

## Study Protocol

Is Tramadol hydrochloride with adrenaline an alternative to lignocaine hydrochloride with adrenaline in dental implant surgery ?? – A randomized controlled clinical trial.

### **ABSTRACT**

#### **BACKGROUND-**

When used as infiltration anaesthesia, tramadol is known to provide a local anaesthetic effect.

#### **OBJECTIVES-**

The purpose of this study was to examine the anaesthetic potency of local infiltrations of 5% tramadol hydrochloride with adrenaline and 2% lignocaine hydrochloride with adrenaline in dental implant procedures. To assess tramadol postoperative analgesia's onset, duration, potency, and effectiveness as a local anaesthetic agent.

#### **METHODOLOGY-**

A split mouth study **will be** conducted in the Outpatient Department of Oral and Maxillofacial Surgery , of Sharad Pawar Dental College , Sawangi , district Wardha , Maharashtra. A total number of 80 patients (split-mouth) who needed dental implants **will be** chosen and divided into two groups of 40 people each. Patients **are** chosen at random, regardless of their gender, caste, or religion. A written consent **will be** obtained from all the patients.

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## EXPECTED RESULT-

The study **is** carried out to check potency of Tramadol hydrochloride with adrenaline to lignocaine hydrochloride in dental implant surgery , it **can have** similar efficacy and used as an alternative where lignocaine **is** contraindicated.

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## CONCLUSION-

Tramadol hydrochloride with adrenaline **may be** used as an alternative to lignocaine hydrochloride in selected cases, if the study proves.

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**Keywords-** Analgesia, Local Anesthetic, Lignocaine Hydrochloride, Tramadol Hydrochloride, Implant.

## 1. INTRODUCTION –

Pain serves as the inspiration for pioneering efforts by dentists to control pain as it has always been a barrier to dentistry. Pain is defined “an uncomfortable frame of mind that may have a physical basis in something that is being done to the body, or may be purely mental” in 1906 [1, 2] . Many people avoid dental clinics due the associated pain which leads to anxiety. The most commonly followed method for blocking pain during oral surgical procedures is done by using Local anesthesia[3]. Amide linkage for local anaesthetic with the formulation of lignocaine was introduced during second era which was developed by Nils Lofgren, the most widely used

cocaine derivative, during World War II in 1943 [4] . Due to the near ideal properties, it represents the gold standard drug , so all new local anaesthetics are compared to it [5, 6, 7].

Allergy to lignocaine is rare but if present then what will be the alternative? Is always a question.

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Drugs from other group or other drug from same group is advocated in literature, but in day to day practice other drug's availability is questionable. In the search of newer alternative local anesthetic agents, tramadol hydrochloride is one of them, which is available easily. Since Tramadol is synthetic opioid in aminocyclohexanol group, therefore is a centrally acting analgesic selective for  $\mu$  receptor. It is shown to have a local anaesthetic effect which is alike to lignocaine after intradermal injections. Opioids nerve conduction blocking effect have been demonstrated in both animal and clinical studies . In this study we will be evaluating its local anaesthetic efficacy in commonly performed dental implant procedures[8].

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## 2. AIMS AND OBJECTIVES –

To compare anesthetic potency of local infiltration of 5% tramadol hydrochloride with epinephrine and 2% lignocaine hydrochloride with epinephrine , in dental implant procedures. To evaluate onset, duration, potency and tramadol postoperative analgesia is examined as a local anesthetic agent.

## 3. DISCUSSION-

Shoeb Kasim Jendia , Abhishek Talathi [2018] [9] conducted study on total 50 patients requiring intraoral procedures, by locally infiltrating tramadol and lignocaine in canine region randomly. They found no statistically significant difference in terms of onset of anesthesia ( $p=0$ .

214) and duration of anaesthesia ( $p=0.549$ ) between the two groups. They conclude that local infiltration of Tramadol and lignocaine has a similar local anaesthetic effect.

**Dr. Madhumita Srivastava, Dr. Ravinder Singh bedi, Dr. Jitendra Aurora, Dr. Aaditya Sunil Markandey and Dr. Gaurav Vishal [2018]** [10] prospectively compared anesthetic efficacy of tramadol and lignocaine hydrochloride with adrenaline in simple exodontia. The study was conducted on 50 patients assessing onset of anaesthesia and pain. They suggested that wherever Lignocaine HCL is contraindicated Tramadol HCL with adrenaline can be used as alternative with added advantage of no reversal drug or post op analgesia needed.

**Shoeb Kasim Jendi, Ahmed M. Syed, Sheeraz Badal, Amol Doiphode, Sandesh S. Chougule, Sameer A. Shaikh, Ahmed Ahtesham [2019]** [11] performed a study over 100 patients to compare potency of tramadol with that of lignocaine as local anesthetic for exodontia in terms of their onset and duration of action, intraoperative and post-operative pain and adverse reactions. They conclude that 5% tramadol and 2% lignocaine has similar local anaesthetic efficacy but tramadol is comparatively weaker.

**Bilal Ege , Miray Ege , Mahmut Koparal , Hilal Alan [2019]**[12] study compared the anesthetic potency of tramadol hydrochloride and lignocaine in selected 32 patients who required bilaterally orthodontic maxillary first premolar extractions. There were no differences

noted between the solutions for the anesthetic onset, lignocaine was significantly more efficant statistically for total anesthesia duration . In terms of postoperative pain , it was found when tramadol was compared with it, the VAS scores with lignocaine were high. In general, the tramadol values was dramatically lower than lignocaine values. Which suggested that using tramadol along with epinephrine can be used as an alternative local anesthetic for maxillary first premolar tooth extractions during oral maxillofacial surgery.

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#### 4. MATERIAL AND METHODOLOGY –

A split mouth study will be conducted in the Outpatient Department of Oral and Maxillofacial Surgery , of Sharad Pawar Dental College , Sawangi , district Wardha , Maharashtra. A total number of 80 patients who needed dental implants will be selected. The subjects wil be classified in two groups . This will be a split mouth study with 40 sample size. Patients are selected randomly regardless of their gender, religion and caste. A written consent will be obtained from all the patients.

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Materials Used –

- Freshly prepared Injection of tramadol hydrochloride 5% and adrenaline (1: 80000) .
- Commercially available Injection of lignocaine hydrochloride 2% and adrenaline (1: 80000) .

Inclusion criteria-

- All the patients requiring rehabilitation with dental implants on both sides in same arch.
- All patients taken above 18 years of age.

Exclusion criteria-

- Patients with localized infections in that region.
- Smokers and patients with any systemic illness.
- Patients on long term steroid therapy.

All patients will be randomly distributed into two groups:

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1. Group A-Local infiltration of 5% tramadol hydrochloride and adrenaline (1: 80000) solution.
2. Group B – Local infiltration of lignocaine hydrochloride 2% and adrenaline (1: 80000) solution.

During implant surgery in patients who will receive tramadol infiltration , subjective and objective signs will be noted. If pain persist, the conventional method of anesthesia with lignocaine will be used in that case. The patient will be periodically questioned about pain and following the surgery all the patients will be asked to score pain experience during the procedure on 100mm VAS scale (Visual Analogue Scale) . The patients will be asked to assign scores for each parameter at intervals of 1hrs, 2hrs, 3hrs, 4hrs, 5hrs and 6hrs from the onset of anesthesia. Further any adverse effects will also be recorded. Blood pressure and heart rate will be recorded pre, intra and postoperatively.

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## **5. IMPLICATION-**

Lignocaine being a goldstandard drug is most commonly used as a local anesthesia during oral surgical procedures , however an alternative drug is required when lignocaine can not be used or is contra indicated . In such cases tramadol may be an effective pain allevating agent.

## **6. CONCLUSION-**

Tramadol hydrochloride with adrenaline may be used as an alternative to lignocaine hydrochloride in selected cases, if the study proves.

## **7. REFERENCES-**

1. Kotlow LA. Management of Pain & Anxiety in the Dental Office. New York State Dental Journal. 2003 Dec 1;69(10):52.
2. Stronczek MJ. Determining the appropriate oral surgery anesthesia modality, setting, and team. Oral and Maxillofacial Surgery Clinics. 2013 Aug 1;25(3):357-66.
3. Giovannitti JA, Rosenberg MB, Phero JC. Pharmacology of local anesthetics used in oral surgery. Oral and Maxillofacial Surgery Clinics. 2013 Aug 1;25(3):453-65.
4. Malamed SF. Handbook of local anesthesia. Elsevier Health Sciences; 2004 Jun 8.
5. Mansuri S, Bhayat A, Omar E, Jarab F, Ahmed MS. A randomized controlled trail comparing the efficacy of 0.5% centbucridine to 2% lignocaine as local anesthetics in dental extractions. International journal of dentistry. 2011;2011.
6. Altunkaya H, Ozer Y, Kargi E, Babuccu O. Comparison of local anaesthetic effects of tramadol with prilocaine for minor surgical procedures. British journal of anaesthesia. 2003 Mar 1;90(3):320-2.

7. Howe GL. The extraction of teeth. J. Wright; 1974.

8. Aurora D, Markandey AS, Vishal G. Comparison of local anesthetic efficacy of tramadol hydrochloride (with adrenaline) versus lignocaine hydrochloride (with adrenaline) in non-complicated tooth extractions. Group. 2018;50(28.678):0-30275.

9. Jendi SK, Talathi A. Tramadol hydrochloride: An alternative to conventional local anaesthetics for intraoral procedures-a preliminary study. Journal of oral biology and craniofacial research. 2019 Jan 1;9(1):111-4.

10. Aurora D, Markandey AS, Vishal G. Comparison of local anesthetic efficacy of tramadol hydrochloride (with adrenaline) versus lignocaine hydrochloride (with adrenaline) in non-complicated tooth extractions. Group. 2018;50(28.678):0-30275.

11. Jendi SK, Syed AM, Badal S, Doiphode A, Chougule SS, Shaikh SA, Ahtesham A. Comparison of Local Anaesthetic Efficacy of Tramadol Versus Lignocaine for Extraction of Tooth Under Supraperiosteal Infiltration. Journal of maxillofacial and oral surgery. 2019 Mar 8;18(1):100-5.

12. Ege B, Ege M, Koparal M, Alan H. Comparison of the Anesthetic Efficiency of Lidocaine and Tramadol Hydrochloride in Orthodontic Extractions: A Split-Mouth, Prospective, Randomized, Double-Blind Study. Journal of Oral and Maxillofacial Surgery. 2020 Jan 1;78(1):52-62.

13. Al-Haideri YA. Comparison of local anesthetic efficacy of tramadol hydrochloride (with adrenaline) versus plain tramadol hydrochloride in the extraction of upper molar teeth. Journal of Oral and Maxillofacial Surgery. 2013 Dec 1;71(12):20

35-8.