

# Role of local infiltration of Tramadol vs. Bupivacain in postoperative Laparoscopic Cholecystectomy pain management

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## ABSTRACT

**Aim:** To compare local infiltration of Tramadol vs. Bupivacain in postoperative cholecystectomy in terms of mean pain score.

**Study Design.** Randomized controlled trial.

**Place and Duration of Study:** Department of Surgery, CMH, Muzaffarabad, Azad Kashmir from December 2018 to December 2019.

**Methodology:** Total of 100 patients with 50 in each group. Cholecystectomy done with wound infiltration using Tramadol (T) in group A while Bupivacain (B) in group B at time of skin closure. Postoperative pain assessment was done by using visual analogue score (0-10) a 12 hours.

**Results:** One hundred patients with mean age of  $46.93 \pm 10.23$  years were studied and male to female ratio was almost 1:2.5. The mean pain score at postoperative day one at 12 hours was recorded as (VAS  $3.5 \pm 1.787$ ) in group A (Tramadol) while mean pain score recorded as (VAS  $6.0 \pm 1.195$ ) in group B (Bupivacain). The p value was found significant  $< 0.05$ .

**Conclusion:** Our study concluded that tramadol can be used as local infiltrate for better postoperative analgesia.

**Keywords:** Visual analogue pain score VAS, Tramadol and Bupivacain.

## INTRODUCTION

In our body the presence of damage or disease is detected by pain receptors. These receptors are free nerve endings. In our body, there are three types of pain receptors which are mechanical, thermal and chemical pain receptors.<sup>1</sup> After a surgery patients present with postoperative pain on wound site. The management of postoperative pain is an important part of practice for a surgeon. Early and effective postoperative pain managements give multiple benefits i.e. earlier mobilization, less duration of hospital stay, hospital stay and cost effectiveness in form of reduced cost.<sup>2</sup>

Pain management is usually done in step ladder pattern. Initially such drugs are chosen that act on peripheral pain receptors like acetaminophin or non-steroidal anti-inflammatory drugs (NSAIDs). If these medicines fail to control the pain of the patient, then the second step is to use a weak opioid drugs such as codeine or tramadol. These second step drugs usually has few side effects so we have to add some other medicine along with them to reduce their side effects. Now if the effective pain control is still not achieved, then strong opioid drugs such as morphine are used to control pain.<sup>3</sup> In a continuous search for an effective pain killer it was seen that if 5% tramadol is used locally it gives its local anesthetic effects, and it gives an easy, safe and comfortable method for pain management<sup>4</sup>. Tramol is used in postoperative cases through intravenous or oral route for pain management, but it has important side effects, such as nausea and vomiting. A study comparing intra incisional injection tramadol, pethidine and Bupivacain on post cesarean pain relief showed that subcutaneous tramadol improves analgesia and has a significant morphine sparing effect compared with Bupivacain and control group<sup>5</sup>. In a study use of tramadol as subcutaneous vs. intra venous was compared and showed that local infiltration decreases postoperative opioid consumption<sup>6</sup>. Another study showed that tramadol produced effective and low cost postoperative analgesia during open urology procedure<sup>7</sup>. Commonly small procedures which are easy to be performed under local anesthesia are performed by infiltration of incision sites with long acting local anesthetics like Bupivacain which blocks all peripheral nerves or plexuses of that area. Opioids are used in routine to control postoperative pain.<sup>8</sup> The rationale of present

study was to compare the role of local infiltration of tramadol and Bupivacain in controlling postoperative laparoscopic cholecystectomy pain and hence reducing the use of various analgesics including intravenous opioids after surgery which is associated with morbidity.

## MATERIALS AND METHODS

This study was carried out at CMH/SKBZ Muzaffarabad, Azad Kashmir from December 2018 to December 2019 after taking permission from Hospital Ethical Committee. Total 50 patients having no known comorbidity and only having chronic cholecystitis or only chollithiasis were taken from the surgical OPD by non-probability consecutive sampling technique and then divided in two groups by lottery method. Demographic information like name, age, gender and addresses was obtained and entered in pre designed proforma. Surgical procedure and intervention (local infiltration) was explained to all patients and written informed consent was taken. Group A Tramadol (opioid analgesic) at dose of 1mg/kg body weight diluted in 10ml of normal saline and in group B Bupivacain (local anesthetic, 0.25%) at dose of 1.5mg/kg body weight. diluted in 10ml of normal saline was used for local infiltration at the end of surgery before skin closure. Patients were weighed pre operatively and dose of drug to be used will be calculated and arranged. It was ensured that single trade name of injections of both types should be used to control bias and confounding. Post-operative pain assessment was done using Visual Analogue Score (VAS) at 12 hours. Pain is marked on VAS table by post graduate trainee and data is entered in pre designed performa. SPSS version 20.0 was used for entry of collected data. Frequency and percentages were calculated for gender. Descriptive statistics such as mean and standard deviation were calculated for age and post-operative pain. Independent sample t-test was applied for post-operative pain between two groups. P value  $< 0.05$  was taken as significant. Stratification was used to control effect modifiers like age and gender. Independent sample test was applied post stratification.

## RESULTS

Total of 100 patients were successfully recruited into the trial: 50 in each Tramadol (group A) and Bupivacain (group B). Mean age of patients in both groups was recorded as  $46.93 \pm 10.23$ . In both

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groups male to female ratio was 1: 2.5. In group A (Tramadol) 12(24%) patients were males and 76% (n=38) were females while in group B (Bupivacain) 16(32%) patients were males and 68% (n=34) females. Age wise distribution of patients revealed that (n=36) patients were in age group 41-50 years of which 15 were male and 21 females and in age group 51-60% (n=36) of which 7 were males and 29 females. Mean VAS for both populations was  $4.75 \pm 1.494$ . Mean VAS for group A (Tramadol) was recorded as  $3.5 \pm 1.78714$  (Table 1) and in group B (Bupivacain) it was  $6.0 \pm 1.1952$  with  $p < 0.00$ . Majority of patients 62% (n=62) in both groups experienced mild to moderate pain as recorded on VAS (0-5) at 12 hours after operation whereas 38% patients experienced moderate to severe pain on VAS (6 or more). Higher VAS (6-8) was seen in 46% males whereas 65% females experienced mild to moderate postoperative pain. Pain score was less in young males and females i.e. age groups 20-40. Only 13% patients experienced severe pain in age group 20-40 as compared to 50% for 40-50 and 38% for 50-60. When groups were compared for statistical significance in terms of visual analogue pain score at 12 hours after surgery using independent-T test, there was statistically significant difference  $P=0.000$  between the two groups.

Table 1: Tramadol Vs Bupivacain

Groups	n	Mean	SD
Group A (Tramadol)	50	3.5000	1.78714
Group B (Bupivacaine)	50	6.0000	1.19523

P value 0.000

## DISCUSSION

This study was a randomized control trial. The rationale of this study is to compare the results of Tramadol and Bupivacain in postoperative pain relief when used as local infiltration in port site at the time of skin closure in patients who were offered laparoscopic cholecystectomy. In this study total of 100 patients were studied of which 28 % were male and 72% female. This suggests that cholelithiasis affects both sexes but female gender predominate. This finding is comparable to previous studies and text which showed that predominantly females who are fatty and fertile affected by gall stones. Mean age of patients in both populations was  $46.93 \pm 10.23$  years and majority 72 % of patients were in age group 40-60 years and same is mentioned in literature i.e. cholelithiasis is commonly seen in age 40 years and above<sup>9</sup>.

Only single parameter i.e. postoperative pain assessed in terms of VAS was seen in current study. Following cholecystectomy patient is early mobilized and then sent home but this can be achieved only if patient remains pain free post operatively. This analgesic effect in routine is achieved using pain stepladder described in literature review.<sup>10</sup> Pain degree measured as VAS at 12 hours post operatively was significantly lower in the Tramadol group as compared to the Bupivacain group in our study.

Similarly Tsaousi et al<sup>11</sup>, have published data that showed Tramadol to be effective when used as local infiltrate in reduction of post-operative pain. It was also mentioned in those studies that there was significantly reduced analgesic consumption post operatively which was not part of our study. In our study Mean VAS for group A is  $3.50 \pm 1.79$  which is comparable to previous studies.<sup>12</sup> Because tramadol group showed a better pain score, it is expected to see a difference in the rate of problems which are related to the postoperative pain such as delayed mobilization of patients. This study showed that tramadol has reduced postoperative pain significantly (better VAS) than Bupivacain at 12 hours post operatively. The pain score was seen higher in males which can be explained by the fact that males have tight muscle and difficult anatomy and for better exposure large incisions are made and muscle cut contrary to females where small incisions and muscle separation are sufficient<sup>13</sup>. We also observed in our study that pain scores were lower in 20-40 years group i.e. young patients both males and females and its reason can be high threshold of pain in young people who do not have any co morbidities.

This study was conducted because Tramadol is readily available and already in use for postoperative pain control given either enterally or parenterally. Similarly Bupivacain is used as local infiltrate at time of wound closure. Many surgeons use Bupivacain during surgery because of its established role in pain control but few avoid its use because of its potential complications e.g. cardiotoxicity.<sup>14</sup> We assumed that tramadol will be more safe and effective in this regard and it was proved in our study.

We conducted our study to overcome this potential complication of bupivacain. As mentioned in previous studies conducted on tramadol that it is safe and has no cardiac side effects and can be given via either route.<sup>15,16</sup> In few studies tramadol was used in place of prilocaine for minor surgical procedures and outcome was encouraging.<sup>17</sup> It is suggested that similar study should be done in future to determine tramadol as local anesthetic which will also help to establish whether tramadol works as anesthetic or its effect is depot in controlling postoperative pain.

In current study patients were observed for postoperative pain at 12 hours interval and we have not documented analgesics used to relieve pain, their dosage and route of administration which is a limitation to this study. Also we have not monitored pain score for 48 hours (routine patient stay after cholecystectomy) that would have helped to eliminate bias of pain record at one time. These issues can be overcome by conducting further studies with narrower age group, pain score recording at various times and also VAS at coughing, walking etc. and then taking.

## CONCLUSION

We conclude that Tramadol can be used as an alternative to bupivacain as local infiltrate to reduce postoperative pain. The added advantage of tramadol is its safety i.e. it is not cardiotoxic as compared to bupivacain if accidentally enters circulation. The above result also causes reduced postoperative analgesic consumption used via either route.

**Concept of interest:** Nil

## REFERENCES

1. Sheddou LU. Comparative physiology of nociception and pain. *Physiology*. 2018;33(1):63-73.
2. Kehlet H. Postoperative pain, analgesia, and recovery—bedfellows that cannot be ignored. *Pain*. 2018;159:S11-6.
3. Hah J, Mackey SC, Schmidt P, McCue R, Humphreys K, Trafton J, Efron B, Clay D, Sharifzadeh Y, Ruchelli G, Goodman S. Effect of perioperative gabapentin on postoperative pain resolution and opioid cessation in a mixed surgical cohort: a randomized clinical trial. *JAMA Surgery*. 2018;153(4):303-11.
4. Muneveroglu C, Gunduz M. Postoperative pain management for circumcision; Comparison of frequently used methods. *Pakistan J Medical Sciences*. 2020;36(2):91.
5. Khalaf WM, Ibrahim ME, Safwat S. Subrectal and subcutaneous wound infiltration with bupivacaine versus pethidine for post cesarean section pain relief: randomized controlled Trial. *Open J Obstet and Gynecol*. 2018;8(11):1071.
6. de Oliveira Junior JO, de Freitas MF, de Andrade CB, Chacur M, Ashmawi HA. Local analgesic effect of tramadol is mediated by opioid receptors in late postoperative pain after plantar incision in rats. *J Pain Research*. 2016;9:797.
7. Cacciamani GE, Menestrina N, Pirozzi M, Tafuri A, Corsi P, De Marchi D, Inverardi D, Processali T, Trabacchin N, De Michele M, Sebben M. Impact of combination of local anesthetic wounds infiltration and ultrasound transversus abdominal plane block in patients undergoing robot-assisted radical prostatectomy: perioperative results of a double-blind randomized controlled trial. *J Endourology*. 2019;33(4):295-301.
8. Swain A, Nag DS, Sahu S, Samaddar DP. Adjuvants to local anesthetics: Current understanding and future trends. *World J Clinl Cases*. 2017;5(8):307.
9. Pak M, Lindseth G. Risk factors for cholelithiasis. *Gastroenterology Nursing*. 2016;39(4):297-309.
10. Budiansky AS, Margaron MP, Eipe N. Acute pain management in morbid obesity—an evidence based clinical update. *Surgery Obesity and Related Diseases*. 2017;13(3):523-32.

11. Tsaousi GG, Chatzistravou A, Papazisis G, Grosomanidis V, Kouvelas D, Pourzitaki C. Analgesic efficacy and safety of local infiltration of tramadol in pediatric tonsillectomy pain: A systematic review and meta-analysis. *Pain Practice*. 2020;3.
12. Sahmeddini MA, Azemati S, Mottlagh EM. Local infiltration of tramadol versus bupivacaine for post cesarean section pain control: a double-blind randomized study. *Iranian J Medical Sciences*. 2017;42(3):235.
13. Packiasabapathy S, Sadhasivam S. Gender, genetics, and analgesia: understanding the differences in response to pain relief. *J Pain Research*. 2018;11:2729.
14. McDaniel M, Flores KB, Akpa BS. Predicting inter-individual variability during lipid resuscitation of bupivacaine cardiotoxicity in rats: a virtual population modeling study. *Drugs in R&D*. 2021;21(3):305-20.
15. DeLemos B, Richards HM, Vandenbossche J, Ariyawansa J, Natarajan J, Alexander B, Ramakrishna T, Murtaugh T, Stahlberg HJ. Safety, Tolerability, and pharmacokinetics of therapeutic and supratherapeutic doses of tramadol hydrochloride in healthy adults: a randomized, double-blind, placebo-controlled multiple-ascending-dose study. *ClinPharmacol Drug Development*. 2017;6(6):592-603.
16. Mattar OM, Abdalla AR, Shehata MS, Ali AS, Sinokrot M, Abdelazeim BA, Taher A, Samy A, Mahmoud M, Abbas AM. Efficacy and safety of tramadol in pain relief during diagnostic outpatient hysteroscopy: systematic review and meta-analysis of randomized controlled trials. *Fertility and Sterility*. 2019;111(3):547-52.
17. Kouba DJ, LoPiccolo MC, Alam M, Bordeaux JS, Cohen B, Hanke CW, Jellinek N, Maibach HI, Tanner JW, Vashi N, Gross KG. Guidelines for the use of local anesthesia in office-based dermatologic surgery. *J Am Academy Dermatol*. 2016;74(6):1201-19.