# **ORIGINAL ARTICLE**

# Comparison of Intraperitoneal Instillation of Bupivacaine versus Tramadol for Post-operative Pain in Patients Undergoing Laparoscopic Cholecystectomy

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## ABSTRACT

**Background:** Cholecystectomy, the surgical removal of the gallbladder, is commonly performed via laparoscopic methods, which is widely regarded as the standard treatment for symptomatic cholelithiasis. Laparoscopic cholecystectomy is often done as day-case surgery due to its advantages, including reduced pain, shorter hospital stays, and a quicker return to daily activities. A key aspect of this procedure is intra-peritoneal instillation for pain management. Two commonly used agents for this are bupivacaine, a local anesthetic, and tramadol, an opioid pain medication. However, there is ongoing debate about which of these agents is more effective for post-operative pain control.

**Objective:** This study aims to compare the efficacy of bupivacaine and tramadol in managing pain following laparoscopic cholecystectomy.

Methodology: This randomized controlled trial was conducted at the department of General Surgery Pir abdul qadir shah jeelani institute of medical sciences, Gambat over a six-month period. A total of 100 patients were included, selected using a non-probability consecutive sampling technique. Informed consent was obtained from all participants. Patients were randomly assigned to two groups using the lottery method. One group (group T) received 100mg of intraperitoneal tramadol, while the other group (group B) received 0.25% bupivacaine. Pain levels were assessed 24 hours post-operatively using the Visual Analogue Scale (VAS). The data were analyzed using SPSS 17, with a t-test applied to compare mean pain scores between the two groups, considering a p-value of ≤0.05 as statistically significant.

**Results:** The mean age of participants was  $36.81\pm7.59$  years, with 68% male and 32% female patients. In terms of body mass index (BMI), 30% of patients were of normal weight, 25% were overweight, and 45% were obese. The overall mean pain score was  $5.39\pm1.61$ . The mean pain score in the bupivacaine group was  $6.10\pm1.52$ , whereas in the tramadol group, it was  $4.68\pm1.39$ . This difference was statistically significant with a p-value of 0.000.

**Conclusion:** The results of this study indicate that tramadol is a more effective analgesic than bupivacaine for controlling postoperative pain in patients undergoing laparoscopic cholecystectomy.

Keywords: Cholecystectomy, Tramadol, Bupivacaine, Pain, Intraperitoneal instillation.

## INTRODUCTION

Laparoscopic cholecystectomy is the gold-standard procedure for gallbladder removal. The advantage of this procedure over the open approach is minimal trauma to the patient that attenuates the surgical stress response, reduces postoperative pain, enables early mobilization and shorten recovery time<sup>2, 3</sup>.

Although pain after laparoscopic cholecystectomy is less intense than after open surgery, it is not a pain-free procedure. Some patients still experience considerable discomfort during the first 24 postoperative hours. Pain is the dominating complaint (17-41%) and the primary reason for prolonged convalescent after laparoscopic cholecystectomy<sup>4</sup>.

Effective analgesic treatment after laparoscopic cholecystectomy has remained a clinical challenge. Several analgesic interventions with varying targets and mechanisms have been investigated for their influence on early pain after laparoscopic cholecystectomy. Variable analgesic effects of periportal infiltration of local anesthetics, infiltration of the periportal parietal peritoneum, intraperitoneal spraying above the gall bladder, instillation into the sub-diaphragmatic space and into the sub-hepatic space covering the area of hepatoduodenal ligament have been reported, but some of them failed to show analgesic effects<sup>5</sup>.

Intraperitoneal instillation of some drugs can be effective for relief of pain after laparoscopic surgery; Intraperitoneal instillation of drugs for pain relief is effective when used before creation of pneumoperitoneum<sup>6</sup> However, other studies conclude that administration at the end of surgery is effective<sup>7</sup>.

Received on 18-06-2023 Accepted on 11-11-2023 Cholecystectomy is the surgical removal of the gallbladder. It is a common treatment of symptomatic gallstones and other gallbladder conditions. Surgical options include the standard procedure, called laparoscopic cholecystectomy, and an older more invasive procedure, called open cholecystectomy<sup>10</sup>. Laparoscopic cholecystectomy has rapidly become the procedure of choice for routine gallbladder removal and is currently the most commonly performed major abdominal procedure in Western countries<sup>11</sup>.

A National Institutes of Health consensus statement in 1992 stated that laparoscopic cholecystectomy provides a safe and effective treatment for most patients with symptomatic gallstones and has become the treatment of choice for many patients. This procedure has more or less ended attempts at noninvasive management of gallstones<sup>12</sup>. The initial driving force behind the rapid development of laparoscopic cholecystectomy was patient demand. Prospective randomized trials were late and largely irrelevant because advantages were clear. Hence, laparoscopic cholecystectomy was introduced and gained acceptance not through organized and carefully conceived clinical trials but through acclamation<sup>13-14</sup>. Laparoscopic cholecystectomy decreases postoperative pain, decreases the need for postoperative analgesia, shortens the hospital stay from 1 week to less than 24 hours. Laparoscopic cholecystectomy also provides improved cosmesis and improved patient satisfaction as compared with open cholecystectomy<sup>15</sup>

Trials have shown that laparoscopic cholecystectomy patients in outpatient settings and those in inpatient settings recover equally well, indicating that a greater proportion of patients should be offered the outpatient modality 14.Laparoscopic cholecystectomy has received nearly universal acceptance and is currently considered the criterion standard for the treatment of symptomatic cholelithiasis. Many centers have special "short-stay" units or "23-hour admissions" for postoperative observation following this procedure<sup>14,15</sup>.

One study reported that Visual Analogue Scale (VAS) of pain after 24 hours of operation was3.47 with bupivacaine which was significantly higher than 2.53 with tramadol (P<0.05). Authors concluded that locally infiltrated tramadol provided an improved postoperative analgesia in comparison to bupivacaine<sup>8</sup>

Another study reported that post-operative mean pain with bupivacaine was 0.06±0.72 while 0.70±0.65 with tramadol after 24 hours of procedure (P>0.05)<sup>9</sup>. The rationale of this study is to compare the mean pain score with intraperitoneal instillation of bupivacaine versus tramadol in patients undergoing laparoscopic cholecystectomy. Bupivacaine is commonly used local anaesthetic drug which is used to control pain. Tramadol is used as analgesic and is found to be effective. But due to lack of evidence in local literature we are unable to implement the use of tramadol instead of bupivacaine as bupivacaine is associated with more side effects.

One study showed tramadol<sup>8</sup> is better while other showed bupivacaine<sup>9</sup> So through this study we want to resolve the issue. The study will help change the current practices for control of pain in patients undergoing laparoscopic cholecystectomy specifically and all other laparoscopic cases generally.

Cholecystectomy is the surgical removal of the gallbladder. It is a common treatment of symptomatic gallstones and other gallbladder conditions. Surgical options include the standard procedure, called laparoscopic cholecystectomy, and an older more invasive procedure, called open cholecystectomy<sup>10</sup>

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## **METHODOLOGY**

This randomized controlled trial was conducted at the department of General Surgery, Pir Abdul Qadir Shah Jeelani Institute of Medical Sciences, Gambat over six months, following the approval of the study synopsis. The sample included 100 patients, with 50 patients in each group. The sample size was calculated based on a 95% confidence level and 80% power of the test, using a mean post-operative pain of 0.06±0.72 with bupivacaine and 0.70±0.65 with tramadol in patients undergoing laparoscopic cholecystectomy. Non-probability consecutive sampling was used for patient selection. Inclusion criteria comprised patients aged 25-50 years, either gender, diagnosed with cholelithiasis (stones on ultrasound) and scheduled for laparoscopic cholecystectomy, with stones >5mm and  $\geq 2$  stones, along with >6 months of right hypochondrium pain. Exclusion criteria included patients with common bile duct stones, those whose surgery was converted to open, complicated gallbladder cases, and those with cardiac arrhythmias.

Following ethical approval, 100 eligible patients were enrolled after obtaining informed consent. Demographic data were recorded, and patients were randomly assigned to two groups via the lottery method. Group T received intraperitoneal tramadol 100mg, while Group B received 0.25% bupivacaine. All surgeries were performed by a single surgical team. Post-operatively, patients were assessed for pain at the 24-hour mark using the Visual Analogue Scale. Data were collected on a specifically designed proforma.

#### RESULTS

In this present study total 100 cases were enrolled. Table 1 indicates the mean age of the patients was  $36.81\pm7.59$  years with minimum and maximum ages of 25 & 50 years respectively. In this study 68% patients were males and 32% patients were females. The male to female ratio was 2.1:1. In our study, 30(30%) patients had normal BMI, 25(25%) were overweight and 45(45%) were obese. There were 39(39%) patients who had habit of pan chewing while 61(61%) were non-pan chewing patients. There were 28 (28%) smokers while 72 (72%) non-smokers.

The study results showed that the mean pain score of the patients was 5.39±1.61 with minimum and maximum score of 2 and 9 respectively after 24 hours of surgery.

In this study, the mean pain score with bupivacaine was 6.10±1.52 and with tramadol was 4.68±1.39. Statistically there is significant difference found between the groups and pain score i.e. p-value=0.000.

Variable	n	Mean	SD	Minimum	Maximum	Frequency	Percent
Age (years)	100	36.81	7.59	25.00	50.00	-	-
Gender	-	-	-	-	-	Male	68%
						Female	32%
BMI	-	-	-	-	-	Normal	30.0%
						Overweight	25.0%
						Obese	45.0%
Pan Chewing	-	-	-	-	-	Yes	39.0%
						No	61.0%
Smoking	-	-	-	-	-	Smoker	28%
						Non-smoker	72%)

Table 1: Descriptive Statistics and Frequency Distribution

Table 2: Descriptive Statistics of Pain Score

Variable	n	Mean	SD	Minimum	Maximum
Pain Score	100	5.39	1.61	2.00	9.00

Table 3: Comparison of Pain Scores in Both Study Groups						
Study Groups	n	Mean	SD	t-value	p-value	
Bupivacaine	50	6.10	1.52	4.85	0.000 (Significant)	
Tramadol	50	4.68	1.39			

Table 4 depicts that in patient with normal BMI, the mean pain score with bupivacaine was  $5.57\pm1.55$  and with tramadol was  $4.56\pm1.71$ . The difference was insignificant i.e. p-value>0.05. In overweight patients, the mean pain score with bupivacaine was  $7.07\pm1.44$  and with tramadol was  $4.66\pm1.07$ . Statistically the difference was significant i.e. p-value<0.05. In obese patients, the mean pain score with bupivacaine was  $5.86\pm1.35$  and with tramadol was  $4.77\pm1.34$ . Statistically the difference was significant i.e. p-value<0.05. In obese patients, the mean pain score with bupivacaine was  $5.86\pm1.35$  and with tramadol was  $4.77\pm1.34$ . Statistically the difference was significant i.e. p-value<0.05. In pan chewing patients, the mean pain score with Bupivacaine was  $5.95\pm1.39$  and with tramadol was  $4.56\pm1.26$ . Similarly, in patients with no pan chewing, the mean pain score with Bupivacaine was  $6.22\pm1.64$  and with tramadol was  $4.73\pm1.46$ . Statistically the difference was significant i.e. p-value<0.05. Among

smokers, the mean pain score with Bupivacaine was  $5.46\pm1.12$ and with tramadol was  $4.86\pm1.80$ . The difference was statistically insignificant (P>0.05). Similarly, among non-smokers, the mean pain score with Bupivacaine was  $6.32\pm1.59$  and with tramadol was  $4.60\pm1.19$ . Statistically the difference was significant i.e. pvalue<0.05.In patients of age  $\leq$ 35 years, the mean pain score with Bupivacaine was  $6.15\pm1.56$  and with tramadol was  $4.70\pm1.42$ . Similarly in patients of age>35 years, the mean pain score with Bupivacaine group was  $6.04\pm1.51$  and with tramadol was  $4.65\pm1.38$ . Statistically there is significant difference observed between both groups when data was stratified for age of patient

i.e. p-value<0.05. In male patients, the mean pain score with Bupivacaine was 5.94±1.56 and with tramadol was 4.8±1.49. Similarly in female patients, the mean pain score with Bupivacaine was 6.50±1.40 and with tramadol was 4.44±1.19. Statistically there is significant difference observed between both groups when data was stratified for gender of patient i.e. p-value<0.05.

Table 4: Comparison of	Pain Scores in Both	Study Gr	oups Stratified by	Various Factors
Stratification Factor	Study Groups	n	Mean + SD	n-value

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Age ≤ 35 years	Bupivacaine	26	6.15 ± 1.56	0.001
	Tramadol	24	4.70 ± 1.42	
Age > 35 years	Bupivacaine	24	6.04 ± 1.51	0.001
	Tramadol	26	4.65 ± 1.38	
Male	Bupivacaine	36	5.94 ± 1.56	0.003
	Tramadol	32	4.80 ± 1.49	
Female	Bupivacaine	14	6.50 ± 1.40	0.000
	Tramadol	18	4.44 ± 1.19	
Normal BMI	Bupivacaine	14	5.57 ± 1.55	0.104
	Tramadol	16	4.56 ± 1.71	
Overweight BMI	Bupivacaine	13	7.07 ± 1.44	0.000
	Tramadol	12	4.66 ± 1.07	
Obese BMI	Bupivacaine	23	5.86 ± 1.35	0.009
	Tramadol	22	4.77 ± 1.34	
Pan Chewing	Bupivacaine	23	5.95 ± 1.39	0.003
	Tramadol	16	4.56 ± 1.26	
No Pan Chewing	Bupivacaine	14	6.22 ± 1.64	0.000
	Tramadol	18	4.73 ± 1.46	
Smoker	Bupivacaine	13	5.46 ± 1.12	0.315
	Tramadol	15	4.86 ± 1.80	
Non-smoker	Bupivacaine	37	6.32 ± 1.59	0.000
	Tramadol	35	4.60 ± 1.19	

## DISCUSSION

Laparoscopic cholecystectomy is the preferred method for treating cholelithiasis due to its advantages over open surgery, such as reduced bleeding, improved cosmetic results, less postoperative pain, and faster recovery. These benefits lead to shorter hospital stays and reduced costs. This randomized controlled trial, conducted at Mayo Hospital Lahore, compared the mean pain scores of patients who received intraperitoneal bupivacaine versus tramadol during laparoscopic cholecystectomy. Our study found that the tramadol group had a significantly lower mean pain score ( $4.68 \pm 1.39$ ) compared to the bupivacaine group ( $6.10 \pm 1.52$ ), with an overall mean score of  $5.39 \pm 1.61$ . These results show that tramadol is more effective at managing postoperative pain than bupivacaine<sup>21</sup>.

Previous studies support our findings. Golubovic et al. reported that intraperitoneal bupivacaine or tramadol, or their combination, significantly reduces postoperative pain and the need for additional analgesics<sup>22</sup>. Similarly, Shukla et al. found that combining bupivacaine with tramadol resulted in lower pain scores compared to bupivacaine alone. Other studies, including one by Memis et al., also showed that combining tramadol with bupivacaine provided better pain relief. Additionally, Akinci et al. found that intravenous tramadol offered superior pain relief compared to intraperitoneal tramadol. Our study also observed significant differences in pain scores when stratified by factors such as gender, age, BMI, and smoking. Based on these findings, tramadol appears to be a more effective analgesic for managing

pain after laparoscopic cholecystectomy, potentially reducing the need for additional analgesic medications<sup>24</sup>.

#### CONCLUSION

Our study results concluded that the tramadol is more effective analgesic drug as compared to bupivacaine. Lesser pain score was noted in tramadol group patients as compared to bupivacaine group patients. Now in future we are able to implement the use of tramadol for prevention of pain after laparoscopic surgery.

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