

# Efficacy of Bupivacaine Inferior Alveolar Nerve Block Versus Intravenous Use of Tramadol for Postoperative Pain Control in Mandibular Parasymphysis Fractures

SHEHRYAR ALAM KHAN<sup>1</sup>, GULRAIZ ZULFIQAR<sup>2</sup>, AYESHA BINTE ASLAM<sup>3</sup>

<sup>1</sup>Postgraduate Resident (PGR) Oral & Maxillofacial Surgery, (AIMC) Jinnah Hospital, Lahore

<sup>2</sup>Head of Department (HOD), OMFS, (AIMC) Jinnah Hospital, Lahore

<sup>3</sup>Consultant Oral and Maxillofacial Surgeon, (AIMC) Jinnah Hospital, Lahore

Correspondence to: Shehryar Alam Khan, Email: [dr.shehryaralamkhan@gmail.com](mailto:dr.shehryaralamkhan@gmail.com), Cell: 03145250219

## ABSTRACT

**Background:** One of the most crucial parts of any operation is postoperative monitoring and management. Numerous clinical strategies for administering analgesic drugs have been developed to reduce postoperative pain in patients. High opioid doses before, during, and after surgery might cause respiratory depression, sleepiness, nausea, vomiting, itching, difficulties urinating, and ileus. Most surgeries cause maxillo-mandibular fixation (locked jaw). In the early postoperative period, ventilatory depression and vomiting are common that's why this study focuses on the two types of drug intervention and measures the effects.

**Objective:** To evaluate the efficacy of bupivacaine inferior alveolar nerve block vs intra-venous tramadol (opioid) in postoperative pain control.

**Study Design:** Prospective, randomized control trial

**Study Setting:** The study was conducted in Jinnah Hospital, Lahore from 6 April 2022 to 6 October 2022.

**Methodology:** The non-probability sampling technique was used to recruit the patients. Patient aged between 18 – 40 years with simple mandibular parasymphysis fracture was included in the study. However, patients with diabetes, ischemic heart disease & bone diseases were excluded from the study. The patients were divided into two groups. One group received bupivacaine while the other group received tramadol (opioid). The pain of the patient was calculated using the Visual Analog Scoring system. The frequency of pain was recorded postoperatively between 0-3hrs, 3-6hrs, 6-12hrs, and 12-24hrs. The data were analyzed by using SPSS version 22.

**Results:** Fifty-two patients were recruited in this trial and randomly assigned to the bupivacaine group and tramadol group, there were no significant differences between the two groups in terms of demographic data including age, gender, BMI and mean operation time ( $P>0.05$ ) as shown in table 1. The Visual Analog and Category Pain Scale (VAS) significantly reduced in both the groups. The more decline in pain was observed from 12hrs to 24hrs in bupivacaine group from  $4.46\pm 0.64$  to  $2.27\pm 1.00$  respectively. In addition, a repeated-measures ANOVA was utilized to evaluate the VAS ratings between the two groups, revealing that the VAS values in the bupivacaine group were considerably lower than those in the tramadol group 16 and 24 hours after surgery ( $P=0.001$  and  $P=0.000$ , respectively).

**Practical implication:** The study's justification is the dearth of local or regional information on this topic. Therefore, the objective of this research was to evaluate the effectiveness of tramadol intravenously against bupivacaine inferior alveolar nerve block for postoperative pain control in mandibular parasymphysis fractures.

**Conclusion:** In conclusion, 2mL.5% Injection Bupivacaine (1:200000) administered at the fracture site in the mandibular parasymphysis fractures area post-operation relieved somatic wound pain better than tramadol without major side effects. Thus, local infiltration of bupivacaine over the section incision is recommended for safe and efficient post-operative pain.

**Keywords:** Bupivacaine, Tramadol, Mandibular Parasymphysis Fractures, Alveolar Nerve Block

## INTRODUCTION

One of the most crucial parts of any operation is postoperative monitoring and management. Treating postoperative pain as soon as possible is recommended for the fastest possible recovery and release from the hospital. Numerous clinical strategies for administering analgesic drugs have been developed to reduce postoperative pain in patients<sup>1, 2</sup>. It is normal practice to provide nonsteroidal anti-inflammatory drugs (NSAIDs) and opioid medication to patients experiencing pain as a result of surgical trauma<sup>3</sup>. The vast majority of Oral and Maxillofacial Surgery treatments involve the treatment of fractures brought on by trauma. Postoperative care often entails the administration of narcotic pain relievers and nonsteroidal anti-inflammatory drugs in large doses<sup>(4)</sup>. An increased risk of respiratory depression, drowsiness, nausea, vomiting, pruritus, trouble urinating, and ileus has been linked to the administration of high dosages of opioid medications before, during, and after surgery. The majority of surgical procedures result in the patient developing Maxillo-mandibular fixation (locked jaw). Ventilatory depression and vomiting are among the significant categories in this situation, particularly in the early postoperative hours, because of the potential for adverse effects of opioids to cause major, life-threatening problems<sup>5</sup>. In an effort to lessen the severity of these unwanted consequences, several strategies have been recommended. For this purpose, one method that has been considered is a nerve block using a long-acting local anesthetic. Many surgical techniques, such as open

reduction of limb fractures, graft donor site operations, laparoscopy, and arthroscopy, have benefited from the use of these fluids. Bupivacaine, alone or in conjunction with intravenous nonsteroidal anti-inflammatory drug (NSAID) administration, has been utilized as a safe local anesthetic treatment for pain management after cleft lip surgery and third molar surgery in the maxillofacial sector<sup>6, 7</sup>.

The local anesthetic bupivacaine has a longer duration of action, making it ideal for surgical procedures. Epidural injections of bupivacaine into the spinal column provide anesthesia for childbirth, surgery, and other medical operation<sup>(8)</sup>. Depolarization may be avoided with bupivacaine because it blocks sodium ion input into neurons by binding to the intracellular part of sodium channels. For the most part, the diameter, myelination, and conduction velocity of damaged nerve fibers are correlated with the development of anesthesia<sup>9</sup>. Loss of pain sensation occurs first, followed by temperature, touch, proprioception, and finally skeletal muscle tone from a clinical standpoint. Evidence suggests that Bupivacaine's analgesic effects can be attributed to the drug's ability to bind to and block the activity of prostaglandin E2 receptors, subtype EP1 (PGE2EP1), thereby reducing the body's production of prostaglandins and associated symptoms like fever, inflammation, and hyperalgesia. Adverse reactions to anesthesia may be minimized with careful dosing<sup>10, 11</sup>.

In this study, the patients admitted to a trauma hospital with mandibular para-symphyseal fractures received an inferior alveolar

nerve block with bupivacaine to assess its effectiveness in postoperative pain management and decrease total analgesic medication demand. The pain of the patient was calculated using the Visual Analog Scoring system and also by the frequency of intermediate analgesics such as acetaminophen given to both patients given either bupivacaine or tramadol (opioid) postoperatively.

**MATERIALS AND METHODS**

**Study Design:** Prospective, randomized control trial  
**Study Design and Setting:** The study was a prospective, randomized control trial from 6 April 2022 to 6 October 2022.

**Sample Size Calculation:** With a significance level of 5%. The proportion of patients who did not analgesic in Group A (Bupivacaine) = 28% Proportion of patients who had need of analgesic = 100%. Ratio of sample size B:A = 1. This tool determined the sample size, n, using the following formula: It may be written as  $n = (Z\alpha/2 + Z\beta)^2 * (p1(1-p1) + p2(1-p2)) / (p1-p2)$  where  $Z/2$  is the Normal distribution's critical value at a significance level of  $\alpha/2$  (e.g., for a confidence level of 95%, is 0.05 and the critical value is 1.96) and  $Z\beta$  is the Normal distribution's critical value at a significance level of  $\beta$  (e.g., for a power of 80%,  $\beta$  is 0.2 and the critical value is 0.84) and  $p1$  and  $p2$  were the expected sample proportions of the two groups (12). A total of 52 were calculated for the completion of the study, 26 samples in each group.

**Sampling technique:** The non-probability sampling technique was used to recruit the patients.

**Sample selection:** Patient aged between 18 – 40 years with simple mandibular parasymphysis fracture was included in the study. However, patients with diabetes, ischemic heart disease & bone diseases were excluded from the study. The selection participant process is presented in figure 1.

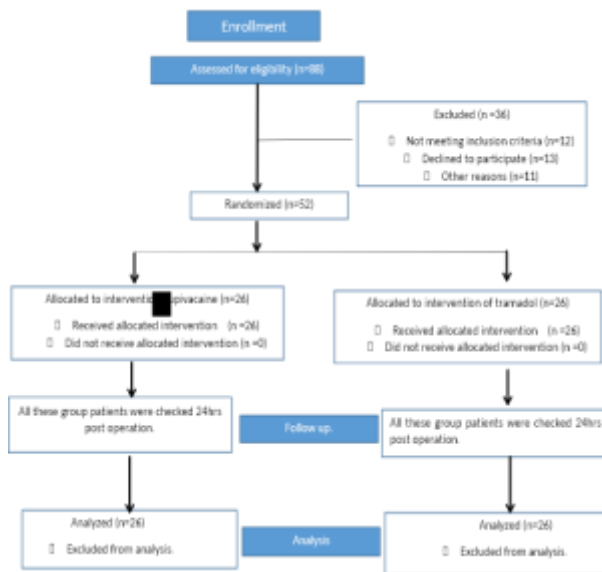


Figure 1: Selection of Participants

**Operational definitions: Parasymphysis fracture:** In this study, any fracture line that was simple and between the distal surface of the mandibular central incisor to the mesial surface of the mandibular canines was considered a parasymphysis fracture.

**Inferior Alveolar Nerve Block:** Nerve Block that was given with 2mL .5 % Injection Bupivacaine (1:200000) given at the side of the fracture in pterygomandibular space using a 25 G needle.

**Data Collection Procedure:** After taking approval from the hospital's ethical committee, subjects fulfilling the selection criteria were enrolled in the study from Accident and Emergency

Department/ OPD Jinnah Hospital Lahore. Informed consent was taken.

Patient Mandibular para symphysis fractures only in the head and neck were included and the diagnosis was confirmed by computed tomography of the face with 3D reconstruction. Open and reduction of the fracture was done under Local Anesthesia, following Champy's rule with two miniplate of 2mm one at the lower border of the mandible and one at the upper border mandible was placed to fix the fracture.

Post-operatively one group of patients was given an injection of tramadol 50mg diluted with 100mL N/S, while another group was given 2mL .5% injection of bupivacaine for inferior alveolar nerve block. The patients were monitored for pain using a Visual analog and category scale (figure 2) post-operatively in 0-3h, 3-6h, 6-12 h, and 12-24h. In pain, both groups were given injections of Acetaminophen 1g (Provas) and their frequency was noted.

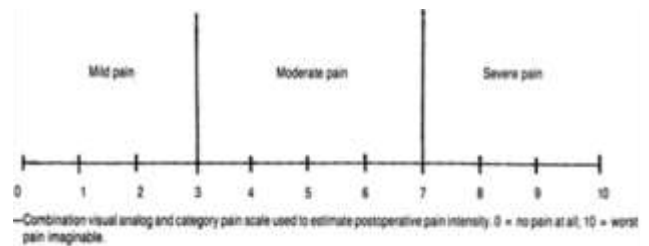


Figure 2: Visual Analog and Category Pain Scale (VAS).

**Data analysis:** The data analysis for this study was carried out using version 20.0 of the IBM-SPSS. Descriptive analysis was performed on demographic factors such as age, gender, BMI, and operation time. An Independent t-test was used for the visual analog and category pain scale. If the p-value was lower than 0.05, the data were statistically significant.

**RESULTS**

Only 88 patients who were eligible for the study were selected. Due to pulmonary diseases (n=2), a definitive diagnosis of convulsion disorder (n=6), and the presence of valvular heart disease (n=4), 12 patients were removed from the research. In the end, mandibular para symphysis fractures only in the head and neck, 52 patients were recruited in this trial and randomly assigned to the bupivacaine group and tramadol group (Figure 1). There were no significant differences between the two groups in terms of demographic data including age, gender, BMI and mean operation time (P>0.05) as shown in table 1. However, 6 patients of bupivacaine intervention and 15 patients of tramadol were given injection Acetaminophen 1g (Provas).

Table 1: Demographic characteristics distribution between bupivacaine and tramadol group

Variables	Bupivacaine Group (n=26)	Tramadol Group (n=26)	P-value
Age (y)	33.58±9.48	33.23±7.80	0.35
Male	10 (19.23)	12 (23.07)	0.57
Female	16 (30.76)	14 (26.92)	0.39
BMI (kg/m <sup>2</sup> )	21.96±3.49	22.04±3.86	0.57
Operation time (min)	48.04±4.07	48.42±4.1	0.99

The Visual Analog and Category Pain Scale (VAS) significantly reduced in both the groups. But the at 3, 6,12 and 24 hours post operatively (P>0.05). The more decline in pain was observed from 12hrs to 24hrs in bupivacaine group from 4.46±0.64 to 2.27±1.00 respectively. In addition, a repeated-measures ANOVA was utilized to evaluate the VAS ratings between the two groups, revealing that the VAS values in the bupivacaine group were considerably lower than those in the tramadol group 16 and 24 hours after surgery (P=0.001 and P=0.000, respectively).

Table 2: Comparison of Visual Analog and Category Pain Scoring (VAS) between bupivacaine and tramadol group

Time Interval	Bupivacaine Group (n=26)	Tramadol Group (n=26)	P-value
VAS 0-3hrs	7.42±0.57	7.96±0.91	0.002
VAS 3-6hrs h	5.69±0.61	6.12±0.86	0.032
VAS 6-12 hrs h	4.46±0.64	5.27±0.91	0.002
VAS 12-24 hrs	2.27±1.00	3.42±0.64	0.018

Figure 3 shows the scoring of pain by using visual analog and category pain scale (VAS). After 3 to 6 time interval the scoring was significantly reduced. However, after 12 to 24 hours, the VAS scores in the bupivacaine group were considerably on the lower side than in the tramadol group (figure 3).

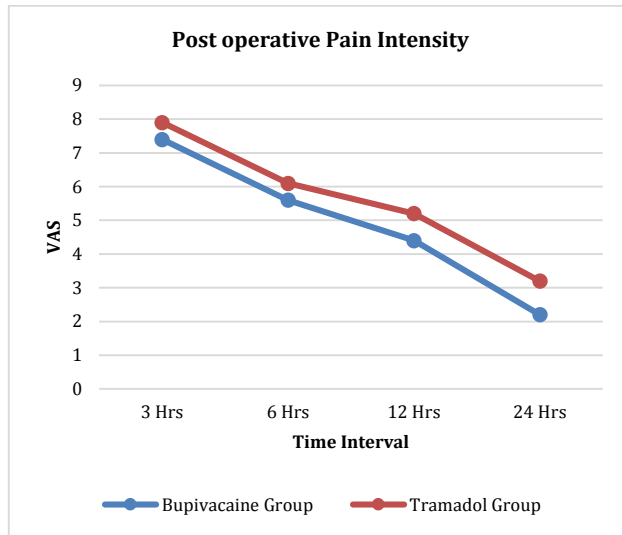


Figure 3: Shows postoperative pain intensity (VAS) in the bupivacaine and tramadol groups during the first 24 postoperative hours.

## DISCUSSION

Maxillofacial operations often rely on opioid administration to alleviate the pain. In maxillofacial procedures, where patients often have an intermaxillary fixation, which prevents the correct evacuation of vomit via the oral route<sup>(13)</sup>. This study focuses to evaluate the efficacy of bupivacaine inferior alveolar nerve block vs. intra-venous tramadol in postoperative pain control. In this study age, gender, BMI, and operation were not significantly different between bupivacaine and tramadol groups. The vomiting side effect linked with the opioids may be a particularly life-threatening consequence. Therefore, it may be a wise clinical goal after maxillofacial procedures to decrease the number of opioids required for recovery. Opioid use may be decreased with the use of long-acting anesthetic, which may give the pain relief to the patient. The effectiveness of these anesthetics in a range of surgical settings has been studied<sup>(14)</sup>. Clinical usage of bupivacaine and lidocaine in third molar surgery was studied by Bouloux and Punnia-Moorthy in a randomized, double-blind, crossover trial. On one side, bupivacaine was utilized for the third molar surgery, whereas on the other, lidocaine was employed<sup>15</sup>.

However, even when every precaution has been taken to ensure a pain-free intra-operative phase, anesthetists still face significant obstacles when it comes to managing postoperative pain. Adverse physiological consequences may occur if postoperative pain is intolerable<sup>16</sup>. We measured post-operative pain intensity, duration, and responsiveness against both medications (Bupivacaine and Tramadol) by using Visual Analog and Category Pain Scale. The results demonstrated that after both drug administrations in their respective group, both showed a significant decline but Bupivacaine showed the more significant

drop in pain in patients after 12 to 24 hrs of operation. The investigation done by Tjanic et al. that bupivacaine's analgesic effects only lasted for eight hours after surgery. They found no significant difference in their study's secondary measures, save for postoperative discomfort<sup>17</sup>.

Also the use of a sustained-release diclofenac formulation in conjunction with bupivacaine and lidocaine for postoperative pain management after third molar surgery<sup>(18)</sup>. However, the other investigation by Jain et al, demonstrated that the used of tramadol causes vomiting and nausea in two patients. There was discernible difference between the use of lornoxicam and intravenous tramadol<sup>(19)</sup>. It is necessary to use fewer and less analgesics when the level of pain at the surgical site diminishes. Because of the negative reactions to the medicine at larger levels, we have decided to use a lower dose in the trial<sup>(20)</sup>. In our finding the bupivacaine was used as an inferior alveolar nerve block similarly the previous study of Singh and Bhardwaj also used a continuous mandibular nerve block with bupivacaine. Opioids are used routinely to manage pain after almost all surgical procedures. Consequences from opioids medication use are crucial factors to consider sometime the use of this medication are inevitable<sup>(21)</sup>.

The most prevalent postoperative problems after oral and maxillofacial procedures. After maxillofacial procedures, Silva et al. found that this problem occurred in 40% of patients. Opioid analgesic medication use may be decreased and their negative effects avoided with the use of bilateral cranial nerve blocks. Patients who have suffered both maxillofacial and brain injuries may benefit from this approach as well<sup>(22)</sup>. Abdel Aziz et al. identified lower VAS scores in the tramadol group. The study included patients following (symphyseal / parasymphyseal area) fractures. Lower VAS ratings and no side effects were seen in both studies, even though the dosages of the analgesics used in each were different<sup>(23)</sup>.

However, sedation is also potentially lethal for some people. The significant variation in the study group's latency to the first dosage of opioids noted the risks of vomiting and aspiration are increased with emergency maxillofacial procedures<sup>(24)</sup>. In unconscious patients, a bilateral para-symphiseal fracture is an emergency because the genioglossus and geniohyoid muscles might move the fractured segment posteriorly, blocking the airway along with the tongue's position<sup>(25)</sup>. The use of a bilateral phrenic nerve block at the end of surgery delays the first need for opioid drugs and reduces the total dose of analgesic drugs, giving the medical and nursing staff ample time to re-evaluate the level of patients' medical and consciousness conditions without any sedative drug interaction<sup>(26)</sup>. Research on the clinical and social aspects of opioid analgesic addiction is ongoing. Opioid medicines also carry the risk of addiction in people who are mentally vulnerable to it. The overall number of opioids prescribed after surgery, as well as patients' demand for them, might be reduced, which could have a significant impact on these problems<sup>(9)</sup>. Our findings, establish that bupivacaine is a good post-operative pain reliever as compared to tramadol. Furthermore, postoperative nausea and vomiting after tramadol consumption is observed often, and its management is a complex therapeutic problem.

The current study's benefits lie in the fact that it is an interventional study, which contributes to the management of Mandibular Parasymphysis Fractures by using two different medications. However, further research is needed to establish the safest and most effective bupivacaine dose for use during surgeries and to identify any potential long-term effects. In order to compare the pain-relieving effect of bupivacaine with its local infiltration impact, it would be preferable to include another group in the research that received another route of administration of bupivacaine.

## CONCLUSION

In conclusion, this research showed that 2mL .5 % Injection Bupivacaine (1:200000) given post-operation was more efficient than tramadol in relieving somatic wound pain without causing

serious adverse effects. Consequently, Bupivacaine is offered as a safe and effective post-operative painkiller following general anesthesia, and its local infiltration across the section incision is suggested.

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