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LAPAROSCOPIC CHOLECYSTECTOMY;

The effect of intraperitoneal instillation of bupivacaine on the mean post-operative pain scores

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ABSTRACT… Introduction: Laparoscopic cholecystectomy is the treatment of choice for symptomatic cholelithiasis. Intraperitoneal instillation of bupivacaine is one of the methods used to improve pain relief after laparoscopic cholecystectomy. **Objective:** To compare the mean pain score after intraperitoneal instillation of bupivacaine with placebo during laparoscopic cholecystectomy. **Study Design:** Randomized Control trial. **Setting:** This study was carried out a surgical unit PGMI Lady Reading Hospital and Hayatabad Medical Complex, Peshawar. **Duration:** The duration of study was 6 months from 15th May to 15th December, 2013. **Subjects and Methods:** 92 patients in each group were included in study to compare the mean pain score of intraperitoneal instillation of bupivacaine (Group A; study group) with 0.9% normal saline solution (Group B; placebo group) using visual analogue scale after laparoscopic cholecystectomy at 12th hour after surgery. Data was entered in software SPSS version 16.0. T test was used to compare the mean pain scores. **Results:** The mean age of patients in Group A and B was 41.82 ± 7.34 and 40.95 ± 9.24 respectively (p=0.483). Group A has low mean pain score (3.619 ± 0.676) according to Visual Analogue Scale then Group B (3.837 ± 0.667) with a statistically significant p value (p=0.036). A t test failed to reveal a statistically reliable difference between gender (p=0.513) and age (p=0.767) wise distribution of mean pain between group A and B. **Conclusions:** Mean pain score of intraperitoneal instillation of bupivacaine is significantly less than 0.9% normal saline solution at 12th hour after laparoscopic cholecystectomy.

Key words: Intraperitoneal Instillation; Mean Pain Score; Laparoscopic Cholecystectomy.

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INTRODUCTION

The economic and health impact of cholelithiasis is significant due to its high morbidity. Since the introduction of laparoscopic cholecystectomy in the early 90s, which is considered a safe treatment for cholelithiasis, a possible unjustified increase in surgical procedures has been observed[1]. The incidence of symptomatic cholelithiasis is reported to be 2.2/1000 USA population with more than 500,000 cholecystectomies performed yearly[2]. Many studies have demonstrated the safety, feasibility and cost effectiveness of laparoscopic cholecystectomy as a day care procedure[3].

The type of pain after laparoscopic surgery differs considerably from that seen after laparotomy. Whereas laparotomy results mostly in parietal pain, patients after laparoscopic cholecystectomy complain more of visceral pain results from the stretching of intra-abdominal cavity, peritoneal inflammation and phrenic nerve irritation caused by residual carbon dioxide in the peritoneal cavity. Postoperative pain due to cholecystectomy may be transient and most of the time it lasts for 24 hours but may extend up to 3 days. Immediately after surgery, the intensity of pain is more in the first 24 hours and then decreases gradually. In comparison to open cholecystectomy, the intensity of post operative pain is less after laparoscopic cholecystectomy, but there will still be moderate to severe pain and other complications like nausea and vomiting in the first 24 hours[4]. Moreover shoulder tip and back pain

have been reported in some studies as being more common after laparoscopic approach than open for treatment of gallstones[6]. Another study observes the incidence of post laparoscopic cholecystectomy pain as follows; visceral pain (78.33%), parietal pain (70%) and shoulder tip pain (23.33%)[7]. Different management options are offered for pain relief. Amongst these intraperitoneal instillation of local anaesthetic or its infiltration around the laparoscopic port sites before and after surgery has been found quite effective[8]. Comparative studies have shown that the number of patients experiencing post operative severe pain was less in patients receiving intraperitoneal instillation of bupivacaine as compared to those who were administered intraperitoneal normal saline as placebo. Post operative analgesic requirement in the first 24 hours after surgery was also significantly less in the former group[9].

Although LC 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. With the growing trend of LC in our population and the increasing demand for reducing hospital stay to ensure bed availability, effective means of controlling post-operative pain in these patients needs to be established through clinical studies before we are doubtful in advocating their routine use. The current study was aimed to compare mean pain scores between intra-peritoneal bupivacaine instillation with placebo in LC.

OBJECTIVE

The objective of the study was to compare the mean pain score after intraperitoneal instillation of bupivacaine with placebo during laparoscopic cholecystectomy.

HYPOTHESIS

Hypothesis of the study was that mean pain score with intraperitoneal instillation of bupivacaine is less than placebo after laparoscopic cholecystectomy.

MATERIAL AND METHODS

Study Design

It was a randomized controlled trial.

Study Setting

The study was carried out at Surgical Unit Hayat Abad Medical Complex, Peshawar.

Sample size

The sample size was 92 in each group using 3.8 ± 1.28 mean pain score with bupivacaine and 3.3 ± 1.13 mean pain score with placebo after LC10, 80% power and 95% confidence interval.

Sample Technique

It was a consecutive (non probability) sampling technique.

Duration of Study

6 months from 15th May to 15th December, 2013.

SAMPLE SELECTION

Inclusion Criteria

The following patients were included in the study;

- All patients with chronic cholecystitis between the ages of 20 to 60 years.
- Either Gender.

Exclusion Criteria

The exclusion criteria of the study was as follow;

- Patient with diabetes mellitus were excluded because of their pain threshold which is altered due to neuropathies.
- Patients who received opioids or tranquilizers for more than one week prior to LC were excluded.
- Patients were excluded from the study if the operation was converted from LC to open cholecystectomy and if intraperitoneal drain was placed due to any reason after open cholecystectomy which may cause additional pain.

The above conditions were confounder and if included, were liable to bias the study results.

DATA COLLECTION PROCEDURE

The study was conducted after approval from hospital's ethical and research committee. All

patients with chronic cholecystitis meeting the inclusion criteria were included in the study and were admitted through OPD for further work up. The purpose and benefits of the study was explained to all patients and if agreed upon, a written informed consent was obtained.

All patients were worked up with detailed history and clinical examination followed by routine baseline pre operative investigations including complete blood count, prothrombin time, bleeding and clotting time, LFTs, blood grouping and cross match, urine routine examination, blood urea and sugar, ECG and serum electrolytes. The patients were randomly allocated in two groups by lottery method; Group A & B. Group A was a study group and received 50 ml of bupivacaine (0.25%) instilled intraperitoneally into the gall bladder bed and under surface of diaphragm and Group B was a control group and received 50 ml of 0.9% normal saline instilled intraperitoneally into the gall bladder bed and under surface of right diaphragm. In both groups, infiltration at the port site wounds was done with 5ml of 0.25% bupivacaine.

On the evening before surgery, the visual analogue scale scoring system was explained to all patients. All patients were premedicated with oral diazepam (10 mgs) administered on night prior to surgery as night sedation. All patients were induced and maintained with standard anesthetic technique i.e. induced with buprenorphine (3-4 mgs) and propofol (2 mgs) and tracheal intubation was facilitated with atracurium (0.4- 0.5 mgs/kg). The anesthesia in all patients was maintained with oxygen in air (50%:50%) with Isoflurane supplementation. The muscle relaxation was maintained by the incremental doses of atracurium (0.1mg/kg) as and when required.

Immediately after intubation a nasogastric tube was introduced and stomach contents were aspirated prior to tilting of the patient and nasogastric tube was removed just before extubating the patient.

Postoperative pain intensity was assessed using 10 point on VAS. VAS scoring was done at 12th hour. Post operatively, all patients in both groups were kept under observation for at least one day.

All the surgical procedures were conducted by a single experienced surgeon in the capacity of Assistant Professor or above. All the above mentioned information along with the demographic details were recorded on predesigned proforma and entered into a computer database. Strict exclusion criteria was followed to control confounders and bias in the study results.

DATA ANALYSIS PROCEDURE

Data was analyzed by using a statistical software SPSS version 16.0. Mean ± Standard deviation was calculated for continuous variable like age and pain at 12th hour. Frequency and percentages were calculated for gender. T test was used to compare the pain scores between intraperitoneal instillation of bupivacaine and placebo. P value of < 0.05 was considered significant. Mean pain scores in both the groups was stratified among age and gender to see the effect modifications. All the results were presented in the form of graphs and tables.

RESULTS

The total number of patients in group A (intraperitoneal instillation of bupivacaine) and group B (intraperitoneal instillation of 0.9% Normal Saline/Placebo) after Laparoscopic Cholecystectomy were 92, comprising of 8 (8.70%) males and 84 (91.30%) females in group A and 10 (10.87%) males and 82 (89.13%) females in group B. This gender distribution in both groups showed insignificant p value i.e. 0.8048.

In Group A, there were 39 (42.39%) and 53 (57.61%) patients from the age groups of 20-40 and 41-60 years respectively while in group B there were 47 (51.09%) and 45 (48.91%) patients respectively. Age distribution between the 2 groups was insignificant statistically ($p=0.301$).

The age range was from 20 to 60 years in both groups. The mean age of patients in Group A and B was 41.82 ± 7.34 and 40.95 ± 9.24 respectively.

A t test failed to reveal a statistically reliable difference between the mean ages of patients in Group A and B; p = 0.483.

The mean pain according to Visual Analogue Scale in Group A and B was 3.619 ± 0.676 and 3.837 ± 0.667 respectively at 12th hour after Laparoscopic Cholecystectomy. A t test revealed a statistically reliable difference between the mean pain of patients in Group A and Group B; p = 0.036. (Table No. I)

According to gender wise distribution of mean pain at 12th hour of Laparoscopic Cholecystectomy according to Visual Analogue Scale, male patients were having mean pain of 3.75 ± 0.707 and 3.90 ± 0.737 in group A and B respectively, while female patients in group A and B were having mean pain of 3.607 ± 0.677 and 3.80 ± 0.663 respectively. A t test failed to reveal a statistically reliable difference of mean pain between males and females patients of group A and B; p = 0.513.

The mean and standard deviation of pain in the age group of 20-40 years was 3.717 ± 0.793 and 3.766 ± 0.597 in group A & B respectively at 12th hour of Laparoscopic Cholecystectomy according to Visual Analogue Scale. While in the age group of 41-60 years, it was 3.547 ± 0.574 and 3.911 ± 0.733 in group A and B respectively. A t test failed to reveal a statistically reliable difference of mean pain between the age groups of group A and B; p = 0.767.

Groups	Mean+SD	P-Value
Group A	3.619±0.676	0.036
Group B	3.837±0.667	

Table-I. Mean and standard deviation of pain in patients of group "A" (intraperitoneal instillation of bupivacaine) and group "B" (intraperitoneal instillation of normal saline/placebo group) after 12th hours of laparoscopic cholecystectomy

DISCUSSION

Cholelithiasis occurs in 10% of the population of Western countries and in 17% of the population in Asian countries. Cholecystectomy is currently a frequently performed operation. The most common reason for a cholecystectomy is gallbladder stones[11,12]. It is a procedure to be performed as a day case or short stay procedure and therefore, the provision of adequate postoperative pain relief is of considerable importance. Instillation of intraperitoneal LA to reduce postoperative pain has been studied through randomized trials for more than 10 years[13].

In our study, female patients were predominant in both groups. In a local study, female predominance also has been reported[3]. This female predominance is due to the fact that gall stones are more common in females as compared to males. The mean age of patients in Group A and B failed to reveal a statistically reliable difference.

Postoperative pain after laparoscopic cholecystectomy (LC) is generally less than open cholecystectomy; however, the postoperative shoulder and abdominal pain experienced by patients still causes preventable distress. Intraperitoneal irrigation of the diaphragmatic surface and gallbladder fossa using normal saline, bupivacaine, or lignocaine may effectively control visceral abdominal pain after an LC. The principal source of pain after laparoscopic procedure is controversial. Some clinicians have noted that the placement of trocars through the abdominal wall is the primary source of pain; whereas others believe that most pain arises from intraperitoneal dissection and insufflations of CO2 resulting in distension of abdominal wall and prolonged elevation of diaphragm[14]. Early pain after laparoscopic cholecystectomy is a complex process and includes different pain components secondary to surgical trauma to the abdominal wall, intraabdominal trauma secondary to the gall bladder removal, abdominal distention, pneumoperitoneum using carbon dioxide etc. Therefore pain should be treated multimodally.

This study demonstrated that intraperitoneal administration of 50 ml of bupivacaine (0.25%) had useful effects on postoperative pain relief especially in the early postoperative period after LC and found that the mean pain in the study

group was significantly low than the placebo group (p = 0.036). The mean pain according to Visual Analogue Scale in Group A and B was 3.619 ± 0.676 and 3.837 ± 0.667 respectively. Gender and ages of the patients in both groups were not significant in affecting the mean pain scores according to VAS. Our study results are in accordance to the study conducted by Ahmed BH, et al[15], Rehan AG, et al[16] and Bhardwaj N, et al[17].

Ahmed BH, et al,[15] conducted a randomized control study on 200 patients who were randomized to one of four groups of 50 patients each, including Group A placebo control, Group B with isotonic saline irrigation, Group C with bupivacaine irrigation, and Group D with lignocaine irrigation. All patients received preperitoneal abdominal wall infiltration with 0.25 per cent bupivacaine to control parietal (somatic) abdominal pain. Then in a prospective double-blind fashion at four points (0, 4, 8, 12 and 24 hours) during the first 24 postoperative hours, both shoulder and abdominal pain by visual analogue and verbal rating pain scores were recorded. They found in each group a significant difference in visual analogue and verbal rating pain scores and analgesic consumption when compared with controls. Lignocaine controlled pain was significantly better than saline or bupivacaine. Bowel function recovery was similar in all patients, and there were no significant complications. Finally they concluded that Lignocaine was the most efficacious local anesthetic and has a high safety profile at recommended doses. Rehan AG, et al,[16] randomized 60 patients undergoing laparoscopic cholecystectomy into two groups of 30 each. Group A received 40 ml of intraperitoneal injection of 0.25% bupivacaine and 20 ml of same concentration bupivacaine injection at 4 ports, 5 ml each at the end of surgery. Group B received no treatment. Post operative patient monitoring and pain assessment was done by VAS score at 1,4,12 and 24 hours by another Doctor blinded to the procedure. On analysis of VAS score, the study group had less scores compared to control group but it was statistically not significant (p>0.05). Also the rescue analgesic requirement was significantly less in study group p<0.00).

Bhardwaj N, et al,[17] conducted a double blind, randomized controlled trial on 40 patients undergoing laparoscopic cholecystectomy and divided them into two groups to received 20 ml of normal saline intraperitoneally (group 1) or 20 ml of 0.5% bupivacaine with 1:200,000 adrenaline (group 2) instilled at the end of surgery in the trendlenberg position. Postoperatively the patients were assessed for pain scores (VAS, VRS and shoulder pain) and analgesic consumption at 1, 4,8,12 and 24 hours. The VAS was significantly higher in group I compared to group 2 at 1st, 4th and 8th postoperative hour (P<0.001; P<0.05). The total number of patients requiring analgesics was higher for group I than group 2 (P<0.05).

Other studies by Labaille T et al,[18] and Torres L,et al,[19] has also shown that intraperitoneal administration of local anesthetic have a modest analgesic effect after laparoscopic cholecystectomy. Ng A, et al,[20] did a systemic review considering 13 clinical trials and it was found in 7 studies that the intraperitoneal administration of bupivacaine in the doses of 50-200 mg in volumes of 10-100 ml, produced significant analgesia and also supplemental analgesic consumption for postoperative pain control was significantly reduced.

Verma GR et al,[21] studied 60 patients with 0.5% bupivacaine-soaked Surgicel placed in the gallbladder bed to determine the character of pain after laparoscopic cholecystectomy and its relief. These patients were divided into four groups of 15 each: group A (bupivacaine-soaked Surgicel kept in gallbladder bed), group B (bupivacaine infiltrated at trocar sites), group C (bupivacaine infiltrated into the gallbladder bed and at trocar sites, and group D (normal saline in the gallbladder bed and at trocar sites). Postoperatively, The visceral pain was significantly less in the group A patients than in the control subjects (p < 0.05), and none of them experienced shoulder pain. The mean VAS score at 4, 8, and, 24 h in the group A patients also was less than in control group D. Trocar site infiltration alone was

not effective in relieving the parietal pain.

On the other hand, some authors have reported that intraperitoneal instillation of bupivacaine does not effectively control the post operative pain in LC. Zmora O, et al has reported that intraperitoneal bupivacaine does not attenuate pain following laparoscopic cholecystectomy like Zmora O, et al,[22] prospectively randomized 60 patients undergoing elective laparoscopic cholecystectomy into 2 groups. Group A received 100 mg of bupivacaine in 50 cc of saline, installed into the gallbladder bed and right subphrenic space. Group B received saline without bupivacaine. Pain was assessed using a visual analog scale at 1, 2, 4, and 14 hours postsurgery and no significant difference occurred in the average pain levels. However, they noted that the average analgesic requirement was lower in the bupivacaine group, but this was not statistically significance.

Traditionally, bupivacaine is used as local anaesthetic as it has a long duration of action but it can cause central and cardiovascular toxicity. Accidental deaths and cardiac arrest have been reported due to local bupivacaine[23]. However, in our study, we did not observe any side effects or complications attributable to the local infiltration of bupivacaine intraperitoneally. In fact, we did not measure plasma concentrations of bupivacaine, and the reason for it was that the doses of bupivacaine in our study was 125mg and it was lower than the dose thought to cause systemic toxicity. For systemic toxicity, the plasma concentration should be above the 3µg/ml and intraperitoneal administration of 100–150 mg plain bupivacaine gives mean plasma concentration from 0.92 to 1.14 µg/ml[24].

To date, there has been no randomized clinical trial in our set up comparing the effectiveness of intraperitoneal instillation of bupivacaine for the postoperative pain relief in laparoscopic cholecystectomy. We performed the study in a community setting with patients of various socioeconomic classes. Participants' compliance was high and our consultant surgeon was highly expert in performing LC. In our study, statistical analyses were straightforward, and missing data analysis was not required. Also, there were no complications during surgery as LC has been reported to have some undesirable common intraoperative complications like iatrogenic perforation of gall bladder, intraperitoneal spillage of bile, infection at trocar sites; therefore, we were unable to compare the two groups with respect to complications of the treatments. Also age and gender distribution had statistically insignificant effects on the effectiveness. Overall, we have good evidence that intraperitoneal instillation of bupivacaine is more advantageous in post operative pain relief. It must also be noted that the short follow up period was the limitation of our study. Further research is needed to establish long term pain control effectiveness and intravenous or oral analgesics consumption after intraperitoneal instillation of bupivacaine in LC.

CONCLUSIONS

From the results of this study it is concluded that:

- Mean pain score after intraperitoneal instillation of bupivacaine is less than instillation of normal saline at 12th hour after laparoscopic cholecystectomy.
- Intraperitoneal instillation of bupivacaine has better pain control than normal saline in laparoscopic cholecystectomy at 12th hour after surgery.

Therefore, it is also suggested to other health professionals to use intraperitoneal instillation of bupivacaine in laparoscopic cholecystectomy for postoperative pain control.

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