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Anaesthetic Efficacy of Topical Emla Cream Combined With Hyaluronidase For Supplemental Intrapulpal Injection In Teeth With Irreversible Pulpitis – A Double Blinded Clinical Trial.

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Abstract

Introduction: Intrapulpal injection technique is one of the most common supplemental techniques used to achieve profound pulpal anesthesia during endodontic treatment. Determination of topical anesthetic application (EMLA-Eutectic Mixture of Local Anesthetics) along with hyaluronidase reduces the pain encountered during the administration of intrapulpal injection in teeth with irreversible pulpitis.

Methods: In this in vivo study, 96 patients were randomly assigned to two groups (n = 48). In the control group a saline soaked cotton pellet was placed in the pulp chamber for 2 minutes as placebo, followed by intrapulpal injection with backpressure. In the treatment group, topical application of EMLA cream mixed with hyaluronidase was placed followed by intrapulpal injection. The mean pain value was calculated from the data obtained from each group in mm and standard deviation was computed and analysed by student-t-test at a significance level of 0.05.

Results: A significant reduction in pain perception was seen in the treatment group where the pain of injection was reduced when topical EMLA cream + hyaluronidase was used. Conclusion: Topical application of EMLA cream mixed with hyaluronidase when applied to the exposed pulp before administering intrapulpal injections made them less painful.

Keywords : Intrapulpal Injection, Irreversible Pulpitis, EMLA Cream , Hyaluronidase.

Introduction

A painless endodontic therapy is made possible with the help of local anaesthesia. The inferior alveolar nerve (IAN) block with 2% lidocaine is the frequently employed injection technique for achieving local anaesthesia for mandibular teeth in endodontics [1].

However achieving adequate anesthesia in patients can, at times, be a challenge. But when one adds the condition of a ‘‘hot’’ tooth, the challenges increase [2].

Clinically this problem is overcome with the help of one of the supplemental anaesthetic techniques like intrapulpal, intraosseous and intra ligamentary injections.

Profound anesthesia is required to access the chamber and extirpate the pulp. If patient discomfort is encountered, the intrapulpal injection may be used as a supplement for pulpal anesthesia. The most important factor in the success of intrapulpal technique is that the administration must be done underpressure[3].

Birchfield and Rosenburg suggested that the anaesthetic effect of the intrapulpal technique is due to the back-pressure of the solution and is not dependent on the type of solution injected [4]. According to Malamed SF the main drawback with this technique is that the intrapulpal injection by itself can be highly painful [5].

Hyaluronidase is an enzyme commonly used in ophthalmological procedures. This acts by hydrolysis of hyaluronic acid, a normal component of connective tissue and hence enhances the diffusivity of drugs injected along with it [6]. In this study application of a topical anaesthetic and hyaluronidase combination into the pulp chamber was assessed, which could reduce the pain of the intrapulpal injection.

Hence the aim of this study was to evaluate if the topical application of EMLA cream mixed with hyaluronidase to the pulp chamber before administration of intrapulpal injection can reduce the pain encountered with the injection technique itself.

Materials and Methods

Prior to treatment, a detailed case history including patient's demographic details, medical history and dental history was recorded. Patients were screened by means of thorough clinical evaluation done by visual and tactile examination, palpation, percussion, mobility, periodontal examination and pulp sensibility tests.

Informed consent was be obtained from all the patients. 96 Subjects diagnosed with irreversible pulpitis in mandibular molars in which profound pulpal anaesthesia could not be achieved with primary inferior alveolar nerve block were selected for the study.

Lack of profound pulpal anaesthesia was determined to be the situation if the patient experienced pain during chamber access when they had been comfortable with the treatment up to that point. Patients were selected in a random manner to receive one or the other of the two techniques. There were 48 patients in each group.

Inclusion criteria was as follows

- Patients undergoing treatment for mandibular molars diagnosed as irreversible pulpitis based on history and subjective symptoms like spontaneous, nocturnal pain and lingering response to cold testing.
- Only healthy adults with no medical problems (by oral questioning)
- Age group 18 to 50 years

Exclusion criteria was

- Patients who were diagnosed as irreversible pulpitis but who took analgesics in the past 5 days.
- Patients having systemic diseases, allergies or adverse medical conditions.

From the selected patients, teeth in which profound pulpal anaesthesia could not be achieved with primary inferior alveolar nerve block were selected for the study.

Group 1 (Control Group): Intrapulpal injection of 2% lignocaine (1: 80000 adrenaline) ,a saline soaked cotton pellet was placed in the pulp chamber for 2 minutes as placebo, followed by intrapulpal injection with backpressure. In teeth were back pressure could not be achieved a cotton pellet (stoppering technique) was used to achieve backpressure. A standard anaesthetic syringe with 27-gauge needle was used to inject 0.5 ml of the solution within 5 seconds.

Group 2 (Experimental Group): Topical application of EMLA gel mixed with hyaluronidase (1g with 300IU/ml

sterile water) followed by intrapulpal injection of 2% lignocaine (1:80000 adrenaline).

Hyaluronidase pellet in the vial was dissolved with 5ml of distilled water provided by the manufacturer. Now 1ml from this solution was taken and dispensed into a dappen dish with 50 mg EMLA cream measured with a custom made plastic scoop. An applicator tip was used to mix them. With the help of applicator tip EMLA cream mixed with hyaluronidase was placed over the exposed pulp for 2 minutes. Following this, intrapulpal injection of 2% lignocaine (1:80000 adrenaline) was administered with backpressure .

This study was double blinded in that neither the patient nor the person who did the pain assessment was aware of which technique was used.

Each patient rated his or her pain sensation during the injection procedure on a VAS numeric Pain Distress Scale. The visual analogue scale was divided into three categories. No pain corresponded to 0 mm, Moderate pain at 5mm, Severe pain was defined as 10 mm and included the descriptions of strong, intense and maximum possible.

Results

When the mean values of both groups were compared, there was statistically significant difference between the two groups ($p<0.001$). The mean value in the control group was 121.56±21.37 which corresponded to the Pain category “strong", whereas that of the experimental group was 36.35±9.23 which corresponded to the pain category "weak".

Discussion

The inferior alveolar nerve (IAN) block is associated with a failure rate of 15% in patients with normal tissue, whereas IAN fails 44-81% of the time in patients with irreversible pulpitis. Inability to achieve anesthesia in patients with irreversible pulpitis remains a significant barrier to successfully treating patients through endodontics[4]. The challenge of achieving pulpal anesthesia increases with the addition of a condition called “hot tooth”[2] .The term "hot" tooth generally refers to a pulp that has been diagnosed with irreversible pulpitis, with spontaneous, moderate-to-severe pain. A classic example of hot tooth is a patient who is sitting in the waiting room, sipping on a large glass of ice water to help control the pain[7].

The intrapulpal injection is an often used supplemental injection technique for achieving pulpal anaesthesia in teeth in which the primary anaesthetic technique fails to achieve profound pulpal anaesthesia[8,9,11]. The intrapulpal injection technique has many advantages that it is technically simple, does not require removal of rubber dam and the systemic effects are negligible[2]. Moreover, anaesthesia can be achieved with any solution injected with back pressure. Major drawback of the intrapulpal injection is the need for needle to be inserted into a very sensitive and inflamed pulp[4,5]. In about 5-10% of mandibular posterior teeth with irreversible pulpitis, supplement injections even when repeated do not produce profound anesthesia. Pain persists when pulp is entered[10,12]. In the present study topical application of EMLA cream with hyaluronidase was done prior to the injection procedure .

EMLA cream was used in this study, it is an eutectic mixture of the local anaesthetics lidocaine (lignocaine) 25 mg/g and prilocaine 25 mg/g that provides analgesia following topical application[13]. It is a novel formulation of local anaesthetics that has proven to be effective and well-tolerated in the relief of pain associated with various minor interventions in adults and children. The topical application of the combination was done for two minutes because this is sufficient for the onset of action of topical anaesthetics [6,7,14].

Hyaluronidase has been safely used in the field of ophthalmology and hence can be considered harmless in the oral cavity[15]. Hyaluronidase increases the permeability of connective tissue and thus enhances the spread of local anaesthetics used in combination with them [16]. This could be the reason for the increase in the depth of anaesthesia with the topical application of EMLA cream mixed with hyaluronidase to the pulp prior to intrapulpal injection and also for reduction in the pain encountered with the injection technique itself.

In our present study there was statistically significant difference ($p<0.00l$) in pain perception between the two groups. The pain perception was "weak" in the group in which the topical application lignocaine cream mixed with hyaluronidase to the pulp preceded the intrapulpal injection. The better diffusivity of this topical anaesthetic with the aid of hyaluronidase is the suggested mechanism for rendering the intrapulpal injection less painful.

The present study results are similar with that of an earlier study that showed topical application of 20% benzocaine gel mixed with hyaluronidase to the exposed pulp reduces the pain encountered with the intrapulpal injection[1].

Limitations

Limitation of this study is that it has been tried only in mandibular first molars. More extensive studies with increased sample size and different teeth are required to further recommend this technique for clinical endodontics.

Conclusion

The topical application of EMLA cream mixed with hyaluronidase to the exposed pulp prior to the administration of intrapulpal injection can make the intrapulpal injection less painful.

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