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Comparison of local Anesthetic efficacy of tramadol hydrochloride (with adrenaline) versus lignocaine hydrochloride (with adrenaline) in simple dental extractions

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Abstract
Introduction: Tooth extraction is one of the most common procedures practiced by dentists in exodontia. The administration of local anesthetic is thereby invariably used for blocking pain associated with the dental extraction procedure. Study aimed at comparing the local anesthetic efficacy of tramadol hydrochloride (with adrenaline) and lignocaine hydrochloride (with adrenaline) in simple dental extractions was done.
Material and method: 50 healthy patients of both genders requiring bilateral extractions of teeth of either arch were selected as per the inclusion and exclusion criteria. The patients were selected randomly irrespective of gender, age, tooth condition and caste. Subjects were classified into two groups as follows: Group T-Patients who received local infiltration of tramadol hydrochloride 5% with adrenaline & Group L-Patients who received local infiltration of ligniocaine hydrochloride 2% with adrenaline.
Results: In the present study, parameters showed no significant difference between the anesthetic activity of tramadol hydrochloride5% & lignocaine hydrochloride 2%.
Conclusion: The administration of local anesthesia for dental procedures is as old as history of dental extractions itself. Use of lignocaine for local anesthesia remains the corner stone for performing dental procedures. However, incidence of lignocaine hypersensitivity reactions is not uncommon, thereby researches for a suitable alternative continues to strive. This study reveals tramadol hydrochloride as a suitable alternative to lignocaine hydrochloride in simple dental extractions.

Keywords: Comparison, with adrenaline, versus lignocaine, opoids, anesthetic

Introduction
The anesthetic effect of drugs like opoids has been established both *in vivo* and *in vitro* studies. Opoids including meperidine, fentanyl, tramadol and others have been documented in literature for their local anesthetic property. Tramadol in particular has been shown to have LA effect comparable to lignocaine for over two decades now [1, 5]. In addition to use in dentistry, it has been used as a sole anesthetic agent for procedures like circumcision, excision of soft tissue tomor & other minor surgeries. Tramadol a synthetic opoid in the amino cyclohexanol group, is a centrally acting analgesic selective for mu receptors & binds weakly to kappa and delta receptors [6, 8]. The use of tramadol for dental extractions was first carried out in the country of Iraq in 2013 [9]. However, not much studies were conducted for comparing its efficacy with lignocaine as a LA agent for dental extractions [10]. So, this study was designed to compare the local anesthetic efficacy of tramadol hydrochloride with lignocaine hydrochloride for simple dental extractions.

Aims and Objectives
To compare anesthetic efficacy of local infiltration of 5% tramadol hydrochloride with adrenaline and 2% lignocaine hydrochloride with adrenaline, in simple dental extractions under the following parameters-onset of anesthesia, duration of anesthesia, potency and post-operative effect as local anesthetic agent.

Material and Method

The present study was done in the Department of Oral & Maxillofacial Surgery, Govt. Dental College & Hospital, Srinagar after explaining the procedure to all the patients in their vernacular language & taking their written informed consent. A total of 50 healthy subjects between the age group of 17 and 40 years, both male and female who needed bilateral extraction in either arch were included in the study. Subjects including medically compromised individuals, pregnant females, lactating mothers & those allergic to the drug were excluded from the study. Intradermal drug allergy test was performed in all subjects by injecting 0.1ml of test dose on flexor aspect of right forearm with 1ml tuberculin syringe with short needle under all aseptic conditions prior to the procedure.

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

- **Group T:** received local infiltration of freshly prepared tramadol hydrochloride injection &
- **Group L:** received local infiltration of lignocaine hydrochloride injection followed by simple closed extraction with standard protocol.

  The selected parameters including pain on injection, onset of anesthesia, pin prick grading, total volume of drug required to produce desirable anesthesia, duration of anesthesia in minutes, rescue analgesia, vital data monitoring, systemic adverse reaction and a 10-cm visual analog scale (VAS) was used to assess pain.

Results

Pain on injection was scored as 0= no pain, 1=mild pain, 2= moderate pain, 3= severe pain. The pain on injection was higher in Group T (Tramadol group), but was not statistically significant (p value=0.495). Onset of anesthesia was almost same in both the groups. Total volume of anesthesia used was also allmost same in both groups with slightly more volume needed in tramadol group.

80% of patients in both the groups experienced no pain during the extraction procedure.8 patients of Group T and 9 patients of Group L experienced mild pain, 2 patients of both the groups experienced moderate pain and 2 patients of Group T and 1 patient of Group L experienced severe pain on VAS Scale which is statistically not significant.

Duration of anesthesia was noted for both the groups, minimum duration for Group T was 32 minutes & for Group L was 46 minutes, whereas maximum duration for Group T was 136 minutes and for Group L was 180 minutes. The mean duration of anesthesia for lignocaine group was higher than the tramadol group, however it was statistically insignificant with p value of < 0.001.

Out of 50 patients, 19 needed analgesic in Group T and 28 patients in Group L needed analgesic post operatively. The mean time in minutes required by the patient for taking analgesic was higher for Group T with the value of 174.6 minutes and that for Group L was 29.2 minutes. Standard deviation was 243.56 minutes & 52.30 minutes respectively for Group T and Group L. The p value for this parameter was<0.001 which implies that their was statistically significant difference between the two groups in terms of need for post-operative analgesia.

Out of 50 patients, 1 patient in both Group T & Group L needed rescue analgesia.

During the extraction period, both systolic and diastolic blood pressure was monitored & the values remained within physiologic limits throughout the procedure in both the groups. So no statistically significant difference was found.

Table 1: Variables Groups Standard deviation

S.no	Variables	Groups	Standard deviation	P value
1.	Pain on injection	Group T	0.423	0.495
		Group L	0.392	
2.	Onset of anesthesia	Group T	0.746	0.191
		Group L	0.608	
3.	Pin prick test	Group T	O.386	0.712
		Group L	0.320	
4.	Total volume of anesthetic used	Group T	0.321	0.301
		Group L	0.295	
5.	Duration of anesthesia	Group T	32.59	<0.001
		Group L	48.50	
6.	Need for analgesia	Group T	243.56	<0.001
		Group L	52.30	

Discussion

Tramadol is a centrally acting, synthetic, weak opoid analgesic that has a versatile mode of action.It was synthesised by Grunenthal GmbH, a pharmaceutical company of Germany in 1962 & has been available as a pain medication since 1977.Tramadol hydrochloride is a racemic (1:1) mixture of the (+) and (-)enantiomers. The mechanism of action of tramadol is related to linking of the two enantiomers on the serotonin & non adrenaline re uptake, and on the other hand the O-desmethyl metabolite of tramadol acts on the mu opioid receptor. The recommended dosage for tramadol is 50-100mg every 4-6h not to exceed 300-400mg/day & can be administered orally or parenterally. Elderly patients (>75years) & patients with renal or hepatic dysfunction may require dosage alterations. It is contraindicated in patients with diminished respiratory function. Tramadol is rapidly and almost completely absorbed after oral & intramuscular administration, rapidly distributed & is known to cross the blood brain barrier & has a vasodilating property [11, 12].

Tramadol has a strong analgesic property & has been used in dentistry for pain control since years now. It was critically pre-reviewed by WHO in 1992 and 2006 & inferred that tramadol has low level of abuse, even following an increase in the extent of its therapeutic use [13, 14]. The side effects of tramadol are same as for other opoids which include central nervous system (CNS) depression, including coma, nausea and vomiting, tachycardia, cardiovascular collapse, seizures and respiratory depression upto respiratory arrest. Few cases of tramadol-related severe respiratory depression have been described in the literature because of over-dosing. Intravenous naloxone is the antidote for tramadol poisoning [10]. Pang *et al.* was the first to report on the local anesthetic efficacy of tramadol when compared with lignocaine on the skin of forearm [23]. The studies of Al Haideri and Al Sandook examined the effect of tramadol with adrenaline in comparison with lignocaine containing adrenaline in minor oral surgical procedures & found tramadol with vasoconstrictor provided profound anesthesia similar to lignocaine containing vasoconstrictor [17]. Only one study compared the effect of tramadol with plain lignocaine in oral soft tissue & suggested that tramadol can be a good

alternative to lignocaine for oral surgical procedures.

In the present study, we evaluated & compared the efficacy of tramadol hydrochloride with lignocaine hydrochloride in terms of pain on injection, onset and, duration of anesthesia, allergic reactions and post-operative analgesic effect. True allergic reactions and systemic anaphylactoid reactions to opoids are rare. However local skin rash with intradermal tramadol injection was reported by Altunkaya *et al*. [23]. Study by Vahabi *et al*. reported no significant local skin reactions with sc tramadol. In the present study, no significant allergic reaction to either drug was reported [18]. Also, our study showed no statistically significant difference in the onset of anesthesia between the two groups. This was in accordance with the pilot study of Tahani A. Alsandook in 2013.

In the present study, time was recorded from immediately after injection (time zero) till the time when patient felt no pain on pin prick. The p value of 0. 712 reveals that the time for onset of anesthesia is more for tramadol but it is not statistically significant. This is in accordance with the pilot study of Tahani A Alsandook [17].

The volume of anesthetic used in both groups was assessed in our study & the mean of volume of anesthetic used in lignocaine group came out to be higher (1.8ml) than the tramadol group, with p value=0.301. So this study reveals that more volume of lignocaine is needed for adequate anesthesia as compared to tramadol, however the difference is not significant. Tahani A Alsandook in 2013 study showed no significant difference between the two groups in the volume of LA solution administerd to produce analgesia [17].

Vitals monitored during the extraction procedure (BP, Pulse) also revealed no significant change pre intra and post-operatively.

Conclusion

The present study depicts that tramadol hydrochloride with adrenaline has a local anesthetic effect similar to lignocaine hydrochloride when injected as infiltration in oral soft tissues. Thereby, it can be safely used as an alternative to conventional local anesthetic agents in minor oral surgical procedures.

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