITONEAL IN-STILLATION & PERINCISIONAL INFILTRATION OF BUPIVACAINE DURING LAPAROSCOPIC CHOLECYSTECTOMY ON POST OPERATIVE PAIN

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Abstract

Objectives:To determine the efficacy of combined intraperitoneal instillation and perincisional infiltration of 0.5% bupivacaine in term of frequency of pain following laparoscopic cholecystectomy.Study design:Randomized Controlled Trial.Place and duration of study

Department of Surgery, Holy Family Hospital, Rawalpindi from 4th December 2012 to 4th June 2013.**Patients and**Methods:100 adult patients of either gender, planned for laparoscopic cholecystectomy for Cholelithiasis were included.The clinical & demographic variables were laid down. 50 patients each were allocated to two groups. Group I (The treatment Group) received 20 ml Bupivacaine solution (in a dose of 4mg/kg body weight) instilled in the right sub diaphragmatic space and another 20 ml infiltrated into the port sites, 6 ml infiltrated through the abdominal wall around each midline port site and 4 ml administered at the lateral port sites. Group II (The Control Group) received no treatment. Patients were assessed for pain relief at 06 hours post surgery.

Descriptive statistics were used to calculate mean and standard deviation for quantitative variables and frequency with percentages for qualitative data. Independent sample t-test was used to compare mean of quantitative variables and chi-square test for qualitative variables. P-value <0.05 was considered significant.

Results

In group I, 48.0 % patients showed efficacy (in terms of pain relief) to the treatment employed, while in group II, the percentage of such patients (pain relief without any treatment) was 14.0% . *P* value was found to be .000 (<<< 0.05).

Conclusion

Intraperitoneal instillation and perincisional infiltration of bupivacaine during laparoscopic cholecystectomy is an effective treatment option for postoperative pain control.

Key Words: *laparoscopic cholecystectomy, Cholelithiasis, Gallstones, levobupivacaine*

Introduction

Cholelithiasis is one of the commonest biliary pathology that we come across these days. The most popular procedure for its rapid post operative recovery, low post operative complications, early mobilization and discharge time is laparoscopic cholecystectomy. It is one of the commonest day-case surgeries where tissue injury is minimal. Although laparoscopic cholecystectomy is associated with less pain than contemporary open procedures; it is definitely not pain free and the magnitude of postoperative shoulder and abdominal pain in the early postoperative period is still quite significant. This postoperative pain is a major concern not only for the patients, but also for also healthcare workers; and it often contributes to overnight hospital stay after this minimally invasive surgical procedure[i]. Pain after laparoscopic cholecystectomy is a result of many mechanisms such as tissue injury, abdominal distension, local trauma secondary to gallbladder removal, chemical irritation of the peritoneum, and the pneumoperitoneum[ii]. Investigators[iii,iv] have proposed that the combination of somato-visceral local anesthetic treatment using local anesthetic bupivacaine and levebupivacaine reduces incisional, intra-abdominal, and shoulder pain after laparoscopic cholecystectomy. In one study[vi], post operative pain in bupivacaine instillation is 18% and in control group is 60% and rescue analgesia in study group is 35% and control group 84%. In few studies [vii ,viii,] preincisional and intraperitoneal instillation don't significant reduce the frequency of post operative pain e.g. in one study[viii] post operative pain in bupivacaine group is 6.08 ± 0.40 and in control group is 8.44 ± 0.51 which is not so significant.

Laparoscopic procedures are new advancement and recently introduced in Pakistan and studies done previously showed variable results regarding its efficacy. Therefore, we aim to explore the efficacy of intraperitoneal instillation and perincisional infiltration of bupivacaine during laparoscopic cholecystectomy, so that, we might be able to reduce postoperative pain by recommending better management options.

The rationale of this study is to see if intraperitoneal instillation and perincisional infiltration of bupivacaine during laparoscopic cholecystectomy is an effective treatment option for postoperative pain control.

Material and Methods

These randomised controlled trial were performed on 100 patients in the Department of Surgery, Holy Family Hospital, Rawalpindi. All male and female patients planned for laparoscopic cholecystectomy from 4th December 2012 to 4th June 2013 for Cholelithiasis who were greater than 14 years of age were included in this study after approval from Ethical committee of the hospital. Patients who were allergic to local anaesthesia, those who developed some complication of general anaesthesia, those who developed some complications during laproscopic surgery and those patients who ended up in open laporotomy were excluded from this study.the criteria for pain relief was patient's subjective feeling at 6 hrs after instillation and infiltration of local agents or without locak anaesthetic administration at all.the study was performed on 100 patients.patients were selected from indoor department of general surgery (HFH) according to inclusion criteria through non-probality convenience sampling.

After the informed consent, patients' demographic data along with registration number were entered in the Performa. Patients were randomly assigned to two groups based on lottery method. Group I (The Bupivacaine or treatment Group) received 20 ml Bupivacaine solution instilled in the right sub diaphragmatic space, and another 20 ml infiltrated into the port sites, 6 ml infiltrated through the abdominal wall around each midline port site and 4 ml administered in the similar fashion at the lateral port sites. Group II (The Control Group) received no treatment during the procedure. All the patients were kept under strict surveillance and were assessed by trainee researcher for pain relief according to the criteria defined. At 06 hours post-surgery efficacy was determined by trainee researchers. Data had been collected using pro-forma.Statistical package for social sciences (SPSS version 22) were used to analyze the data. Descriptive statistics were used to describe the results i.e. mean and standard deviation (SD) for quantitative variables like age. Frequency and percentages

were presented for qualitative variables including gender, postoperative pain. Chi square test was applied to compare efficacy as per defined criteria in both groups. A p-valve less than 0.05 was considered as significant

Results

100 patients were included in this study i.e. 50 in each group. In group I, 12 (24%) patients were male and 38 (76%) were female. Mean age of group I was 46.92 years (SD= 8.10 SD). In group II, 11 (22%) patients were male and 39 (78%) were female. Mean age of group II was 47.12 years (SD=8.46). (Table-1)

The null hypothesis in this study was occurrences of percentages of patients showing efficacy to treatment in Group I and and spontaneous relief in pain without treatment in Group II are statistically independent, i.e., there is no association between them or the observed difference in the column and row variables is not significant and is just a random (by-chance) phenomenon. The alternative hypothesis of this study was occurrences of percentages of patients showing efficacy to treatment in Group I and and spontaneous relief in pain without treatment in Group II are statistically dependent, and the observed difference was significant.

In -group I, 06 hours after the procedure, 48.0 % of the patients showed efficacy (in terms of pain relief) to the treatment employed, while in group II, the percentage of such patients (pain relief without any treatment) was 14.0% (table 2). There was significant difference in frequency of pain relief between both the groups ($p<0.001$).

Table 1: Demographic Profile of the study Population

	Group I (Treatment group)	Group II (control group)
Male	12 (24%)	11 (22%)
Females	38 (76%)	39 (78%)

Table 2: Results of efficacy of treatment and no treatment

Efficacy	Group I (Treatment group) n-50	Group II (control group) n=50	*P*-value
Absent	26 (52.0%)	43 (86.0%)	<0.001
Present	24 (48.0%)	07 (14.0%)	

Discussion

Cholelithiasis is one of the commonest biliary pathology that we come across these days. The most popular procedure for its rapid postoperative recovery, low postoperative complications, early mobilization and discharge time is laparoscopic cholecystectomy. Cholecystectomy is one of the most commonly performed abdominal surgical procedures, and in developed countries, many are performed laparoscopically. Laparoscopic cholecystectomy is considered the "gold standard" for the surgical treatment of gallstone disease. This procedure results in less postoperative pain, better cosmetics, shorter hospital stays and disability from work than open cholecystectomy [ix, x,]. Laparoscopic cholecystectomy is performed under general anesthesia. The generally short duration of the procedure minimizes the need for gastric decompression or placement of a urinary bladder catheter. Serious complications that occur with laparoscopic cholecystectomy, including bile duct injury, bile leaks, bleeding, and bowel injury result in part from patient selection, surgical inexperience, and the technical constraints that are inherent to the minimally invasive approach. Other adverse outcomes, such as retained common bile duct stones (incidence of around 10 %), post cholecystectomy syndromes [xi], and misdiagnoses (sphincter of Oddi dysfunction) occur with the same frequency with both laparoscopic and open cholecystectomy. Post cholecystectomy syndrome (PCS) is a complex of heterogeneous symptoms including persistent abdominal pain and dyspepsia that recur and persist after cholecystectomy. PCS is defined as "early" if it occurs in the postoperative period and "late" if it occurs months or years after surgery. The symptoms of pain and dyspepsia referred to as PCS can be caused by a wide spectrum of conditions, both biliary and extra biliary such as tissue injury, abdominal distension, local trauma secondary to gallbladder removal, chemical irritation of the peritoneum, and the pneumoperitoneum. Laparoscopic procedures are new advancement and recently introduced in Pakistan and studies done previously showed variable results regarding its efficacy. Present study was planned to explore the efficacy of intraperitoneal instillation and per incisional infiltration of bupivacaine during laparoscopic cholecystectomy, so that, we might be

able to reduce postoperative pain by recommending better management options. 100 patients were recruited in this study after the informed consent from every patient. Adult patients of both genders who were planned for laparoscopic cholecystectomy for cholelithiasis were included in the study. All those patients who ended up in open laparotomy, developed any complication during laparoscopic surgery, developed any complication due to general anesthesia and those who were given history of any allergic reaction to local anesthesia were excluded from the study. After detailed history and clinical examination, patients were informed about the inclusion in the study, type of treatment offered, and benefits and risks of the treatment. Patients were randomly assigned to two groups based on lottery method. Group I (The Bupivacaine or treatment Group) received 20 ml Bupivacaine solution instilled in the right sub diaphragmatic space, and another 20 ml infiltrated into the port sites, 6 ml infiltrated through the abdominal wall around each midline port site and 4 ml administered in the similar fashion at the lateral port sites. Group II (The Control Group) received no treatment during the procedure. All the patients were kept under strict surveillance and were assessed by trainee researcher for pain relief according to the criteria defined at 06 hours post surgery. In group I, 06 hours after the surgery out of 50 (100 %) patients, 26 (52.0%) patients did not describe intensity of pain as no pain to mild pain as per VAS and 24 (48.0%) patients described that treatment was effective. In group II, out of 50 (100 %) patients, 43 (86.0%) did not describe intensity of pain as no pain to mild pain as per VAS and 07 (14.0%) patients showed spontaneous relief in pain without any treatment. The *P* value was found to be .000 (<<< 0.05) showing that the observed difference between two groups was statistically significant and there was significant difference in efficacy (in terms of pain relief) with and without treatment with group I (treatment group) showed higher rate of pain control than group II (control).

Our results are in concordance with the results already published on the subject. A. A. Louizos and S. J. Hadzilia [xiii] in their randomized controlled clinical trial aimed to test the use of preincisional and intraperitoneal levobupivacaine (L-B) 0.25% in laparoscopic cholecystectomies for postoperative analgesia. They concluded that the combination of preincisional local infiltration

and intraperitoneal instillation of L-B 0.25% shows an advantage for postoperative analgesia after laparoscopic cholecystectomy.

Alam M S and Hoque H W [xiv] in their study aimed to evaluate the effect of intraperitoneal and port site instillation of local anesthetics on pain relief in early postoperative period following laparoscopic cholecystectomy. They concluded that Infiltration of bupivacaine in to port site and intraperitoneal space is simple, inexpensive and effective technique to minimize early postoperative pain and can be practiced for elective laparoscopic cholecystectomy.

Roberts KJ et al in his study [xv] assessed the efficacy of LA injected to the peritoneum of the right hemidiaphragm or topical wash with a control group. They performed a double-blind randomized sham controlled trial of 128 consecutive subjects who underwent elective LC. Patients received subcutaneous bupivacaine, a diaphragmatic injection of bupivacaine or sham, and topical wash over the liver/gallbladder with bupivacaine or sham depending upon allocation. The primary outcome was VAS pain scores on the ward. Secondary outcomes included VRS pain scores in theatre recovery, analgesic use, physiological observations, time to eating and ambulation, and successful day-case surgery. They found that pain scores were significantly lower in both LA groups versus control in theatre recovery but only in the subperitoneal diaphragm injection group when the patients returned to the ward. Subperitoneal diaphragm injection was associated with a reduced time in theatre recovery ($p = 0.04$). they concluded that intraperitoneal techniques of LA during LC decrease postoperative pain and shorten time in theatre recovery. Injection of LA to the right hemidiaphragm is associated with lower pain scores for a longer period following LC than a previously validated wash technique.

Gouda M El-labban & Emad N Hokkam [xvi] in their randomized controlled study compared the effect of intraincisional vs intraperitoneal infiltration of levobupivacaine 0.25% on post-operative pain in laparoscopic cholecystectomy. They concluded that Intraincisional infiltration of levobupivacaine is more effective than intraperitoneal route in controlling post-operative abdominal pain. It decreases the need for rescue analgesia.

Bisgaard T & Klarskov B [xvii] investigated the effects of a somato-visceral local anesthetic blockade on pain and nausea in patients undergoing elective laparoscopic cholecystectomy. They implied that a combination of incisional and intraabdominal local anesthetic treatment reduced incisional pain but had no effect on deep intraabdominal pain or shoulder pain in patients receiving multimodal prophylactic analgesia after laparoscopic cholecystectomy.

Hilvering B, Draaisma WA [xviii] aimed to determine the effect of combined subcutaneous infiltration and intraperitoneal instillation of levobupivacaine before the start of LC on postoperative abdominal pain up to 24 h after surgery. They concluded that combined subcutaneous and intraperitoneal administration of levobupivacaine did not influence postoperative abdominal pain after LC.

George Pappas-Gogos & Konstandinos E. Tsimogiannis [xvix] designed a clinical trial to assess the use of preincisional and intraperitoneal ropivacaine, combined or not with normal saline, to reduce pain after laparoscopic cholecystectomy (LC). They concluded that Preincisional local infiltration plus intraperitoneal infusion of ropivacaine at the beginning of LC combined with normal saline infusion at the end of the procedure is a safe and valid method for reducing pain after LC.

Conclusion

Intraperitoneal instillation and perincisional infiltration of bupivacaine during laparoscopic cholecystectomy is an effective treatment option for postoperative pain control.

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