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# Comparative Evaluation of Effectiveness of a Vibraject and Topical Anaesthetic Agent in Reducing Pain and Anxiety During Local Anaesthesia Injection

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## ABSTRACT

**Aim**: The aim of this present study was to compare the effectiveness of Vibraject with Topical anaesthetic agent during local anaesthesia administration in reducing pain and anxiety.

**Materials and Methods**: The patients attending pediatric dental OPD for routine dental procedures will be taken as subjects for the study and divided into two groups, A (using vibraject), B (using topical anaesthetic agent). 60 Participants will be randomly assigned to each group. The pain and anxiety level will be measured by using SEM, Wong- baker pain rating and faces anxiety rating scale for each group and will be compared using the student t-test.

**Results:** Data collected showed Vibraject has significantly reduced anxiety and pain both during insertion of the needle and during deposition of the solution when compared to the conventional injection technique.

**Conclusion:** On comparison, Vibraject exhibited significantly higher efficacy ($p<0.001$) in reducing pain as compared to Benzocaine using the evaluation parameters, that is, Sound, Eye, Motor (SEM) scale and Wong-Baker FACES pain rating scale and faces anxiety rating scale (FAS).

**Keywords:** Pain, gate control theory, vibration, local anaesthesia.

## INTRODUCTION

Administration of local anaesthesia is one of the most common methods of pain control in paediatric dentistry. The local anaesthetic administration requires needle penetration, and this event is frequently accompanied by significant pain and trepidation in many patients.[1] The objective experience of painful injection and the subjective learning about this is considered one of the major reasons for fear-related behaviour in dentistry. Likewise, pain resulting from injection of local anaesthetics was found to be the most common cause of fear and anxiety among dental patients. Such fears are a frequent cause of exhibiting uncooperative behaviours and avoiding dental appointments among paediatric patients. This behaviour has long been recognized as the most difficult aspect of patient management and can be a barrier to good care.[2] In paediatric patients, pain control forms an important part of child behaviour guidance and helps in the positive acceptance of dentistry by the child patient. Moreover, on a secondary perspective, pain control on the first dental visit may improve the patient's attitude towards further dental visits.[3]

With time, a variety of techniques have been evolved to overcome the perception of this painful sensation. The most commonly employed technique

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is to anaesthetize the surface (mucosa) so that there is a reduction in perception of pain during injection. This surface anaesthesia can be achieved by applying topical anaesthetics, by applying vapocoolants to get cryo-anaesthesia [5], using transcutaneous electronic nerve stimulation (TENS), and by vibrating the related mucosa.[4] Other methods proposed for reducing the pain associated with local anaesthesia include modifying patient's behaviour, using distraction techniques, hypnosis and alteration of factors related to an injected solution such as pH & temperature [6], varying rates of infiltration of local anaesthesia[7] and using microneedles [8].

Amongst these, the application of a topical anaesthetic prior to needle insertion is the most preferred and widely used method [9]. It functions by blocking signal transmission in the terminal fibres of sensory nerves, thus altering the pain reaction of the individual.[10]However, the results about its success rates have been found to be varied. Hutchins et al. reported topical anaesthetic to be effective in reducing the pain of needle penetration.[2] Conversely, Gill and Orr and Burns et al. failed to show any difference in effectiveness between a topical anaesthetic and placebo in reducing needle insertion pain.[11-12] Among all topical anaesthetics, lignocaine is considered the gold standard, while Benzocaine is known for its excellent surface anaesthetic ability.[5]

But conventional topical anaesthetic gels and patches are time-consuming and often expensive.[13] Therefore, from the above-quoted studies, it is clear that topical anaesthetics have mixed results. In spite of all these mixed findings, the topical anaesthetics are still the most commonly used pre-treatment procedure during the local anaesthetic injection.

However, dentists are still on a constant search for tools that contribute towards painless administration of local anaesthesia. Recently, a novel concept has been introduced in the field of 'pain less dentistry' which uses, "Vibration" as pain reduction technique.[14-21] The principles of "Vibration during local anaesthesia administration" have been incorporated into a small and easy-to-use syringe attachment, named and available as "VIBRAJECT". Vibraject holds an off-set rotating micro-vibration creator that can be easily placed on any standard dental syringe. This is a non-invasive way and claims to make patients comfortable with local anaesthetic injection while making no direct contact with the patient.

Fig 1: Clinical Procedure for Group 1.

Fig 2: Clinical Procedure for Group 2.

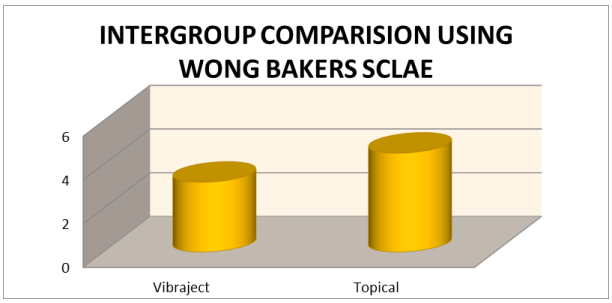


Fig 3: Bar diagram showing mean score of different group using Wong bakers faces pain rating scale.

This device is developed on the principle of the Gate-Control Theory of Melzack and Wall which states that pain transmission through small diameter "A-delta" and "C" nociceptive fibres is depressed at the secondary neuronal cell bodies in the dorsal horn if nerve impulses evoked by tactile sensation (e.g., using appropriate pressure or vibration) are simultaneously transmitted through large-diameter A-beta tactile fibres. This lead to the

theory that the pain signals can interfere while stimulating the periphery of the pain site.[22]

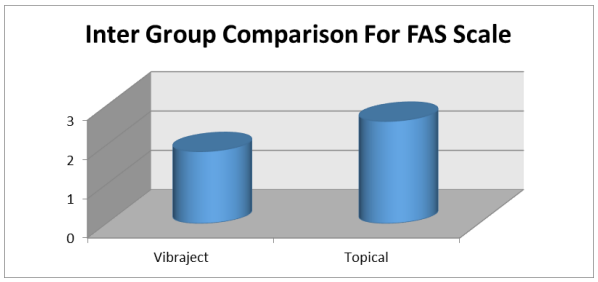


Fig 4: Bar diagram showing mean score of different groups using faces anxiety rating scale

Similarly, micro-vibration using the Vibraject during the LA injection leads to simultaneous transmission of non-noxious stimuli through "A-delta" fibres resulting in a reduction in pain and discomfort associated with injections.

Studies on the effectiveness of the Vibraject have exhibited varying results, Where Terrett et al. and Blair reported it to be effective in reducing the pain of injection among adults [14-15] While Roeber et al. found no significant advantage over a conventional approach to anaesthesia injection for children in their study.[23] Consequently, there is a lack of any conclusive evidence regarding its efficacy in controlling the pain associated with needle prick among children.

Hence, the present clinical study was undertaken to evaluate and compare the efficacy of the conventional method, i.e. application of Benzocaine prior to local anaesthetic administration and the novel method of using Vibraject during local anaesthetic administration in reducing the pain of injection.

## MATERIAL AND METHODS

The present study was a randomized controlled study in which a total of 120 patients were selected from among those, visiting the Out-Patient Clinics of Post Graduate Department of Paedodontics and Preventive Dentistry, Christian Dental College Ludhiana. The protocol ethics were approved by the Ethical Committee of the university, and informed consents were taken from patients'. Inclusion criteria were being systemic healthy and being aged 6-12 years who required administration of local anaesthesia for any of the dental procedure a viz extraction, pulpal procedures, deep fillings, minor surgical procedures etc.

Prior to the commencement of the procedure, the possible discomfort, risks and benefits regarding the study and usage of the materials were explained fully to the parents of children involved in the study and the consent was obtained, before their recruitment in the study.

**Randomization:**

A total of 120 patients between the age group of 6-12 years were recruited for the study [24] and were randomly divided into two equal groups with 60 patients in each group, and the groups indicated the type of method to be used during the local anaesthesia administration shown in figure 1 and 2. Random allocation was done using blinded packages which were prepared by non-clinical staff, carrying the name of either of the two study products. Each patient was asked to pick a slip, according to which patients were divided into either group.

**Evaluating scales**

During the insertion of the needle, the patient was evaluated for pain perception using Sound, Eye, Motor (SEM) scale [25] by another observer who was responsible for giving SEM scores during the administration of local anaesthesia injection. Simultaneously, the whole procedure was also videotaped using Sony Digi Cam HD recorder. After administration of local anaesthesia, the patients were also asked to rate the pain perception, and anxiety using the Wong-Baker FACES pain rating scale [26] and anxiety rating scale.[27]

## RESULT

A total of 120 patients were enrolled in each group comprised of 60 patients. Group 1 consisted of 60 patients in whom local anaesthesia was administered with a syringe fitted with Vibraject. Group 2 also comprised of 60 patients in whom local anaesthesia was administered with a syringe but with prior application of Benzocaine topically for 1 minute. There was no significant difference ($p>0.05$) in relation to age and gender between the two groups. On, Comparison between Vibraject and topical anaesthetic gel in SEM ($p < 0.05$) between the two techniques as shown in Table 1. Wong

baker pain rating scale and FAS ($p < 0.05$) shown in figure 1 and 2, respectively.

Table 1: Intergroup Comparison of Scores for Different SEM Parameters and their statistical comparison Using 'Student t' Test.

| | Group | N | Mean | Std. Deviation | p-value |
|---|---|---|---|---|---|
| Sound | Vibraject | 60 | 1.63 | 0.73 | 0.005* |
| | Topical | 60 | 1.98 | 0.61 | |
| Eye | Vibraject | 60 | 1.58 | 0.67 | 0.0001* |
| | Topical | 60 | 2.05 | 0.64 | |
| Motor | Vibraject | 60 | 1.75 | 0.66 | 0.03* |
| | Topical | 60 | 2.01 | 0.67 | |

## DISCUSSION

One of the major reasons behind unsuccessful dental appointment is fear of pain and anxiety from injections.[28] Thus, it is mandatory for the dentist to master the skill of local anaesthetic administration as it is necessary for many treatment procedures in their dental practice. Behaviour modification and shaping techniques like voice control, desensitization, modelling etc. are also sometimes used to gain the co-operation of fearful and anxious patients, which are known to be quite effective measures, but these methods are usually incapable of eliminating objective fears of needle insertion in the child associated during the administration of local anaesthesia and are time-consuming also. Thus, in order to avoid this seemingly inevitable pain of needle insertion, it becomes necessary to employ other adjunctive measures. [29]

A topical anaesthetic is the most widely used technique in dentistry, to reduce the pain during the administration of the local anaesthetic injection.[30] They function by blocking signal transmission in the terminal fibres of sensory nerves. Among various topical anaesthetic agents available, Benzocaine introduced in the market in the year 1902 is still the most popular topical anaesthetic agent used in dentistry.[29] It is an ester of aminobenzoic acid and contains no basic nitrogen group which makes it unable to form soluble anaesthetic salts. Further, due to its low water solubility and consequent slow absorption, it has a long duration of action.[29] Benzocaine also has the advantage of having an acceptable taste and exhibits no known systemic reactions. However, some authors have reported that Benzocaine could be a cause of allergic reaction in some patients (1.7%).[31]

Other methods of pain control during local anesthesia administration are Electronic Dental Anesthesia – EDA, Jet Injection, and Computer Controlled Local Anesthetic Delivery Devices – CCLAD, Intra-osseous Systems – IO Systems.[32-35]However, these systems also have their shortcomings. For instance, EDA is contraindicated in patients with a pacemaker or Cochlear implant, pregnancy and several other systemic conditions.[36] Jet Injections are costly and have the potential to frighten patients due to the sudden noise and pressure sensation that occurs on delivery of the anaesthetic. They can also produce small residual hematomas. Their questionable efficacy for pulpal anaesthesia makes them relatively unpopular technique. The disadvantages of WAND are its higher cost and relatively low speed of injection.[37]

To overcome the above-mentioned limitations, a novel concept has been introduced in the field of 'pain-less dentistry' which uses, "Vibration" as pain reduction technique [14-21] "Vibration" has been used since old ages to relieve pain associated with injuries. It has also been successful in masking the pain associated with needle prick, thus paving its way in dentistry also.[2] The pain reduction with 'Vibration' has been regarded to be based on 'Gate Control theory of Pain'.

As described by Erlanger and Gasser, mammalian nerve fibres are divided into A, B, and C groups and further subdividing the A group into α, β, γ, and δ fibres. Pain sensations which are perceived by nociceptors, travel through A-δ and C fibres and distractive stimulus perceived by mechanoreceptors, travel primarily through A-β fibres.[34] The A-β fibres have larger axon than A-δ and C fibres which leads to faster transmission of the signal through A-β fibres. These facts led to the origin of the famous 'Gate Control Theory of Pain' further elaborated the mechanism of pain transmission.[22] As per this theory, hypothesized by Melzack and Wall,[22] A-β nerve fibres (which transmit information from touch and vibration receptors in the skin) stimulate inhibitory interneurons in the spinal cord, which in turn act to reduce/block the amount of pain signal transmitted from A-δ and C fibres across the midline of the

spinal cord and from there to the contralateral side of the brain.[22,38]

In the orofacial region, vibration stimuli are used to relieve the pain of dental origin, whether pulpal, periodontal or post-surgical. Reduction in pain intensity of 75–100% was observed when the vibrations at 100 Hz were applied at various points in the facial region of the skull.[21]

This concept of vibrations led to the invention of 'Vibraject' an easy-to-use syringe attachment. The Vibraject has proved to be efficacious even at the most painful sites, i.e. upper anterior and palatal infiltrations (as the density of the palatal soft tissues is less and has firm adherence to the underlying bone and palatal mucosa is more resistant to the effects of topical anaesthetics).[39] Vibratory analgesia can also be achieved in chronic pain conditions of temporomandibular disorder.[19]

Hence, Vibraject which transmits vibration during local anaesthesia injection might have led to simultaneous transmission of non-noxious stimuli through A-β fibres resulting in a reduction in pain and discomfort associated with injections while Benzocaine gel which acts by anaesthetizing the free nerve endings on surface tissue (2-3mm) while tissues deep to the area of application are poorly anaesthetized.[40]

Moreover, as these vibrations were constant during the entire procedure of local anaesthesia administration (i.e. from needle prick to local anaesthetic solution administration), it resulted in a continuous blockade of pain signal transmission to the brain (by continuous stimulation of A-β fibres). This further explains the low SEM scores and Wong-Baker pain rating scale as achieved by the Vibraject.

Lastly, there might be some dilution of topical anaesthetic due to presence of watery saliva in children which might have led to the decreased availability of the topical anaesthetic to the injection site on the oral mucosa and flow of Benzocaine away from the site of application to the surrounding mucosa, thereby reducing the anaesthetic effect on the tissue and sometimes causing patient discomfort. Similar findings were also reported in a study conducted by Leyda AM & Carmen.[41]

Our results are also in accordance with the study conducted by Nanitsos E et al. to determine the effect of vibratory stimuli on pain experienced during local anaesthetic injections. They compared it to non-vibration stimulus injections and found that the injections with vibration resulted in less pain.[20] Similar results were seen by Hutchins HS et al. who compared the effectiveness of tissue vibrations, a topical anaesthetic in reducing the pain of intra-oral local anaesthetic injection and concluded that the topical anaesthetic with vibration caused a statistically significant decrease in pain values.[2] Unoger C et al. who determine the effect of vibration stimuli on pain and anxiety during local anaesthesia administration. They found that vibration is a useful technique that reduces pain without causing anxiety.[42]

However, Saijo M et al. did a pilot study by using a vibrating dental local anaesthesia attachment (Vibraject, LLC, Calif). No statistically significant decrease in pain scores was found at needle insertion or anaesthetic injection.[43] Also, recently, Roeber B et al. evaluated the effectiveness of Vibraject in reducing pain-related disruptive behaviour and self-reported pain in children receiving local anaesthesia. No significant difference was found between injection with and without the Vibraject on any measures of pain.[23]

However, one major limitation of Vibraject is that in case of some over-anxious patients, it can be the cause of increased anxiety levels on the count of the feeling of vibrations on the oral mucosa but, this anxiety should not be misinterpreted as pain sensation. This anxiety can be reduced by simply implying the basic behaviour management techniques such as Tell, Show, Do (TSD) technique etc.

Thus, considering the limitations and advantages of Vibraject over conventional measures, it was found that Vibraject is an excellent device to alleviate the anxiety and pain of needle insertion and local anaesthesia administration in the oral cavity. The adjunct advantage of this device is that it is less expensive than the other newer techniques and also requires the least armamentarium. Further, It is less technique sensitive with no disposable items. Future studies can expand our research and examine other materials and techniques to compare their effectiveness as a pre-injection anaesthetic with that of Vibraject.

## CONFLICTS OF INTEREST

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

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