

Efficacy of painless injection technique - Vibraject – Clinical trial in Chennai, India

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ABSTRACT

Background: Pain is the most common cause of needle Phobia. In order to overcome this many advanced injection techniques has been implemented. The most recent and advanced technique was using a small vibrating device to the conventional injection technique.

Objectives: To evaluate the efficacy of vibraject versus conventional injection technique.

Material and methods: Prospective, randomized, cross- over, single blinded design was carried out among adults above 18 years of age in private hospital in Chennai city, Tamil Nadu, India. Out of 52 subjects, 37 were willing to participate in the study. Split mouth technique was carried out. A calibrated single examiner used an appropriate amount of anaesthetic solution, 2% lidocaine with 1:100,00 dilution of epinephrine was injected slowly and then patient was asked to report their discomfort and pain was noted using verbal descriptor scale. Sign test was calculated to check the efficacy of vibraject to that of conventional injection technique.

Results: The total sample size consists of 37 study subjects. Out of total study subject, 35 subjects reported increased pain score while using conventional injection technique than using vibraject with a significant difference ($Z=-5.5$, $p=0.00$). Out of total study subject, 14 subjects reported increased pain score while using conventional injection technique than using vibraject. The p value for 2-tailed sign test shows ($p=0.04$) there was significant difference between two techniques.

Conclusion: Vibraject has significantly reduced pain both during insertion of needle and during deposition of solution when compared to the conventional injection technique.

Key words: Vibraject, pain, needle phobia, conventional injection technique

Introduction

Pain is one of the most common reasons for physician consultation. In dentistry pain is like double edge sword to the dentist. It was estimated that 75% of US adult experience some degree of dental fear. [1] Studies reviewed dental phobia and concluded that about 9% of children and adolescent suffers from dental phobia particularly needle phobia. [2] Injections play a vital role in medical and dental care. About 12 billion injections and 100 million

childhood vaccination were given worldwide annually. [3]

Approximately 10% of world population has needle phobia as reported by American Psychiatric Association Diagnostic and statistical manual of Mental disorder (DSM – IV). [4] Study done in United States stated that 9% of 10 to 50 years of age population have injection Phobia. [5] In a questionnaire survey 23% of 200 Swedish and 27% of 177 American college students reported needle phobia as the main reason for not donating

blood.^[6, 7] This needle phobia is associated with anxiety which later leads to syncope.^[8] In Swedish study, 68% patients with needle phobia had biological relatives who were needle phobic.^[9, 10] Not only general population even dental and medical practitioners have dental phobia.^[11]

Effective local anaesthesia is the single most important pillar upon which modern dentistry stands.^[12, 13] Injections of local anaesthesia are one of the effective methods to reduce pain. But injection of local anaesthetic itself is a great source of patient fear.^[14, 15] In order to overcome the fear of injections many newer technologies have been developed. For example Computer controlled local anaesthesia drug delivery (C-CLAD) device, Intraosseous (IO) system for local anaesthesia injections etc.^[16]

The Computer controlled local anaesthesia drug delivery (C-CLAD) device has base unit, Single Tooth Anaesthesia (STA) wand headpiece assembly. This has advantage of more accurate needle insertion for deeper nerve blocks, less pain on injection and lesser fear of injections.

Since injections are indispensable, recently many advances have been made in drug delivery system and injection techniques. Few examples for this would be TENS which was first used by Shane and Kessler used for sedation during dental procedures in 1967 and this was then followed by Wand.^[17] Though advancements were made, time consumption, devices portability and use of these devices in a field programme is questionable.^[17, 18] Some studies have shown that newer drug delivery system cause tissue blanching.^[18, 19, 20]

In order to overcome these limitation newer device called vibraject LLC

(USA) was first introduced in 1995. It's a small vibrating dental injection attachment device. The device has a clip bracket that gets easily attach to most kind of dental injections. The device has a small motor adapts to the clip bracket. This attaches to the needle which causes vibration so slightly. The clip bracket is autoclavable which prevent cross contamination between patients.

The vibraject works on Gate-Control theory. Theory states that pain and noxious sensation (touch, pressure, and vibrations) was carried to brain via thin and large diameter nerve fibers through dorsal horn of spinal cord. This dorsal horn of spinal cord acts a 'gate' which allows large fiber activity to reach the brain if its intensity is relatively high than thin fiber activity. So as result if intensity of vibration or other noxious stimulus is more than pain intensity, the perception of pain is blocked by dorsal grey horn of spinal cord.^[21]

Since this device sounds more convincing as there are not many studies reported to prove its efficiency, hence the aim of the study is to evaluate pain using vibraject an vibrating attachment to the conventional syringe.

Materials and methods

Study design

This study was prospective, randomized, cross-over, single blinded design. This study was carried out among adults above 18 years of age in private hospital in Chennai city, India. Chennai is the capital of Tamilnadu and is located in the coramendal coast of Bay of Bengal. This study was conducted in Chennai because it has world class medical facilities, including both government and National Accreditation Board for Hospitals (NABH) – accredited

private hospitals so this will be helpful for referrals during the course of the study. Since the vibrating device was attached to the conventional injections it was difficult to carry out double blind study design. Before start of the study, the design and conduct of this trial was approved by Institutional Review Board for health and science. The ethical approval no. is Ph.D/003/2011. This study was conducted from August 2012 to February 2013 in Ramapuram, Chennai in north- eastern part of Tamilnadu.

Sample size calculation

The calculated sample size was 35 subjects for 95% confidence interval where the proportion was kept at 60% and 25% with power of 90%, alpha error at 5%.

Study size and enrolment

The participants were informed about the research and consent forms were disseminated. The subjects were informed that their participation is voluntary and they could withdraw from the study at any time for any reasons.

Patients who are above eighteen years and having dental problems that needs a minor invasive procedure necessitating the need of a local anaesthetic injection on both sides of the oral cavity were included in the study. Subjects with any sort of systemic disorders and mental or physical disability were excluded from the study.

Out of 52 subjects, 37 were willing to participate in the study. Split mouth technique was used and randomization was achieved on the basis of coin flipping. Subject's right quadrant was assigned to one group and left quadrant was assigned to another group,

Study procedure

Prior to injection, self – reported questionnaire with the details of age, sex,

address and date of procedure was recorded. A calibrated single examiner carried out the study. Since it's a split mouth technique, subjects were given appointments for two consecutive days. In the first appointment dental procedures was carried out following local anaesthesia using conventional injection technique. (Without the attachment of the vibrating device) and on the next appointment a vibrating device (vibraject) attachment was fixed on the conventional syringe and dental procedures were carried out.

In both the cases the procedure were divided into 2 sessions. One session was piercing the tissue with the injection before any anaesthetic solution in injected. Depth of needle penetration was about 4mm and the subjects were asked to report the discomfort. The pain was recorded using verbal descriptor scale with the help of the assistants.

An appropriate amount of anaesthetic solution, 2% lidocaine with 1:100,00 dilution of epinephrine was then injected slowly and then again patients was asked to report their discomfort and pain was noted using verbal descriptor scale.^[22]

Examiner calibration

The examiner was calibrated to the study protocol and drug delivery with both conventional and vibraject injection techniques. The intra examiner variability was assessed using 10% of the study population. The kappa value was $k= 0.8$ which was known to be good agreement.

Statistical Analysis

The data was recorded in Microsoft excel sheet. The statistical analysis test was carried out Confidence intervals (CIs) were calculated. Sign test was calculated to check the efficacy of vibraject to that of conventional injection technique. The

statistical software package SPSS 14.0 (SPSS Inc., Chicago, IL, USA) was used for statistical analysis.

Results

The total sample size consists of 37 study subjects. Out of which 22 (59.5%) were males and 15 (40.5%) were females. Figure 1, represents the age distribution of the study subjects. Out of 37 study subjects, more number of study subjects 40.5% were under 40-50 years of age.

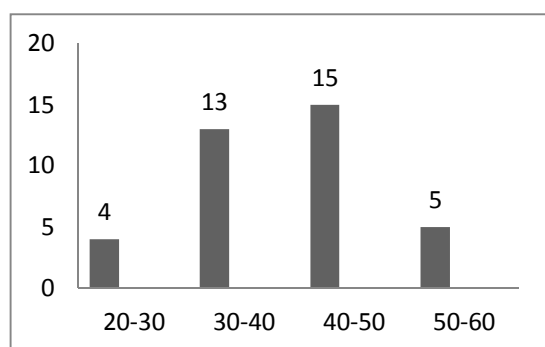


Figure 1: Represents the age distribution of the study subjects

Chi-square test was computed to check the association between gender and pain evaluation during needle piercing using conventional injection technique and using vibraject. The p value shows no significant

association between the groups. The chi-square value for conventional injection technique and using vibraject are $\chi^2=1.5$, $df=2$ $p=0.46$, and $\chi^2=3.9$, $df=4$, $p=0.2$ respectively. Since value was not statistically significant

Chi-square test was computed to check the association between age and pain evaluation during needle piercing using conventional injection technique and using vibraject. The chi-square value for conventional injection technique and using vibraject are $\chi^2=11.3$, $df=6$ $p=0.077$, and $\chi^2=19.5$, $df=12$ $p=0.0076$ respectively and the values were not statistically significant.

The difference in pain score between groups on piercing is shown in Table 1. Sign test was computed to evaluate the difference in pain score during piercing using conventional injection technique and vibraject. Out of total study subject, 35 subjects reported increased pain score while using conventional injection technique than using vibraject. The p value for 2-tailed sign test shows ($Z= -5.5$, $p=0.00$) there was significant difference between two techniques.

Table 1: Shows the difference in pain score between groups on piercing

On piercing / insertion of needle using Vibrajet - On Piercing / Insertion of Needle using Conventional Injection technique	N
Negative Differences(a)	35*
Positive Differences(b)	1
Ties(c)	1
Total	37

*($Z= -5.5$, $p=0.00$)

- (a) On Piercing / Insertion of Needle using Vibrajet < On Piercing /Insertion of Needle using Conventional Injection technique
- (b) On Piercing / Insertion of Needle using Vibrajet > On Piercing /Insertion of Needle using Conventional Injection technique
- (c) On Piercing / Insertion of Needle using Vibrajet = On Piercing /Insertion of Needle using Conventional Injection technique

Table 2, Shows the difference in pain score between groups during deposition of solution. Sign test was computed to evaluate the difference in pain score during deposition of solution using conventional injection technique and vibraject. Out of total study subject, 14 subjects reported increased pain score while using conventional injection technique than using

vibraject, 2 subjects reported decreased pain score while using conventional injection technique than using vibraject and 21 subjects states no difference in pain between both the technique while deposition of local anaesthetic solution. The p value for 2-tailed sign test shows (p=0.04) there was significant difference between two techniques.

Table 2: Shows the difference in pain score between groups during deposition of solution

During deposition of solution - Using Vibraject - During deposition of solution - Conventional Injection technique	N
Negative Differences(a)	14*
Positive Differences(b)	2
Ties(c)	21
Total	37

*(p=0.04)

a During deposition of solution – Using Vibraject < During deposition of solution – Conventional Injection technique

b During deposition of solution – Using Vibraject > During deposition of solution – Conventional Injection technique

c During deposition of solution – Using Vibraject = During deposition of solution – Conventional Injection technique

Discussion

The local anaesthesia is indispensable in dentistry. But the fear of pain and discomfort may leads to systemic complications like tachycardia, vasovagal syncope. [4] Although many advanced technique and improvements in syringes, development of topical anesthesia, and the application of very fine needles have been reported in many studies, no conclusive painless injection method has been established. [23]

Vibraject was an advanced injection technique was first introduced in 1995 in United States. This works on the Gate – Control theory of pain. If the intensity of vibration or other noxious stimulus is more

than pain intensity, the perception of pain is blocked by dorsal grey horn of spinal cord. This was supported by the study done in Okazahi, Japan. [24] The study done by Blair recommended the use of Vibraject for painless injection. [25] In the present study the 35 subjects out of total 37 subjects have reported marked pain reduction when using vibraject against conventional injection technique. The difference was statistically significant. But this finding was in contrast to the study. [26] In that study no significant pain reduction while using vibraject. In a pilot study done in Tokyo Dental College in 2004 states that there were no significant difference in pain while using vibraject. [21]

The study done in United states have compared wand with vibraject. [27] The practitioner evaluated the level of pain for the needle piercing their tissue, the injection of solution, and their overall pain status. He concluded that there was no statistical difference in the pain perceived by a dental patient when injected using the Vibraject as opposed to injecting with the wand. In the present study, shows that there is a statistical difference in the pain score both while piercing and during deposition of solution ($p=0.00$ and $p=0.004$) respectively. Though statistical significant had been obtained, the results cannot be extrapolated because of the sample size small. As per the manufacture instruction vibration form the vibraject reduces patient discomfort if the patient markedly fears undergoing injection. It also state that the "hum" sound of the motor seems to have a calming effect. [23] Further studies will be needed to verify whether the vibration and hum of the motor of the Vibraject have calming effects.

Vibraject has significantly reduced pain both during insertion of needle and during deposition of solution when compared to the conventional injection technique.

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