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# Comparative study of local anesthetic efficacy of 5% tramadol versus 2 % Lignocaine with 1:100,000 adrenaline for extraction of fully erupted maxillary 3rd molars using infiltration anesthesia



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## **KEYWORDS**

Tramadol; Lignocaine; Supraperiosteal infiltration; Extraction

Abstract Introduction: The majority of dental procedures need local anesthesia for pain control, and lidocaine/ lignocaine is the most commonly used anesthetic agent in dentistry. Although effective and safest, the anesthetic agent still has some complications. To overcome these many alternatives have been used. Tramadol has been shown to have some local anesthetic (LA) effects when used for infiltration anesthesia in dentistry.

Methods: In the present study, the local anesthetic efficacy of tramadol was compared with 2% lignocaine containing 1: 100,000 adrenaline for the extraction of maxillary fully erupted 3rd molar teeth. The parameters recorded included the onset of action, duration of action, intraoperative pain, post-operative analgesic effect, and incidence of an allergic reaction. A total of 200 patients were randomly divided into two groups. In group A -Each patient received 0.6 ml of 5% tramadol (Tramataj- 50 mg prepared by Taj pharma company) 0.4 ml buccally and 0.2 ml palatally for extraction of maxillary 3rd molar as local infiltration following strict aseptic precaution. In Group B- patients received 0.6 ml of 2% lignocaine containing 1: 100,000 adrenaline buccally and 0.2 ml palatally as infiltrations.

Results: It was found that 5% tramadol has a local anesthetic efficacy similar to 2% lignocaine with adrenaline but was found to be a comparatively weaker agent.

Conclusion: tramadol is a valid alternative for performing extractions in normal patients or patients allergic to lidocaine.

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# 1. Introduction

Pain control during extractions is one of the most important and challenging things for the dentist. Lidocaine is considered the safest and most effective local anesthetic agent. (Singh 2012). Although the incidence of allergic reactions and complications to various local anesthetic agents is less than 4.5%, various alternatives have been used for pain control in dentistry. (Daublander et al.,1997).

Tramadol hydrochloride (HCl) a centrally acting opioid analgesic, was made available to use for pain management in Germany in 1977. (WHO Tramadol update review report -2014). It is known to be effective in the treatment of moderate to severe types of pain (Grond S, Sablotzki. A -2004). Since the LA property of Tramadol was reported (Pang et al., 1998), several in vitro and in vivo studies have been conducted to test its efficacy. In 2013, Al Haideri reported the use of tramadol alone or in combination with adrenaline as an alternative to the local anesthetic agent for extraction of the tooth under subperiosteal infiltration. In the current study, a comparison was made to check the LA efficacy of tramadol HCl versus lignocaine HCl with adrenaline for extraction of maxillary fully erupted 3rd molars under supra periosteal infiltration.

#### 2. Materials and Methods

In this study, a total of 200 patients reporting to the Department of Oral and Maxillofacial surgery, after meeting the inclusion criteria were selected in a randomized manner. A detailed case history and written consent were taken from all the patients before participating in this study.

Inclusion criteria

- Patients both males and females aged 20-60 years.
- Patients indicated for extraction of fully erupted maxillary 3rd molars.
- ASA -I physical status patients
- Patients willing to participate in the study

Exclusion criteria

- Impacted maxillary 3rd molars
- pregnant or lactating females,
- patients with a history of drug allergy
- Patients not willing to participate in the study
- Patients with trismus (mouth opening less than 30 mm).

The participants were randomly divided into two groups of 100 each in Group A and Group B(n = 100) In Group A, patients were administered 0.6 ml of 5% tramadol (Tramataj-50 mg) 0.4 ml buccally and 0.2 ml palatally. Group B patients were given 2% lignocaine containing 1: 100,000 adrenaline (0.6 ml buccally and 0.2 ml palatally). The intra alveolar extraction procedure was performed in all patients without sutures.

Then following parameters were assessed in all the patients in both groups.

# 2.1. Incidence of an allergic reaction

Allergic testing was performed in all the patients before administration of supra periosteal infiltration anesthesia. An equivalent of 0.1 ml of the test drug was injected intradermally under all aseptic precaution on the forearm of the right hand using a sterile 2 ml syringe with a

short needle just underneath the surface of the skin. The formation of "bleb" indicated successful injection. Each injection site was evaluated for 10-15 min. The response was measured by the diameter of skin change or wheal if present (Altunkaya H, Ozer Y, Kargi E, Babuccu O -2000).

Scale: 0 = no reaction.; 1 = mild rash; 2 = erythema; 3 = urticarial; 4 = any other systemic change. After no allergic reaction to the drug was confirmed, Supraperiosteal infiltration injection of 0.4 ml of tramadol on the buccal side and 0.2 ml on the palatal side or 0.6 ml 2% lignocaine with 100,000 adrenaline on the buccal side and 0.2 ml on the palatal side.

## 2.2. Onset of anesthesia

Immediately after injection of infiltration anesthesia till patient felt numbness. The time interval as the subjective onset of supra periosteal infiltration anesthesia was recorded using a stopwatch. The objective symptoms were recorded by probing the gingival sulcus with a dental probe. The pain was assessed using the visual analog scale (VAS) from 0 to 10, which was explained to each patient before starting the procedure. The time when the patient felt no pain, i.e. VAS score of 0 was recorded as the objective onset of anesthesia. Extraction was done even if the patient experienced pain but the pain score was less than 3 on VAS, but if the pain score was more than 3 on the VAS scale then an additional dose of 0.4 ml of the same drug was injected using the same technique on the buccal side, and 0.2 ml palatal side if needed. If the third time the patient experienced pain where the score was more than 3 on VAS, then that case was considered a failure. In such patients conventional LA, 2% lignocaine with 1:10,0000 adrenaline was administered as a nerve block for the completion of the procedure.

## 2.3. Duration of anesthesia

The time interval between the appearance and disappearance of numbness at the site of injection as reported by the patient was recorded as the duration of anesthesia. The patient was evaluated every 10 min to check the disappearance of anesthesia by pricking with a dental probe on the buccal soft tissue at the injection site. Then, the patient was made to wait in the department for up to 1-2 h for which written informed consent was obtained from all the patients. (Graph 1)

#### 2.4. Post-operative analgesia

No postoperative analgesics were prescribed to patients on the day of the extraction. They were called for follow-up after 24 h



Duration of anesthesia in minutes

Graph 1 Duration of anesthesia in Group A (Tramadol) and Group B (Lignocaine) in minutes.

and evaluated for the need for analgesics. All the patients received a self-assessment chart and were instructed to evaluate the pain experienced on VAS every hour for 24 h from the time of extraction. All the patients submitted the self-assessment chart during the follow-up visit.

# 2.5. Intraoperative pain

The pain experienced by the patient during extraction of the tooth was recorded using the VAS score from 0 to 10, as interpreted by the patient, where 0 indicates no pain and 10 means the worst pain. The scale was explained to the patient before the start of the procedure. (Graph 2)

The data obtained from the study were subjected to statistical analysis and compared using an independent sample *t*-test on IBM SPSS 21.0 version software.

#### 2.6. Post-injection complications.

In the current study, 3 patients in Group A developed nausea after injection which subsided later and we were able to complete the surgical procedure.

# 3. Results

The cohort of 200 selected patients comprised of 128 were females and 72 males. Group A consisted of 64 females and 36 males, while group B had 60 females and 40 males.

In group A, the mean subjective onset of action was 33.66 sec (range of  $33.66 \pm 5.204$  s, while as in group B, it was 33.46 sec (range of  $33.46 \pm 5.366$ ) s. Thus the onset of action did not differ significantly between the two groups (p = 0.881).



# Intra operative pain score on VAS

Graph 2 Intraoperative pain (VAS score) in Group A (Tramadol) and Group B (Lidocaine).

In group A, the mean objective onset of action was 3.04 (range of  $3.04 \pm 0.79$ ) min. while it was  $3.18 (3.18 \pm 0.70)$  min in group B. The highest onset of action was recorded in group A at 4 min 50 s (4.83 min), while the lowest was recorded in group B at 1 min 20 s (1.33 min). The statistical difference was not significant between the two groups (p = 0.05).

Furthermore, the mean intraoperative pain in groups A and B was was 0.4400 (range 0.4400  $\pm$  1.01338) and 0.2000 (range 0. 2000  $\pm$  0.45175), respectively and the statistical difference was significant between the two groups (p = 0.04). The mean duration of action in group A was 55.60 min, while in group B it was 57.50 min. The highest duration of action recorded was 90 min in group A, and the lowest was 45 min recorded in group B. The statistical difference was not significant (p = 0.432).

The mean duration of postoperative analgesia was 11.92 h in group A and 2 h in group B. The highest duration of analgesia recorded was 24 h in group A and the lowest was 2 h in group B. The statistical difference was significant between the two groups (p = 0.000).

## 4. Discussion

Opioids have been shown to have a local anesthetic effect as observed in both in vivo and in vitro studies. This property of opioids like fentanyl, sufentanil, tramadol, and others is well documented in the literature. Mert et al. suggested that tramadol has an LA effect with a different mechanism of action than that of lignocaine and, the presence of Ca + concentrations increases this activity of tramadol. The LA efficacy of tramadol was first reported by Pang et al in 1998. The study showed that tramadol produced a reduction in sensation to pinprick, touch, and cold when injected intradermally on the forearm. (Pang et al.,1998). In the current study, we found that tramadol has a LA effect similar to lidocaine, but it was relatively weaker, which was in agreement with the results found by Mert et al. in their study (Brau et al., 2000).

Tramadol as a LA for tooth extraction was first reported in Iraq in 2013. The frequency of adverse reactions to the local anesthetic agents in dentistry is unknown because of limited published data.

The incidence of adverse events depends on the mode of administration. If administered

Parenterally and rapidly, then tramadol has high initial plasma concentrations. The most common adverse effect of tramadol reported is nausea, followed by dizziness, drowsiness, sweating, vomiting, and postural hypotension (Cossman and Kohnen, 199)]. In another study tramadol (with adrenaline) induced nausea in 6.45% and vomiting in 1.61% of patients, while lignocaine (with adrenaline) induced nausea in 2.23% of patients with no incidence of vomiting. (Haideri YA., 201)]. In this study, only 3 patients developed nausea after receiving tramadol as infiltration anesthesia, but it subsided and the extraction procedure was completed.

Several studies have reported that tramadol has an LA effect but weaker than lignocaine. Due to the weak

anesthetic property of tramadol, a significant difference was detected in intraoperative pain between the two groups in our study.

In all previous studies, tramadol was used for labial or buccal infiltrations only while in the current study, we gave additional palatal infiltrations for more pain control and patient comfort.

## 5. Conclusion

5% tramadol has a local anesthetic property similar to 2% lignocaine with adrenaline, hence can be used as an alternative to lidocaine similar to antihistamines diphenhydramine, when the patient is allergic to lignocaine. We also concluded that using both buccal and palatal anesthesia exerts adequate pain control and provides patient comfort during extraction. However, it cannot be recommended as the first choice drug due to its weak anesthetic effect. Nonetheless, additional studies are required to assess the value of tramadol application in various dental procedures needing LA.

#### Consent

Consent was obtained from patients for extraction and publishing of data.

# Contribution

Ahtesham Ahmad Qureshi performed the extractions and wrote the manuscript.

Mohammed Mousa Bakri helped in the writing and final editing of the manuscript.

#### Ethical approval

All procedures performed in this study involving human participants were under institutional and national research committee and with the declaration.

All procedures were performed after taking Consent from patients for extraction and publication of data.

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