Comparative evaluation of vibrotactile device with topical anaesthetic patch to reduce pain during administration of local anaesthesia in paediatric dental patients.

ABSTRACT

BACKGROUND: Pain and discomfort are usually associated with dental procedures. Pain control can be achieved by using anaesthesia. Ointments, anaesthetic sprays, gels or adhesive patch are topical local anaesthetic agents which are utilized to reduce pain of local anaesthetic injections, but these methods have their own limitations. Recently, the concept of applying vibration stimuli during local anaesthetic administration has been introduced as a non-pharmacological technique to reduce pain perception associated with injections.Therefore, the painless administration of local anaesthetic agents is crucial in providing optimum dental care.

AIM: To compare and evaluate the effectiveness of topical anaesthetic patch and vibrotactile device in reducing pain during administration of local anaesthesia in paediatric dental patients.

MATERIALS & METHODOLOGY: Twenty children aged 5–12 years, are recruited for the study and randomly allocated into two groups.

Group-1: Ten patients subjected to vibrational device (V -pen) followed by 2% lignocaine injection.

Group-2: Ten patients subjected to anaesthetic patch followed by 2% lignocaine injection.

The pain perception is assessed using a SEM (sound, eye, body movement) and Wong-Baker Faces Pain Rating scale during and after the administration of local anaesthetic, finally THE data is subjected to statistical analysis.

RESULT: According to Mann -Whitney U test**,** statistically significant difference($p<0.05$) was observed with Wong Bakers scale between group-1 and group-2,whereas no statistically significant difference was observed with SEM scale between group-1 and group-2.

CONCLUSION: The results showed that, vibrotactile device is more efficient than topical anaesthetic patch in reducing the intensity of pain during local anaesthetic injection in dentistry**.**

KEY WORDS: Anaesthetic patch; Lignocaine; Local anaesthesia; pain; paediatric dental patients; Vibrotactile device.

INTRODUCTION

According to International Association for the Study of Pain (IASP),pain is defined as an unpleasant sensory and emotional experience arising from actual or potential tissue damage or described in terms of such damage[1]. In dentistry, pain and dental treatment are often closely interconnected. Dentistry relies heavily on pain management, especially when treating younger patients. Modern dentistry cannot function without the use of local anaesthetic.But children's fear of the dentist is exacerbated by the excruciating experience of dental injections. Furthermore, one of the main reasons why adults and children miss dental checkups is dental fear and anxiety associated to needles.It has been established that managing patients with fear-related behaviours is the most challenging aspect of patient care, and it frequently prevents dentists from giving their patients the best care possible[2].

Therefore, one of the most important steps in preventing scared and recalcitrant patients is the painless administration of local anaesthetic drugs. Dental professionals are always looking for less intrusive, more pleasant, more painless methods to induce local anaesthetic prior to dental treatments[2].

Numerous complementary techniques can be used to lessen the pain caused by injecting local anaesthetic agents. These include topical anaesthetics, distraction tactics, counter irrigation, changing the rates of infiltration, buffering and warming the local anaesthetic, reducing the speed of injection, using fine needles with better syringes, precooling the injection site, and using vibration. Numerous studies have reported on these techniques, but no definitive painless injection technique has been established[3].

Topical anaesthesia is defined as superficial loss of sensation in conjunctiva, mucous membranes, or skin, produced by direct application of local anaesthetic solutions, ointments, gels or sprays. The first local anaesthetic (cocaine) was a topical anaesthetic and was serendipitously discovered to have anaesthetic properties, when Albert Niemann in 1860, like many chemists of that era tested his newly isolated compound and noted that it caused numbing of the tongue. Topical anaesthetics reversibly block nerve conduction near their site of administration by targeting free nerve endings in the dermis or mucosa, thereby producing temporary loss of sensation in a limited area. Nerve impulse conduction is blocked by decreasing nerve cell membrane permeability to sodium ions, possibly by competing with calcium-binding sites that control sodium permeability. This change in permeability decreases depolarization and increases excitability threshold until the ability to generate an action potential is lost [4].

One of the many non-pharmacological methods for pain relief is vibratory stimulation [3]. Melzack and Wall provided an explanation of the analgesic effect of vibration using the gate control theory of pain. They

suggested that stimulating nerve fibers that respond to pressure, warmth, and touch could lessen the perception of pain.It is thought that there is a neurological "gate" in the spinal cord that either allows or prohibits pain impulses from ascending the spinothalamic tract to the brain. Inhibitory neurons are activated when larger diameter fibers are stimulated through touch signal mechanoreceptors (e.g., by massage, rubbing, pressure, ice packs, acupuncture, or vibration). This inhibition stops projection neurons from being activated at the synaptic junction in the dorsal horn of the spinal cord. As a result, the gate closes and pain is experienced.

Dental vibe® (Dental Vibe Inc.), which recently was introduced by Dr. Steven Goldberg, gives vibration to the injection site at a sustained frequency and as a counterstimulation.Using v-pen, we have applied the same vibration notion. The Dental Vibe's mechanism of action is the same. If a patient is terrified of injections, a vibrotactile device can make them feel less anxious. It also provides a calming and massaging impact that can speed up the solution's disintegration.

Therefore, the purpose of the current study was to evaluate how well a vibrotactile device works in conjunction with a topical anaesthetic patch when administering local anaesthesia.

MATERIALS AND METHODS:

20 children reporting to the Department of Pedodontics of SVS Institute of Dental Sciences, Mahbubnagar, between the age groups 5-12 years with a mean age (8.8 years) of both genders for various dental treatment who require local anaesthesia were included in this study. Informed consent from the parents and ethical clearance from the teaching institution was obtained.

Inclusion criteria

1. Patients requiring local anaesthesiainfiltration for dental procedures
2. Patients who are willing to participate in the study.

Exclusion criteria

1. Patients with a history of any systemic disease.
2. Patients who have allergic history to local anaesthesia.

A total of 20 children were randomly allocated into 2 groups with 10 subjects in each group. In group 1, vibrotactile device(v-pen)(Fig. 1), is placed near to the injection site 1 min prior to the local anaesthesia

administration and 0.5 ml of 2% lignocaine solution is deposited, vibration continued for 10 s after the removal of the needle as this helps in the dissipation of the local anaesthetic solution.

In group 2, first a topical anaesthetic patch (TAP) is prepared,

Preparation of patch: Topical anaesthetic patch (TAP) is prepared by taking sterile discs on a sterile petri dish and to these discs 4 drops of 2% lignocaine solution is added and left it to air dry under sterile condition by closing the lid of petri dish (Fig. 2).

In group 2 patients,first their mucosa is dried using a sterile gauze at the site of injection and then TAP is placed on the injection site for about 5 min and then 0.5 ml of local anaesthetic (2% lignocaine solution) was deposited with the help of a 27-gauge needle.

The pain assessment was done using a SEM (sound, eye, body movement) scale during administration of local anaesthetic and with Wong-Baker faces Pain rating scale after administration of local anaesthesia.

Designation	Sound	Eye	Motor
1 Comfort	No sound	No sign	Relaxed body/hand status
2 Mild discomfort	Nonspecific sound (probable pain)	Dilated eye without fear (anxiety sign)	Muscular contraction, contraction of hands
3 Moderately painful	Verbal complaint, louder sound	Tears, sudden eye movements	Sudden body & hand movements
4 Painful	Verbal complaint, shouting, crying	Crying, tears all over the face	Hand movements for defense, turning the head to the opposite

The SEM scale, an objective scale, was used to measure pain. An assistant was trained to measure and calibrate the SEM scale. The assistant was blinded to avoid bias.

The second scale was Wong–Baker FPR scale, a subjective scale used to assess pain. A set of six cartoon faces were shown to the child with varying facial expressions ranging from a very smiling face to a very sad face. A brief explanation before the start of the procedure was given to the child about each face after which the child was instructed to choose the face that best described his/ her feelings while receiving local anaesthetic injection. Video recording of the whole procedure was done for further future evaluation. Finally, data was subjected to statistical analysis.

RESULTS

Table 1 and fig. 3 shows the comparison of pain intensities between V-pen and TAP groups according to wong bakers scale and statistically significant difference was observed(P=0.01) between both the groups on performing Mann-Whitney U test.

Table 2 and fig. 4 shows the comparison of pain intensities between V-pen and TAP groups according to SEM Scale and no statistically significant difference was observed(P=0.39) between both the groups on performing Mann-Whitney U test.

DISCUSSION:

Pain is the most common concern during dental procedures, often leading to fear and anxiety in patients. Its perception is not always directly associated with tissue injury; rather, it can be provoked by external stimuli such as the prick of a needle or the sound of a dental drill. To minimize discomfort during local anaesthetic administration, various strategies have been proposed, including slowing the injection rate, applying counter-irritation, distraction techniques, buffering or warming the anaesthetic, using finer needles, precooling, topical anaesthesia, and vibration. Among these, topical anaesthesia remains a routine practice. However, studies on its effectiveness have yielded conflicting results. Minasian and Yagiela [7] suggested that its efficacy could be enhanced if anaesthetic ions were driven into the tissues by iontophoresis before needle insertion. Conversely, prolonged use has been linked to adverse effects such as altered taste and allergic reactions, particularly with ester–amide combinations [8]. These limitations highlight the need for more predictable alternatives.

Vibration has been investigated as one such alternative, acting through counter-stimulation and explained by the gate control theory. According to this theory, vibration activates large-diameter non-noxious fibers that modulate neural transmission, thereby reducing pain perception [10–13]. Previous studies have demonstrated mixed outcomes: Chaudhary et al. [14], Shilpa Priya et al. [3], and Aminah et al. [15] confirmed the benefit of vibration devices like VibraJect and DentalVibe in children, whereas Yoshikawa et al. [19] and Saijo et al. [20] found no significant difference compared to conventional syringes.

In the present study,the vibrotactile device (V-pen) significantly reduced pain scores on the Wong-Baker scale compared to the topical anaesthetic patch, although no significant difference was noted on the SEM scale. These findings are in line with earlier studies by Blair [16], Chandrasekaran et al. [17], and Sreenivasagan et al. [18], which also supported the efficacy of vibrotactile stimulation. On the other hand, studies evaluating anaesthetic

patches, such as those by Shehab et al. [21] and Wu et al. [22], reported good acceptability but inconsistent superiority over gels. In contrast, Tandon et al. [23], Veneva et al. [24], and Hamdy et al. [25] demonstrated that vibrotactile devices were significantly more effective than topical anaesthetic agents, further supporting the concept of counter-stimulation. The variability in patch performance may be attributed to differences in formulation, duration of application, and depth of mucosal penetration.

The Wong-Baker Faces Pain Rating Scale was used in this study due to its simplicity, repeatability, and proven validity in children [15]. The results revealed that children reported less pain with the vibrotactile device, indicating a more comfortable experience compared to the topical anaesthetic patch. The addition of the SEM scale as an objective measure further strengthened the reliability of the findings.

The study was limited by a small sample size and inclusion of only children aged 5–12 years, with pain assessed primarily through subjective scales. Future research should involve larger, multicenter trials across broader age groups and incorporate additional objective pain assessment methods. Overall, the vibrotactile device (V-pen) was more effective than the topical anaesthetic patch in reducing injection-related pain, providing a reliable and child-friendly approach to pain management in paediatric dentistry.

Acknowledgments:

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Fig. 1

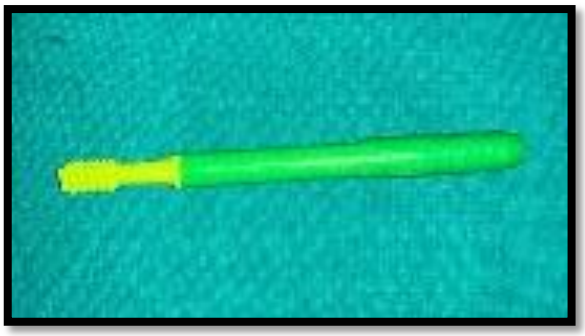

Fig. 2

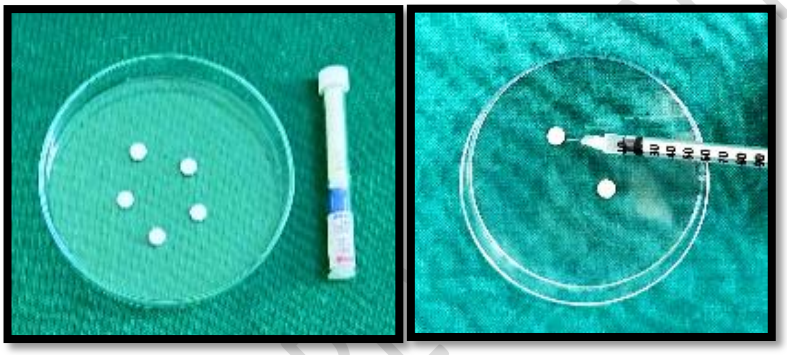

Fig.3


WONG SCALE
MEAN SCALE
16
14
12
10
8
6
4
2
0
13.8
7.2
V-PEN
PATCH
GROUP

Fig.4

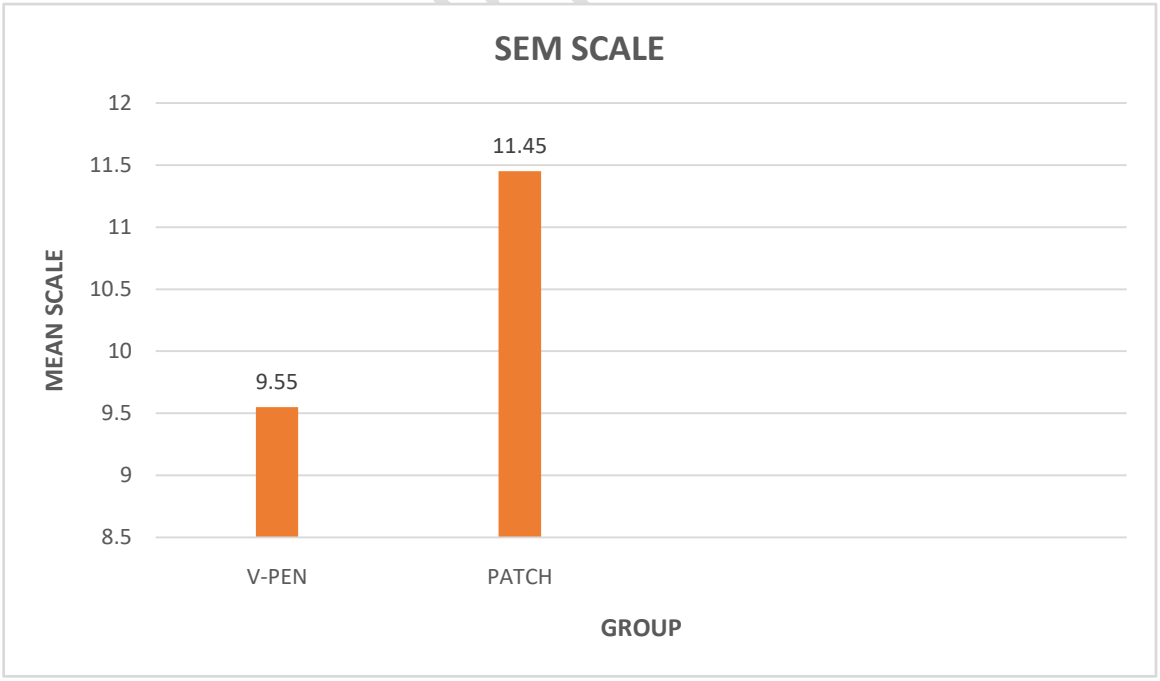
SEM SCALE
MEAN SCALE
12
11.5
11
10.5
10
9.5
9
8.5
11.45
9.55
V-PEN
PATCH
GROUP

Table 1: Intergroup comparative analysis of effectiveness of Vibrotactile device (V-PEN) and Topical Anaesthetic Patch (TAP) in reducing pain (WONG Scale)

SCALE	Groups	Mean Rank	t value^	p value
WONG	V-PEN	7.20	-2.585	0.010*
	TAP	13.80		

^ **Mann-Whitney U Test**

Table 2: Intergroup comparative analysis of effectiveness of Vibrotactile device (V-PEN) and Topical Anaesthetic Patch (TAP) in reducing pain (SEM Scale)

SCALE	Groups	Mean Rank	t value^	p value
SEM	V-PEN	9.55	-0.849	0.396
	TAP	11.45		

^ **Mann-Whitney U Test**