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Comparison of tramadol with lignocaine as local anaesthesia for surgical removal of mandibular third molar: a prospective randomised controlled clinical trial

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Abstract

Purpose: To compare the anaesthetic efficacy of Tramadol Hydrochloride with adrenaline and Lignocaine Hydrochloride with adrenaline in inferior alveolar nerve block for surgical removal of impacted mandibular third molars.

Patients & Methods: A prospective randomised clinical controlled study was performed in the patients who required surgical removal of impacted mandibular third molar. 40 patients of ASA category I or II were allotted randomly into 2 groups of 20 patients each and following parameters were recorded. 1. Onset of anaesthesia, 2. Duration of action, 3. Allergic reaction, 4. Need for post-operative analgesia, 5. Adverse reaction, 6. Amount of local anaesthesia administered, 7.Duration of surgery, 8.Visual Analogue scale. In Group A,(n=20) each patient received initial dose 2.1 ml, from drug A(100mg) of Tramadol HCL with adrenaline (1:200,000) whereas in Group B (n=20) each patient received dose of 2.5 ml, from drug B (62mg of Lignocaine HCL with adrenaline (1:80,000).

Results: No statistically significant difference present between two study groups in Onset of anaesthesia, duration of surgery, visual analogue scale and amount of local anaesthesia, but statistically significant difference is present in duration of action and need for post-operative analgesia proving tramadol as superior, whereas no cases reported having adverse drug reaction or allergic reaction.

Conclusion: Tramadol HCl with adrenaline can be used as an alternative to Lignocaine HCl with adrenaline in cases where Lignocaine HCl is contraindicated or when adequate local anaesthesia with lesser duration of anaesthetic action is required.

Keywords: Adrenaline, Anaesthesia, Analgesia, Lignocaine Hydrochloride, Local Anaesthesia, Lignocaine, Tramadol, Tramadol vs Lignocaine, Tramadol Hydrochloride, Tramadol HCl.

Introduction

Compression was the first method of local anesthesia used in the antiquity.[1] Cold was widely used as local anesthesia until 17th Century. Cocaine was the first drug used as local anesthetic agent around end of 18th Century by Carl Koller

and Halstaed, unfortunately the serious side effects of this drug made the researchers to find safe drugs. Eventually, a safe local anaesthetic agent was introduced in 1948 by Neils Lofgren – Lidocaine, the most commonly used local anaesthetic till date. However, because no drug is currently devoid of potential toxicity the search for new better local anaesthetics continued.[2] Tramadol was synthesized in 1962 by Grunenthal GmbH in Germany and was made available to use for pain management in Germany since 1977. It was registered in UK in 1994 while in USA in 1995.[3] In 2003, Altunkaya et al proved that tramadol HCL can be used as local anesthesia in minor soft tissue procedures.

Toothache is the commonest chief complaint of the patients visiting dental clinics. Surgical removal of wisdom tooth is one of the commonly performed procedure in routine dental practice. Perhaps, pain relief is the most important objective for such patients. Similarly, patient prefers the reduced amount of analgesic intake post operatively i.e. it is ideal if the anesthesia used have a powerful analgesic activity and relatively for a long period. Therefore, if, Tramadol HCL possesses local anesthetic action equivalent to that of Lidocaine, it will be more superior than lidocaine as it will provide postoperative analgesia. So, in the present study we have compared the anaesthetic efficacy of Tramadol Hydrochloride with adrenaline and Lignocaine Hydrochloride with adrenaline in inferior alveolar nerve block in patients requiring surgical removal of impacted mandibular third molars.

Patients and Methods

A randomized, double blinded clinical comparative study was performed in oral and maxillofacial surgery department, NPDCH, SPU, Visnagar from September 2019 to January 2020. The study was approved by institutional ethics committee according to the guidelines of Sankalchand Patel University. Purpose of study was informed to all the participants with prior written informed consent. Irrespective of gender, 20-50 years age group was selected.

Inclusion Criteria

1. Patients requiring surgical removal of impacted lower third molars.
2. Patients who are physically able to tolerate surgical procedures.
3. Patients with an excellent to good control of their systemic conditions.
4. Patients who agree to give signed informed consent prior to the procedure.

Exclusion Criteria

1. Pregnant and lactating females, smokers, medically compromised individuals (ASA III-V)
2. Treatment with therapeutic radiation to head & neck within 12 months.
3. Patient not ready for signing the informed consent.

Ethical Approval: Taken

In **Group A** (n=20) each patient received 2.1 ml of (Drug A i.e.) Tramadol HCL (100mg) with 0.005mg (1:2,00,000) adrenalin.

In **Group B** (n=20) each patient received 2.5 ml Lidocaine HCL (61.6mg) with adrenalin (1:80,000).

Drug A- (100mg) 2ml ampoule **CONTRAMOL™** - with 20 times diluted 1:1000 Adrenaline solution in (19ml) distilled water and adding 0.1 ml (i.e. 4 units of 40 BD=1ml insulin syringe) of diluted adrenaline for the preparation of solution upto 2.1 ml.

Drug B- LIGNOTER™ 30ml vial – 24.64mg/ml Lignocaine 0.0125mg Adrenaline. (LUSTRE PHARMA)

Single investigator performed surgical procedures in both groups. Inferior alveolar nerve block was administered by sterile disposable 26 gauge, 38 mm long leur lock single use disposable dental syringe.

The Parameters and Metrics

After administration of inferior alveolar nerve block the following data was obtained. **Intra-operatively –** Onset of anaesthesia, Allergic Reaction, Amount of Local Anaesthesia Administered, VAS, Duration of surgery and **Post-operatively** - Need for postoperative analgesia, Duration of Anaesthesia, and adverse reaction. Patients were reviewed after 24 hours and information about the duration of anesthesia.

Intra-Operative Study Parameters

Onset of Anaesthesia (in seconds): The time elapsed immediately after injection to the time that patient felt paraesthesia on his/her lower ipsilateral lip, is recorded to be the onset of inferior alveolar nerve block anesthesia. It was recorded in minutes and seconds, but for statistical evaluation the numerical data is converted into seconds.

Measuring of pain intensity by Visual Analogue Scale (VAS 0-10 point scale): The incision and raising of flap was performed after patient feel numbness and is negative of objective as well as subjective symptoms for pain in the area to be operated. Patient was instructed to inform the operating surgeon by raising left hand during operation if pain or discomfort was felt. The degree of pain was evaluated with a 10cm visual analog scale (VAS). Prior to surgery, the operator explained VAS to the subjects, ranging from zero, representing no pain or discomfort to 10, representing maximum pain. The mean of the VAS scores during the operation was calculated and recorded by dental chair side assistant. During the surgery, when the VAS exceeded 3 points, additional half dose 1.25 ml of the same drug in group A and (1.05ml) of the same drug in (group B) was injected into the surgical site, and the amount of local anaesthesia was recorded.

Allergic Reaction (Yes/No): Any allergic reaction following the administration of Drug A and Drug B was recorded in terms of variables Yes or No.

Amount of Local Anaesthesia Administered (in ml): In group A, each patient received 2.1 ml of Drug A. In group B each patient received 2.5 ml of Drug B. Additional half the initial dose was administered in both groups whenever VAS shifted 3cm towards right.

Duration of the surgery (in minutes): The duration recorded (in minutes) represented the time interval from the incision/or gingival separation to the placement of last suture.

Post-Operative Study Parameters

Duration of anesthesia (in minutes): Immediately, postoperatively the time interval between the appearance of lip paraesthesia and its disappearance, as reported by the patient was recorded in minutes.

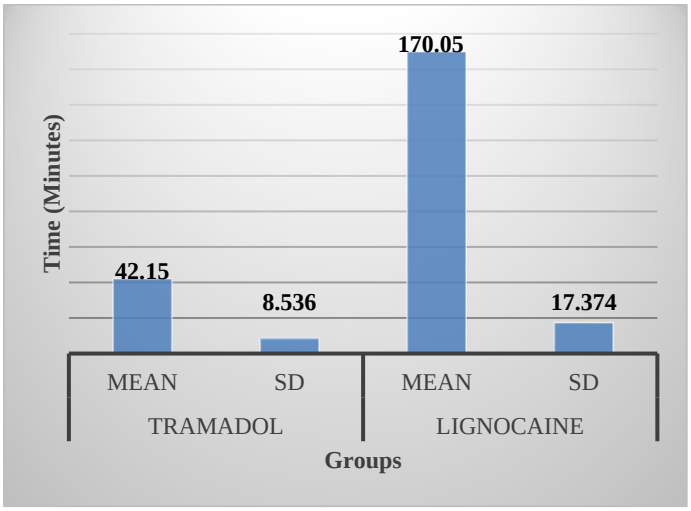
Need for Post- Operative Analgesia (in hours): The patients were instructed to record exactly when the paraesthesia disappear and after what time there was need of post-operative analgesia. This time duration was noted (in minutes) immediate post-operatively and any adverse effects such as nausea and/or vomiting on the day of operation.

Adverse Reaction (Yes/No): The patients were to reply whether they develop or experience any adverse drug reaction following the administration of Drug A and Drug B in terms of variables Yes or No. And if yes, they needed to specify the adverse reaction in terms of nausea, vomiting. Vomiting was treated with oral Tab. Ondanseteron-MD (8mg).

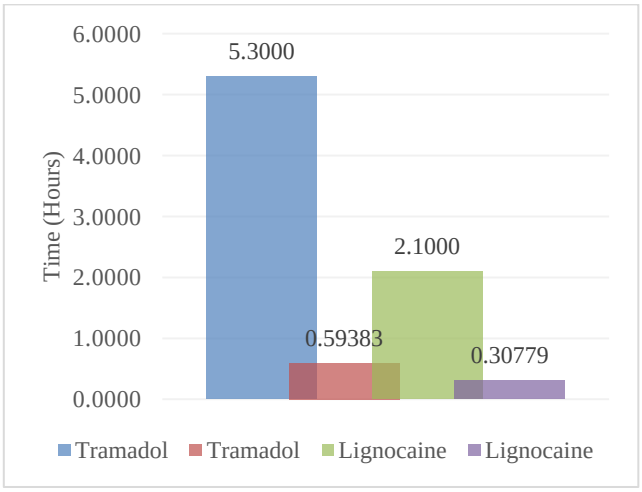
Results

The SPSS Software version 23 to analyse the obtained data. Independent-Samples T-Test was used to compare parametric variables (Amount of Local Anaesthesia administered, degree of pain, duration of surgery, duration of anesthesia). The level of significance was set at ≤ 0.05. In the present study, there was statistically significant difference found amongst both the groups resulting in the

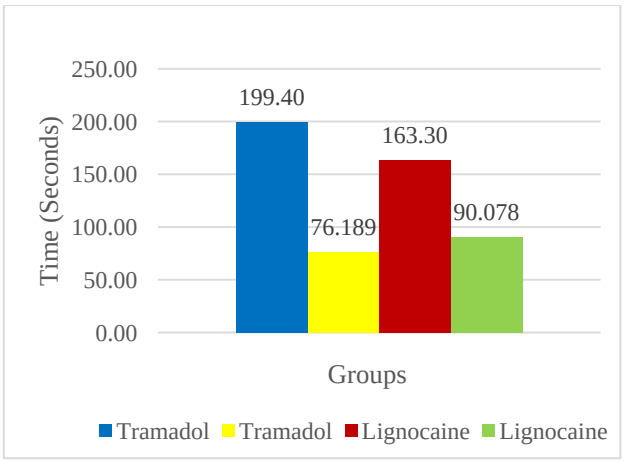
increased anaesthetic efficacy of lignocaine HCl in terms of duration of anaesthesia (170 ± 17 min) as compared to Tramadol (42 ± 8 min) (Graph 1), but, on the other hand there is also statistically significant difference present amongst the both groups in which, the Tramadol HCl when combined with Adrenaline in freshly prepared solution proved itself to be superior to Lignocaine HCl group in terms of delayed need for post-operative analgesia where Group A had (5.3 ± 0.5 hours) when compared to Group B (2.1 ± 0.3 hours) and shorter duration of anaesthetic action (Graph 2) which can prove better in minor oral surgical procedures, such as surgical removal of impacted tooth. There was no statistically significant difference present Onset of Anaesthesia (Graph 3), VAS (Graph 4), Amount of LA administered and duration of Surgery (Table 1). And no cases reported having any adverse drug reaction and allergy.



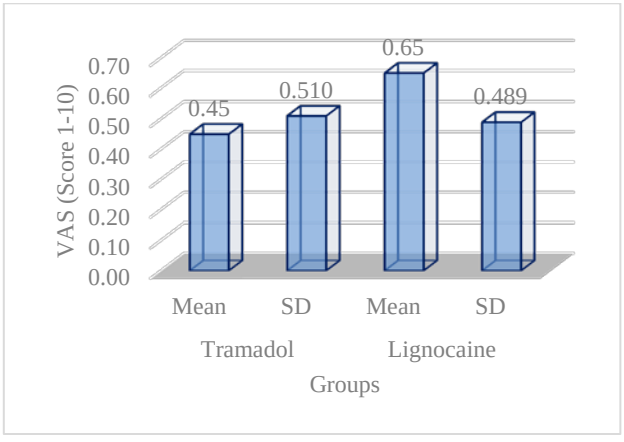
Graph 1: Comparison of Duration of Anaesthesia. (p=0.007). Duration of Anaesthesia is significantly less in Tramadol Group as compared to that of Lignocaine group.



Graph 2: Comparison of Need for Post-operative Analgesia (p=0.008). Statistically significant difference present with tramadol group.



Graph 3: Comparison of Onset of Anaesthesia in seconds. (p=0.179) Not significant.



Graph 4: Comparison of pain by Visual Analogue Scale. (p=0.213) Not significant.

Parameter	Group*	N	Mean	SD	Std. Error Mean	p value	Inference
Onset of Anesthesia	A	20	199.40	76.189	17.036	**0.179**	Not significant
	B	20	163.30	90.078	20.142		
Duration of Action	A	20	42.15	8.536	1.909	**0.007**	**Significant**
	B	20	170.05	17.374	3.885		
Need for Post-Op Analgesia	A	20	5.3000	0.59383	0.13278	**0.008**	**Significant**
	B	20	2.1000	0.30779	0.06882		
Amount of LA administered	A	20	2.1525	0.234	0.05250	**0.309**	Not Significant
	B	20	2.6800	0.439	0.09830		
Duration of Surgery	A	20	25.95	6.312	1.411	**0.122**	Not significant
	B	20	28.85	5.264	1.177		
VAS	A	20	0.45	0.510	0.114	**0.213**	Not significant
	B	20	0.65	0.489	0.109		

***Group A**-Tramadol **Group B** – Lignocaine.

Table 1: The Study Description of Onset of Anesthesia, Duration of Action, need for post-operative analgesia, amount of (LA) local anesthesia administered, duration of surgery and Visual Analog Scale (VAS). Adverse drug reaction and allergic reaction are excluded from study table as none of the subjects experienced such events intra-operatively and postoperatively.

Discussion

Anxiety prevents people from undergoing dental treatment. Therefore, it becomes necessary to relieve the anxiety during dental treatment by using a strong anesthetic in combination with agents that can have analgesic effects. [4]

Tramadol is a synthetic codeine analogue that is a centrally acting weak μ-opioid receptor agonist. Part of its analgesic effect is produced by inhibition of uptake of noradrenaline and serotonin. In the treatment of mild-to-moderate pain, tramadol is as effective as morphine and meperidine. But less effective for chronic & severe pain. [5] Tramadol is an interesting drug having opioid and non-opioid action mechanisms and is bidirectionally effective.[4] Its affinity for the μ-opioid receptor is only 1/6000 that of morphine. The primary O-demethylated metabolite of tramadol is 2-4 times more potent than the parent drug and may account for part of the analgesic effect. Tramadol is supplied as a racemic mixture that is more effective than either enantiomer alone.[5] The (+)-enantiomer inhibits serotonin uptake whereas (–)-enantiomer inhibits noradrenaline uptake and stimulates α2 adrenergic receptors. Tramadol undergoes hepatic metabolism by a number of pathways, including CYPs2D6 and CYPs3A4, and by conjugation with subsequent renal excretion. The elimination t1/2 is 6 h for tramadol and 7.5 h for its active metabolite. Analgesia begins within an hour of oral dosing and peaks within 2–3 h. The duration of analgesia is about 6 h. The maximum recommended daily dose is 400 mg (300 mg in patients >75 years old and for extended-release formulations; 200mg is given for patients with low creatinine clearance). The pKa value for lignocaine is 7.9, while for tramadol it is 9.41.[6,7] Side effects of tramadol include nausea, vomiting, dizziness, dry mouth, sedation, and headache[5], of which the former two are commonly observed as well as

the risk of respiratory depression at the mentioned dose is minimal and does not suppress the hypoxic respiratory response. Few cases of fatal poisoning due to tramadol alone have been reported in the literature.[8] Tramadol is partially antagonized by naloxone. No significant effects on cardiovascular functions or respiration have been reported. [9] Moreover the risk of developing resistance is rather low compared with other analgesics. Anaesthetic effect of tramadol may be due to the non-specific binding to membrane proteins or non-specific membrane effects. [10] Tramadol has been used as local infiltration in many animal as well as in vitro studies.[4,10,11,12,13,14,15,20] Tramadol HCl 5% has a local anesthetic effect similar to that of prilocaine 2% when used intra-dermally for excision of soft tissue lesions.[16,17] When compared with lignocaine, tramadol can be used in local anaesthesia and has ability to decrease the demand of post-operative analgesics. [18] Other studies show that tramadol HCl has a local anesthetic activity similar to, but weaker than that of Lidocaine HCl and an increase in the pH increased the conduction blocking potency of tramadol. [19]

The objective of the current study was to compare the anaesthetic efficacy in various parameters of tramadol HCl (with adrenaline) and Lignocaine HCl (with adrenaline) in inferior alveolar nerve block for surgical removal of impacted mandibular third molars. The current study was correlated with many studies in which tramadol HCl has local anesthetic effect, but it should be noted that the present study involved soft tissue incision as well as a significant amount of bone removal while other studies involved only soft tissue surgery and thus this makes it a pioneer study involving the surgical removal of impacted mandibular third molars.

Similar results were obtained subcutaneous tramadol injection for excision of skin lesions and provided benefit of prolonged post-operative analgesic effect, thereby reducing the analgesic requirement. [20] An accidental finding was noted during the study when the amount of adrenaline was increased to double by mistake which showed a considerable increase in the duration of anaesthesia. However, that case was excluded from the study, but this opens up a new area of research by varying the amount of adrenaline within safe dosage by freshly prepared tramadol HCl and check for increase in the duration of anaesthesia.

Conclusion

Tramadol HCl can be used as alternative to lignocaine HCl in combination with adrenaline to achieve local anesthesia in cases where lignocaine HCl is contraindicated (for e.g. allergy to LA) or when adequate local anesthesia with lesser duration of anaesthesia is to be achieved. Further well designed clinical comparative studies are needed with Tramadol in nerve blocks, as this is less researched. Also the amount of adrenaline can be varied within pharmacological dosages and checked for the change in the duration of action of the tramadol HCl when freshly prepared with adrenaline.

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