Comparison of local anesthetic efficacy of tramadol hydrochloride (with adrenaline) versus lignocaine hydrochloride (with adrenaline) in non-complicated tooth extractions

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Abstract
A Double-blinded study was done in patients, who required extraction of maxillary teeth bilaterally, by close method of extraction. Patients were allocated randomly into 2 groups: Group T, each patient received drug T (5% Tramadol HCl and adrenaline 1:80000); & Group L, each received drug L (2% Lidocaine HCL with adrenaline 1: 80000). Extraction was done under local infiltration anesthesia. For each patient intraoperatively degree of pain on injection, onset of anaesthesia, pin prick grading, local tissue reaction, total volume of anaesthetic required to produce satisfactory anaesthesia, VAS scale and non-invasive vital data monitor & postoperatively, duration of anaesthesia, need for first analgesic, rescue analgesia were recorded. Study findings suggested that Tramadol HCL can be used as alternative to Lidocaine HCL in combination with adrenaline to achieve local anesthesia in situation where Lidocaine HCL is contraindicated. Also no drug is needed reversal of local anaesthetic and no or negligible need of post op analgesia.

Keywords: tramadol hydrochloride, lignocaine hydrochloride, local anesthesia

Introduction
Pain has always been a barrier to dentistry, serving as the inspiration for pioneering efforts by dentists to control pain. Pain was defined in 1906 in The Devil’s Dictionary as “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” [1, 2]. Fear of pain is the main reason people avoid seeing the dentist, Oral surgery being one such speciality in dentistry. The use of local anesthesia is the most common method for blocking pain during oral surgical procedures. During second era amide linkage for local anaesthetic with the formulation of lidocaine which was developed by Nils Lofgren, the most widely used cocaine derivative, during World War II in 1943 [3, 4]. Due to the near ideal properties, it represents the gold standard drug, to which all new local anaesthetics are compared [5, 6, 7]. In the search of newer local anaesthetic agents, tramadol hydrochloride is one of them. Tramadol is a centrally acting analgesic and in this study we will be evaluating its local anaesthetic efficacy. Tramadol, a synthetic opioid in the amino cyclohexanol group, is a centrally acting analgesic selective for µ receptor. It is shown to have a local anaesthetic effect similar to lignocaine following intradermal injections. Nerve conduction blocking effects of opioids have been demonstrated in both clinical and animal studies [8].

Aim & Objectives
To compare anesthetic efficacy of local infiltration of 5% tramadol hydrochloride with adrenaline and 2% lidocaine hydrochloride with adrenaline, in non-complicated tooth extraction patients. To evaluate onset, duration, potency and postoperative analgesia of tramadol as a local anesthetic agent.

Materials & Methods
A split mouth study was conducted in the Emergency and Outpatient Department of Oral and Maxillofacial Surgery, of Saraswati Dental College. A total number of 50 patients who needed
bilateral extraction of maxillary teeth were selected as per the inclusion and exclusion criteria. The subjects were classified in two groups (quadrant wise). All patients were selected randomly irrespective of gender, caste, creed and religion. This study was initiated after obtaining approval from the ethical committee and detailed written informed consent of patients was procured.

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

**Method**
- Local infiltration of above mentioned solution, in Group T patients & commercially available lignocaine solution in Group L patients was done, and prescribed standard extraction protocol was followed. A non-surgical extraction was carried out under local infiltration anaesthesia in patients of both the groups. [Figure: 1]
- Evaluation criteria’s were pain on injection, onset of anaesthesia, pin prick grading, local tissue reaction (on mucosa), total volume of anaesthetic required to produce satisfactory anaesthesia, duration of anaesthesia in minutes, need for first analgesic, rescue analgesia, vital data monitor, systemic adverse reaction and a 10-cm visual analogue scale (VAS) was used to assess pain.

![Fig 1: Local infiltration (Supra periosteal injection)](image)

**Result & Observations**
Total 50 patients were randomly allocated to one of the two groups as follows:

<table>
<thead>
<tr>
<th>S. no</th>
<th>Variables</th>
<th>Groups</th>
<th>Standard deviation</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Pain on injection</td>
<td>Group T</td>
<td>0.512</td>
<td>0.509</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Group L</td>
<td>0.385</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Onset of anesthesia</td>
<td>Group T</td>
<td>0.725</td>
<td>0.195</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Group L</td>
<td>0.612</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Pin prick test</td>
<td>Group T</td>
<td>0.438</td>
<td>0.806</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Group L</td>
<td>0.37</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Total volume of anaesthetic used</td>
<td>Group T</td>
<td>0.37517</td>
<td>0.321</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Group L</td>
<td>0.30275</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Duration of anesthesia</td>
<td>Group L</td>
<td>28.678</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Group L</td>
<td>41.495</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Need for analgesic</td>
<td>Group T</td>
<td>269.531</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Group L</td>
<td>44.258</td>
<td></td>
</tr>
</tbody>
</table>

Pain on injection was scored as 0= no pain; 1= mild pain; 2= moderate pain; 3= severe pain. The pain on injection was higher with tramadol group, but was not statistically significant (p value 0.509). Onset of anesthesia volume of anesthetic used 82% of patients in both the groups had no pain while extraction procedure. 7 patients of Group T and 9 patients of Group L had mild pain. 2% patients of Group T had reading of moderate pain & worst pain on VAS scale which is statistically not significant.

Duration of anesthesia for both the groups was observed and minimum duration in both groups was 30 minutes, whereas maximum was higher for lignocaine group (210 minutes) than tramadol group (180 minutes). The mean duration of anesthesia in lignocaine group is higher 150.8 than the tramadol group. Independent student’s t test was – 8.804 with p value of less than 0.001 which was statistically significant. These values showed that lignocaine group patients experienced longer duration of anesthetic effect than tramadol group.

Out of 50 patients, 16 patients needed analgesic in Group T and 23 patients in Group L needed analgesic after extraction. Independent t test (3.7) shows the mean of time in minute required for analgesic to be taken was higher in Group T with 169.8 minute and that for Group L was 26.7 minute. Standard deviation was 269.531 & 44.258 for Group T and Group L respectively. P value of < 0.001 signifies that tramadol group patients needed less first analgesic dose than the lignocaine group patients and this difference is statistically significant. [Figure: 2]

Out of 50 patients in each group, only 1 patient in Group T needed rescue analgesia and that in Group L, more anesthetic agent was given to control pain in 5 patients. [Figure: 4]

Both systolic and diastolic blood pressures were within the physiologic limits throughout the non-surgical extraction procedure in both the groups. There was no statistically significant difference between the two groups.
Fig 2: Bar diagram depicting mean duration of anesthesia in each group

Fig 3: Bar diagram showing mean of first analgesic taken

Fig 4: Bar diagram showing systemic adverse reaction (Nausea)

Discussion
Exodontia or tooth extraction is defined as the painless removal of a whole tooth or tooth-root, with minimal trauma to the investing tissues, so that the wound heals uneventfully and no post-operative prosthetic problem is created [9]. Tramadol hydrochloride was critically pre-reviewed by WHO in 1992 and 2006 and inferred that tramadol has low level of abuse, even following the major increase in the extent of its therapeutic use [10, 11, 12]. Although few cases of fatal poisoning due to tramadol alone have been reported in the literature and also tramadol intoxication are similar to those of other opioid analgesics [13]. These include central nervous system (CNS) depression, including coma, nausea and vomiting, tachycardia, cardiovascular collapse, seizures, and respiratory depression up to respiratory arrest [14, 15]. Few cases of tramadol-related severe respiratory depression have been described in the literature because of overdosing. Intravenous naloxone has been successfully used to reverse the opioid effects of tramadol overdose [10]. Intra alveolar extraction is usually practiced to extract an erupted intact teeth or remnant of teeth, with the help of a forceps, elevators or both. It is also referred to as extraction by closed method [9]. In our study only maxillary teeth except third molar were extracted. Maximum number of teeth extracted was maxillary first. As the maxillary alveolar bone has thin cortical plates, a simple supraperiosteal infiltration of local anesthetic solution can produce adequate anesthesia for facilitating the extraction procedures. Few cases of tramadol-related severe respiratory depression have been described in the literature because of overdosing. Intravenous naloxone has been successfully used to reverse the opioid effects of tramadol overdose [10]. Intra alveolar extraction is usually practiced to extract an erupted intact teeth or remnant of teeth, with the help of a forceps, elevators or both. It is also referred to as extraction by closed method [9]. In our study only maxillary teeth except third molar were extracted. Maximum number of teeth extracted was maxillary first. As the maxillary alveolar bone has thin cortical plates, a simple supraperiosteal infiltration of local anesthetic solution can produce adequate anesthesia for facilitating the extraction procedures.

Similar kind of study was done by Yahya A.A. Al-Haider in 2013 were he extracted maxillary molars teeth by closed method and inferred that tramadol HCl with adrenaline (1:80,000) exhibits a local anaesthetic effect that enables the surgeon to perform painless extraction of upper molar teeth when infiltrated supraperiosteal [16]. Tahani A. Alsandook also studied anesthetic effect of tramadol by using it in form of nerve block for extraction of conventional and surgical teeth extraction [17].

While reviewing the literature we found that tramadol has been used for infiltration in many of the studies [18, 19, 20, 21, 22]. In our study we used tramadol hydrochloride as a local infiltration anesthesia with maximum doses of 100 mg. Immediately after injection (considered as time zero) to the time that the patient felt no pain on pinprick, this time interval was recorded to be the onset of anesthesia. The p value of 0.195 depicts that time for onset of anesthesia is more for tramadol, but it is not significant. Tahani A. Alsandook pilot study in 2013 found no significant difference between tramadol and lidocaine groups in onset of anesthesia (p value
Local anesthetic action
Our present study parameters show that tramadol hydrochloride 5% posse’s local anesthetic activity similar to 2% lignocaine hydrochloride.
Various researches have been done in various aspect of medical and dental field to evaluate the anesthetic property of tramadol hydrochloride, and studies have confirmed that tramadol exhibits local anesthetic property [16, 17]. In 2014 Kemal Varım Numanog˘lu et al. also used preincisional tramadol infiltration, in children undergoing inguinal hernia repair [22].

Conclusion
Use of anesthetic procedures as old as history of surgery itself and so is local anesthetics. Lignocaine remains the work horse of providing local anesthesia for surgical procedures in dentistry. However, several researches continue to strive, for alternative sources especially where lignocaine is contraindicated. Tramadol hydrochloride is a known analgesic agent in the field of medicine and surgery. Several studies have proven that tramadol hydrochloride also exerts local anesthetic property too.
Our study compare these two drugs on various aspect onset & duration of action, intra and post op complications, adverse effects, and we found that tramadol hydrochloride with adrenaline can, not only be used as an alternative to lignocaine hydrochloride in uncomplicated teeth extraction but also possess several advantages such as short duration of action, so no drug is needed reversal of local anesthetic reduced/or negligible need of post op analgesia.

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