

Topical Amitriptyline Versus Lidocaine as a Newer Anaesthetic Agent: A Clinical Study

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ABSTRACT

Background: Oral amitriptyline, a tricyclic antidepressant, is effective for treating pain. We conducted a double-blind, randomized, placebo-controlled crossover study to evaluate the efficacy of topical 5% amitriptyline and 5% lidocaine in treating patients with neuropathic pain. In pairwise comparison of treatments, topical lidocaine and placebo each reduced pain more than topical amitriptyline ($P < 0.05$). This randomized, placebo-controlled crossover study examining topical 5% amitriptyline and 5% lidocaine in the treatment of neuropathic pain showed that topical lidocaine reduced pain intensity but the clinical improvement is minimal and that topical 5% amitriptyline was not effective.

Keywords: Amitriptyline, lidocaine, local anaesthesia.

INTRODUCTION

Pain is the cynosure of all basic & clinical sciences. Local anesthetic injections are used to alleviate pain & reduce anxiety in dentistry, they themselves are a source of pain & anxiety for many patients.¹ Topical anaesthetics are used to diminish the pain of needle prick before local anaesthetic injection. Lidocaine is used widely as a topical anesthetic agent in many forms. However, some patients still experience moderate to severe discomfort after their use.¹ Recently Amitriptyline is found to be useful as a topical anesthetic agent. This paper presentation is based on clinical study of amitriptyline in gel form compared to lidocaine in gel form as a topical anesthetic agent. This study is aimed to compare the anesthetic efficacy of amitriptyline as an intraoral topical anaesthetic agent compared to lidocaine in gel form.

MATERIALS AND METHODS

This study was performed as a randomized, double blind, split mouth clinical trial. This study

was carried out in the department of Oral & Maxillofacial Surgery, which was consisted of 30 healthy volunteers who agree to participate, aged between 20 to 40 years. The voluntary participants are explained about the study, instructed how to report their pain and informed written consent obtained.

Inclusion criteria

The volunteers without any systemic diseases (eg. Cardiovascular, liver diseases)

Exclusion criteria

Individuals who are taking medications for any diseases

Individuals with history of neurologic problems

Individuals who are allergic to tricyclic antidepressant drugs & lidocaine

PROCEDURE

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Amitriptyline powder was obtained and 2% Amitriptyline gel prepared in pharmacy college. 2% Amitriptyline gel & 2% lidocaine gel was placed in sterilized container & coded. This was a double-blind clinical trial, neither the evaluator nor the volunteer are aware of the formulation of both the gels. The amitriptyline 2% in gel form was applied randomly to mucogingival junction of lower canine region on one side and lidocaine 2% in gel form on the other side. The application site was first cleaned with a sterile cotton roll, and then gel was placed on both the sites.

The onset and duration of action of the drug was assessed by: subjective feeling of numbness and use of pressure by blunt probe at 5, 10, 15, 20, 25, 30, 35 & 40 minutes after the application. A 26-gauge needle was inserted at 10 & 15 minutes after topical application of gel at mucogingival junction to touch the alveolar periosteum on both sides to assess the efficacy of the drug. The pain intensity produced by needle insertion & blunt probe was recorded using a visual analogue scale (VAS) & pain rating score methods. In visual analogue scale (VAS), pain was measured with endpoints marked 0 (no pain) and 10 (unbearable pain). In the pain rating score, the pain is graded by the participant as no pain (0), slight pain (1), moderate pain (2), or severe pain (3). Participants pointed a number on the ruler according to the pain they experienced at insertion.

RESULTS

A total 30 healthy volunteers were included in the present study. There were 21 male and 9 female volunteers. Onset of subjective feeling of numbness in lidocaine was earlier than amitriptyline and feeling of numbness in amitriptyline continues till the end of the time tested, whereas there is recovery of sensation in lidocaine noted at 20 minutes onwards (Chart 1).

This chart shows Objective analysis of onset & duration of both the drugs on VAS. It is noted that VAS was higher in amitriptyline at initial time whereas, lidocaine score was lower. Between 10 to 15 minutes VAS of both drugs was similar. However, VAS continues to be lower for amitriptyline as compared to lidocaine till the end.

Table 1: VAS of amitriptyline and lidocaine by blunt probe.

Time (min) treatment	5	10	15	20	25	30	35	40
Amitriptyline	2.7 (0.0 95)	1.63 (0.64 0)	1.05 (0.7 1)	1 (0.7 3)	1.2 (1.0 3)	1.21 (1.3 1)	1.45 (1.3 2)	1.5 \ (1.53)
Lidocaine	1.39 (1.0 6)	1.21 (1.09)	1.2 (1.1 5)	1.35 (1.0 4)	1.76 (1.0 4)	2.04 (0.7 9)	2.62 (1.0 6)	2.56 6 (1.29)
P - Value Mann Whitney test	0.75	0.72	0.89	0.62	0.68	0.56	0.52	0.32

The interaction between time & expressed level of pain on Visual analogue scale shows the statistically significant results. From the above tables we can see that the standard deviation of lidocaine is constantly increasing from the p value compare to amitriptyline. So, we can say that anaesthetic effect of amitriptyline compare to lidocaine shows statistically significant results. No any complications like redness or ulceration was noted in any volunteers.

DISCUSSION

The present study was performed in an attempt to study the anesthetic properties of 2% Amitriptyline gel compared to lidocaine in healthy volunteers. Amitriptyline belongs to the family of Tricyclic antidepressants (TCAs). Tricyclic antidepressants (TCAs) have been used as adjuvant drugs in chronic pain management for more than 40 years.¹ The analgesic effect of TCAs seems unrelated to their antidepressant action, because the doses used for analgesia are lower than those considered effective in the treatment of depression.^{5,6} Antidepressants, particularly TCAs such as amitriptyline, diminish pain and induce local anesthesia. Different studies have reported the analgesic and anesthetic properties of amitriptyline.⁷

Amitriptyline also blocks the sodium channels and, therefore, acts as a local anesthetic. The onset & duration of amitriptyline on the basis of subjective feeling of numbness shows that after application of amitriptyline gel all patients expressed complete numbness that started at 10 to 15 minutes & lasted for 35 to 40 minutes compared to lidocaine was longer. Whereas, lidocaine numbness started before 5 minutes and lasted for 20 minutes. Other study which was carried out on amitriptyline gel as

adjunct to local anesthetics in irreversible pulpitis pain, showed that anesthetic effect was seen at 9 minutes.³

The onset & duration of both the gels by Probing method assessed by visual analogue scale & pain rating methods shows that onset of lidocaine noted earlier that is between 5 to 10 minutes than amitriptyline which was between 10 to 15 minutes (chart 2). The duration of the anesthetic effect for amitriptyline continues for more than 40 minutes whereas for lidocaine anesthetic recovery noted after 15 minutes (chart 2). The results also show that amitriptyline gives better pain control over the designated site compare to lidocaine. No studies have been reported for assessment of anesthetic onset, duration & efficacy by amitriptyline gel.

Mesurement of control of pain intensity with 26 gauge needle insertion shows that amitriptyline gel shows better topical anesthetic efficacy over the needle insertion technique compare to lidocaine. One study was carried out on clinical anesthetic effectiveness of intraoral mucoadhesive tablets of amitriptyline and their results proved that mucoadhesive tablets of amitriptyline to be a promising anesthetic device for manipulating pain in dental procedure.¹ We have carried out this study by preparing the drug in the gel form and compared it with lidocaine gel. Gel formulation can be applied easily and stick to the mucosal area for longer period.

Our study results showed a significantly better pain control by amitriptyline gel than lidocaine gel in anesthetizing the oral mucosa of desired site. The current study is the first study to assess onset, duration and efficacy by subjective and objective analysis. The results of the current study can be useful for head & neck surgeons & anaesthesiologist applications. Further studies can be carried out with drug in other forms.

CONCLUSION

To conclude, Amitriptyline has delayed onset of action but longer duration of action than lidocaine in gel form.

CONFLICTS OF INTEREST

The authors declare they have no potential conflict of interests regarding this article.

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