

# Comparison of Efficacy of Jet Injector and Topical Anesthetic Gel before Palatal Infiltration Anaesthesia in children of age 6 To 12 years: An In Vivo Study.

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## ABSTRACT

**Aim:** The aim of this study was to compare the efficacy of Jet Injector and Topical Anesthetic Gel in reducing pain during Palatal Infiltration in Children of 6 to 12 years.

**Study Design:** A randomized control trial including 12 children divided under two groups which includes Jet injector (Madajet) and a topical anesthetic gel (2% lidocaine) for palatal infiltration. Both the methods were used alternately using split mouth design in two visits and the child's pain and anxiety was assessed using Visual Analogue Scale, Venham's Picture Test and post-trial questionnaire.

**Result:** The Mann Whitney test was used to evaluate the pain perception and anxiety levels of the children on administration of anesthesia which reported less pain and reduced anxiety level during the use of Jet Injector. Topical anesthetic gel has shown lower mean scores and are statistically significant for VAS score ( $p = 0.029$ ) and Venham Picture test ( $p = 0.004$ ). Chi-square test was used for questionnaires which reported the better acceptance of Jet injector over Topical anesthetic gel.

**Conclusion:** The application of Jet Injector is more efficient than Topical Anesthetic Gel in reducing the pain and anxiety level in children during administration of local anesthesia.

**Index Terms-** Jet injector, Topical anesthesia, palatal anesthesia, pain perception, anxiety.

## I- INTRODUCTION:

Behavioural dentistry is an interdisciplinary science.<sup>1</sup> Pain reduction is one of the most important aspects of paediatric attitude management in dental practice.<sup>2</sup> The most common distressing situation for dental patients in healthcare settings is fear of injections.<sup>3</sup> Paediatric dental practice is the ability to positively guide children throughout their dental experience and promote a positive dental attitude to improve their oral health.<sup>4</sup>

Different methods for alleviating the pain experienced during local anesthesia have been proposed.<sup>5</sup> Modern direct palatal injection technique is hard to perform without serious pain or discomfort, as there is little tissue space between the mucosa and the underlying periosteum at these sites.<sup>6</sup> There is not yet an appropriate topical agent available for reducing pain during local palate anesthesia.<sup>7</sup> However, the additional duration of application can increase the anxiety of the child and the taste of topical anesthetics may not be enjoyable for many children who have failed to manage.<sup>8</sup>

In 1958, Margetis et al reported the first dental analysis using a needleless jet injector.<sup>9</sup> The intraoral Jet Injector system has contributed to one of the alternative approaches for topical anesthesia.<sup>10</sup> Nevertheless, so far, the effectiveness of the jet injector system has not been documented in reducing pain during injection.

## II- MATERIALS AND METHODS:

### Subject selection:

The present study was a randomized clinical trial involving children aged 6 to 12 years who reported to Bharati Vidyapeeth Dental College and Hospital, Pune. The sample size for the split mouth study design was 12 children overall.

After obtaining the ethical clearance from the Institutional Ethics Committee (Registration number ECR/328/Inst/MH/2016), the study was commenced. The procedures, possible discomforts or risks, as well as the possible benefits were fully explained to the parent or guardian, and their informed consent was obtained.

**2.1- Inclusion criteria:**

- Patients aged between 6 to 12 years requiring bilateral local anesthetic infiltrations on palatal surface for restorative procedures/pulp therapy of primary/permanent teeth in the maxillary arch, which need administration of palatal infiltration anesthesia.
- Patient who are rated as Frankel's Positive and Definitely Positive rating scale on 1<sup>st</sup> visit was included.
- No patients had undergone any previous dental local anesthetic experience, in order to be not influenced by a positive or negative memory.

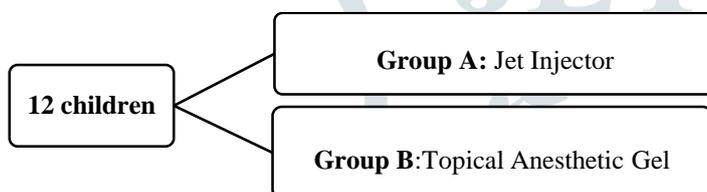
**2.2- Exclusion criteria:**

- Patients with known drug allergies toward topical anesthetic agents
- Patients with pre-existing debilitating systemic diseases and who are handicapped or medically compromised.
- Patients whose parents did not give informed consent to participate in this study.

**III- CLINICAL PROCEDURE:**

A thorough clinical examination of the teeth was performed and a preoperative radiograph was taken to determine an appropriate treatment for each tooth included. The application of both approaches was carried out in two different appointments by the same paediatric dentist on each patient, on one side of the dental arch using Jet Injector and on the other side with Topical anesthetic Gel. Administration sequences were randomly assigned to each individual, using a table of random numbers. After the first appointment had been completed, the patient was recalled after a 15-day interval which was held as washout period This was done to remove the recollection that the child had at first appointment for the purpose of removing the prejudice.

The candidates were randomly allocated into two groups:

**3.1- Group A: Jet Injector**

In an attempt to reduce apprehension from the unfamiliar procedure the instrument was shown to the patient. Jet injector application was done by drying out the palatal region where local anesthesia was to be administered. The instrument's tip was firmly held against the attached gingiva at right angles to its top, and the Jet Injector was kept motionless during activation.



Figure 1: Jet Injector application

**3.2- Group B: Topical Anesthetic Gel**

The Palatal area to be anesthetized was dried with sterile gauze, and a cotton applicator was used to apply topical anesthetic gel to the area. The area was checked for the onset of surface anesthesia every 30s for a period of 3 minutes.



Figure 2: Topical anesthetic application using Lignocad Gel

The children were told to raise their right hand to show pain. The investigator also noticed signs of discomfort in the eye. The test area was wiped away free of the agent after the 3-minute duration. The mucosa was inspected for any signs of local irritation. A palatal infiltration of an average of 0.3- 0.5ml was administered at the palatal side 1 mm away midway where blanching of the tissue can be seen in Jet Injector and Topical Anesthetic Gel respectively and were assessed for their effectiveness in reducing the pain on needle insertion during local anesthesia administration.

#### IV- METHOD OF ASSESSMENT:

Immediately after the injection, the patients were asked to rate the pain level experienced during the injection using a Visual Analog Scale (VAS) of 10 points.

##### 4.1- VISUAL ANALOGUE SCALE:

The VAS is a pain assessment scale (0–10)<sup>11</sup>, with its six cartoon-like facial representations, from a smiling to a weeping face was used in this study.

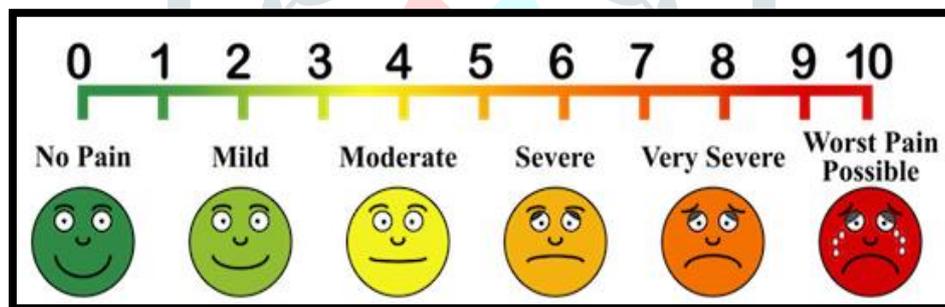


Figure 3: Visual Analogue Scale

The researcher explained to the patient the 10-point Visual Analog Scale (VAS) which was used for subjective assessment. The VAS is a 10-point line anchored from 'no pain' to 'pain as bad as it could be' at each extreme and graduated from green to red colouring. All the children were clarified the procedural specifics according to the level of understanding and each child was asked to tick or choose the corresponding number in which they most could relate.

#### 4.2- THE VENHAM PICTURE TEST:

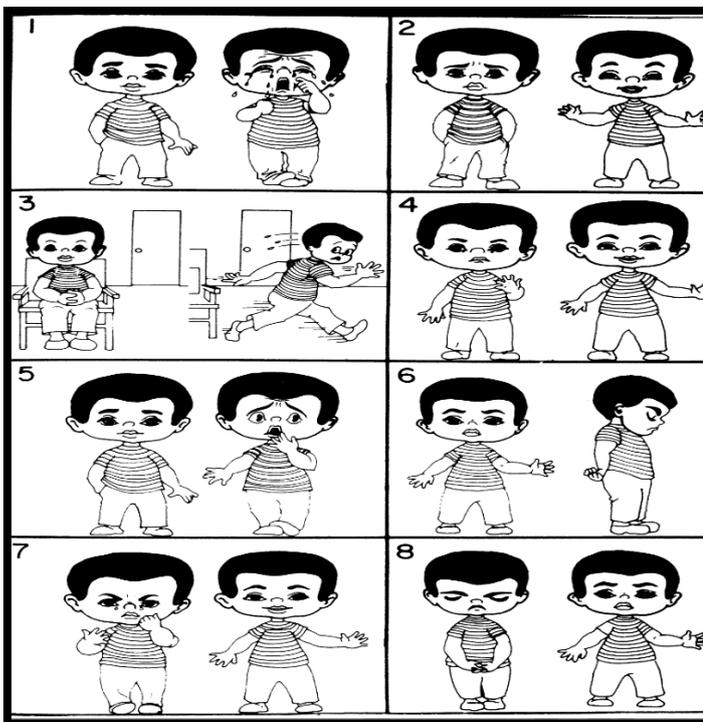


Figure 4: Venham Picture test

- The Venham Picture Test comprises eight cards, with two figures on each card, one 'anxious' figure and one 'non anxious' figure.<sup>12</sup>
- The children were asked to point at the figure they felt most like at that moment.
- All cards have been presented in their numbered order. If the child was recording a score of one at the 'anxious' number, if the child was recording a score of zero at the 'non-anxious' level.
- The number of times the 'anxious' figure was chosen was summed up to give a final score (minimum score, zero; maximum score, eight).
- The VPT was administered first, with every second participant to control for order effects.

An evaluation of post-operative pain tolerance levels in each child was calculated using questions<sup>13</sup> relating to anxiety and comparing overall comfort, acceptability of taste, and preferred agent over the various elements used in dental treatment.

The children were asked to complete the form immediately after administration of Local Anaesthesia. After the evaluation of the individual methods; the conventional technique of buccal infiltration using an average of 0.8ml of local anaesthesia was administered at the mucobuccal fold above the apices of the buccal roots of the molars and the requisite therapy was completed.

#### 4.3- QUESTIONNAIRE:

1. Was there pain before anesthesia at the site of injection? [ YES / NO]
2. Was there pain during application of jet injector? [ YES / NO]
3. Did the noise of Jet injector scare you? [ YES / NO]
4. Was there pain during application of Topical anesthetic Gel? [ YES / NO]
5. Did you like the taste of Topical Anesthetic gel? [ YES / NO]
6. Is the application of Jet injector time consuming? [ YES / NO]
7. Is the application of Topical anesthetic Gel time consuming? [ YES / NO]
8. Were you afraid by the appearance of the Jet Injector? [ YES / NO]
9. Does the Topical anesthetic Gel have unpleasant smell? [ YES / NO]
10. Does the administration of Local anesthesia painful after the use of Jet injector? [ YES / NO]
11. Does the administration of Local anesthesia painful after the application of Topical Anesthetic Gel? [ YES / NO]
12. Which method was better and less painful? [JET INJECTOR OR TOPICAL ANESTHETIC GEL]

Figure 5: Questionnaire

#### V- STATISTICAL ANALYSIS:

The data was collected and the results were statistically analysed using SPSS version 15.0 statistical package (SPSS Inc., Chicago, Illinois, USA). The Mann Whitney test was used to evaluate the pain perception and anxiety levels of the children on administration

of anesthesia using both the techniques; Chi square test was used to evaluate patient acceptance of the technique via the questionnaire.

## VI- RESULTS:

The research had recruited a total of 12 participants. This patients age group ranged from 6 to 12 years. There were 7 girls and 5 guys in this study. The scores from VAS, Venham picture scales and questionnaire have been stored in an excel spreadsheet and statistical analysis was carried out using statistical package for social sciences (SPSS, Inc. Chicago, I11).

According to VAS score, patients experienced significantly less pain on injection with the MadaJet injector as compared to topical anesthetic gel method during palatal infiltration ( $p < 0.05$ ).

**Table 6.1: Comparison of Visual Analogue Scale (VAS score) to evaluate the pain perception in Children among Group A (Jet Injector) and Group B (Topical Anesthetic gel)**

VAS SCORE	MEAN	S.D	MEAN RANK	Mann – Whitney U Test	p value, Significance
GROUP A (JET INJECTOR)	3.6	1.43	9.42	U = 35.0	p = 0.029  statistically significant difference
GROUP B (TOPICAL ANESTHETIC GEL)	5.08	1.44	15.58		

$p > 0.05$  – no statistical difference,  $p < 0.05$  – statistical difference

The Venham picture test showed that there was less pain on using Jet injector with statistically significant difference ( $p < 0.05$ )

**Table 6.2: Comparison of Venham Picture Test (VPT score) to evaluate Behavior change in Children among Group A (Jet Injector) and Group B (Topical Anesthetic gel)**

VENHAM PICTURE TEST	MEAN	S.D	MEAN RANK	Mann – Whitney U test	p value, Significance
GROUP A (JET INJECTOR)	2.41	0.90	8.64	U = 23.5	p = 0.004,  statistically significant difference
GROUP B (TOPICAL ANESTHETIC GEL)	4.0	1.27	16.54		

$p > 0.05$  – no statistical difference,  $p < 0.05$  – statistical difference.

As per questionnaire score statistically significant less pain was experienced with MadaJet Injector as compared to topical anesthetic gel during palatal infiltration injection ( $p < 0.05$ ).

When comparative evaluation of questionnaire relating to anxiety about different elements of dental treatment was done using Chi square test, Jet injector was better and less painful as compared to Topical anesthetic gel but the difference was not statistically significant ( $p > 0.05$ )

**Table 6.3: Comparative evaluation of questionnaire relating to anxiety about different elements of dental treatment**

	Yes n (%)	No N (%)	Chi-square test	P value, Significance
<b>Pain before Jet Injection (Q1)</b>	2	10	5.33	p = 0.021*
<b>Pain during Jet Injection (Q2)</b>	3	9	3.0	P = 0.083
<b>Noise scared you (Q3)</b>	5	7	0.33	P = 0.564
<b>Pain during gel application (Q4)</b>	7	5	0.33	P = 0.564
<b>Liked Taste of gel (Q5)</b>	7	5	0.33	P =0.564
<b>Jet Application time consuming (Q6)</b>	3	9	3.0	P = 0.083
<b>Gel Application time consuming (Q7)</b>	10	2	5.33	P =0.021*
<b>Afraid appearance of jet (Q8)</b>	9	3	3.0	P = 0.083
<b>Gel has unpleasant smell (Q9)</b>	8	4	1.33	p = 0.248
<b>LA painful after use of Jet injector (Q10)</b>	1	11	8.33	p =0.004*
<b>LA painful after use of Topical injector(Q11)</b>	3	9	3.0	P = 0.083
	<b>Group A (Jet Injector)</b>	<b>Group B (Topical Gel)</b>	<b>Chi-square test</b>	<b>P value, Significance</b>
<b>Better and less painful method (Q12)</b>	8	4	1.33	p = 0.248

p > 0.05 – no statistical difference,

\* p < 0.05 – statistically significant difference.

## VII- DISCUSSION:

In this study, MadaJet XL needle free injector was used. It is a jet injection device that delivers the local anesthetic solution using a mechanical pressure system. This injector consists of (Figure 1):

- 1) A head assembly with glass fill chambers holding up to 4 ml of local anesthetic solution.
  - 2) The body with cocking lever and discharge button.
  - 3) Extend a-tip and sheath which can be changed between each patient and allows for pinpoint accuracy at the injection site.
- The entire assembly is autoclavable.<sup>14</sup>

The application of indirect palatal technique is mentioned in this regard, at which a bolus of analgesic solution can be deposited followed by palatal injection over the blanched area. This technique is suggested to be suitable for treatment of primary and permanent teeth of young children instead of the traditional direct technique.<sup>15</sup>

Children who are very anxious report more pain and show more pain associated behaviour and distress associated with the injection of local anesthesia.<sup>16</sup> Different techniques employed to reduce this injection pain can be categorized as follows: Topical anesthetic application in gel or spray or EMLA patches, ethyl chloride spray, reducing needle diameter, counter stimulation,

electronic dental anesthesia, Jet injectors, Computer-controlled local anesthetic delivery (WAND), slow injection rate, warming injection solutions; Psychosocial interventions such distraction, hypnosis, transcutaneous electrical nerve stimulation, and so forth.<sup>17</sup>

Palatal anesthesia is one of the most traumatic and painful procedures experienced by a paediatric patient. The 2-stage injection technique is an alternative to the conventional injections in which regional analgesia of the tissues ahead of the needle can reduce pain on insertion, placement, and deposition.<sup>17</sup>

The pain perception on the palatal tissue is highest in the oral cavity. So, the painless administration of LA is an important step in the development of fearless and uncooperative child. Kincheloe et al in 1991 studied 77 dental patients and found that a topical anesthetic gel (unspecified), when applied for 3 minutes, was no more efficient in reducing the pain of injection than was a placebo.<sup>18</sup>

According to Baeyer C L in 2006, measurement of pain is complicated as it is experienced on an individual level and is dependent on several physiological and psychological factors.<sup>19</sup> Children principally used eyes and mouth to display facial changes in pain reaction in their drawings.<sup>20</sup> In the present study, Visual Analogue Scale was used as it was proved that it is simple to use, readily understood by children, and used successfully on 6-years old children and above.

According to Kuscuo O et al in 2008, pre-injection dental anxiety can affect perceived pain. Thus, participants who have more dental anxiety may perceive greater pain. Controlling pre-injection diffusion of LA as a means of reducing needle penetration discomfort might be helpful in eliminating related confounding factors.<sup>21</sup> Thus, the Venham Picture test was used for behavioural assessment. The result for this showed statistically significant results.

According to Primosch R E et al in 2001, he assessed that Palatal mucosa is more resistant to the effects of topical anesthetics compared with the buccal fold.<sup>22</sup> Anesthesia of palatal mucosa membrane can be achieved painless by the application of Jet injector which is an alternative to topical anesthesia. The Jet injector works on the principle of pressure dynamics, it promises to be a viable mode of pain control during various procedures in clinical pedodontics as well.<sup>23</sup> Makade C S et al in 2014 concluded that Pressure anesthesia was more accepted and preferred than traditional needle anesthesia and also statistically significant difference was seen in favour of the Pressure anesthesia instrument (Jet Injector).<sup>13</sup> However, further research is still largely needed to help children to cope with the intra-oral injections.

#### VIII- CONCLUSION:

- Jet Injector ensures elimination of pain, is less stressful for both the patient and the clinician while administering, and provides instantaneous anesthesia. Taking into consideration the disadvantage of Jet injector, the noise and the appearance is the major drawback which can be eliminated by introducing the use of audio aids such as headphones and the Jet injector can be masked with different attractive sleeves.
- Further, it is autoclavable, reusable and proves to be a substantial alternative to the other conventional local anesthetic techniques. It is cost-effective and thus, can be employed as a useful adjunct to the paediatric dentist's armamentarium.
- However, further research is needed for introducing techniques that make the application of Jet injector on different sites relatively easy with respect to primary teeth in children.

IX- ACKNOWLEDGEMENTS: None.

X- DECLARATION OF CONFLICTING INTEREST: None.

#### XI- REFERENCES:

1. Guinot JF, Yuste BS, Cuadros FC, et al. Objective and subjective measures for assessing anxiety in paediatric dental patients. *Eur J Paediatr Dent.* 12(4):239-44; 2011.
2. Nuttall, N.M., Bradnock, G., White, D., Morris, J. and Nunn, J.: Dental attendance in 1998 and implications for the future. *Br Dent J* 190: 177–182, 2001.
3. Deacon B & Abramowitz J. fear of needles and vasovagal reactions among phlebotomy patients. *Journal of anxiety Disorders.* 20(7), 946-960. (2006)
4. McDonald R., et al. "Dentistry for the child and adolescent". St. Louis, Mo.: Mosby 2010.
5. Lysakowski Christopher, Dumont Lionel, Trame`r M R., and Tassonyi Edo`mer; A Needle-Free Jet-Injection System with Lidocaine for Peripheral Intravenous Cannula Insertion: A Randomized Controlled Trial with Cost-Effectiveness Analysis. *Anesth Analg*; 96:215–9; 2003.
6. Bhalla, J., Meechan, J.G., Lawrence, H.P., Grad, H.A. and Haas, D.A.: Effect of time on clinical efficacy of topical anesthesia. *Anesth Prog* 56: 36–41, 2009.
7. Franz-Montan, M., de Paula, E., Groppo, F.C., Silva, A.L., Ranali, J. and Volpato, M.C. Liposomal delivery system for topical anaesthesia of the palatal mucosa. *Br J Oral Maxillofac Surg* 2, 2010.
8. Wilson, S. and Montgomery, D.: Local anesthesia and oral surgery in children. *In: Pediatric Dentistry: Infancy Through Adolescence.* 4th ed. (Pinkham, J.R., Casamassimo, P.S., McTigue, D.J., Fields, H.W. and Nowak, A.J. eds.) Elsevier Saunders, pp.447–454; 2005.
9. Margetis PM, Quarantillo EP, Lindberg RB. Jet injection local anesthesia in dentistry: A report of 66 cases. *U S Armed Forces Med J.* 9:625-34; 1958.
10. M.P. Santhosh Kumar. Newer Delivery Systems for Local Anesthesia in Dentistry. *Jr Pharm. Sci. & Res.* Vol. 7(5), 252-255; 2015.
11. Luyk N H, Beck F M and Weaver J M. A Visual Analogue Scale in the Assessment of Dental Anxiety. *Anesth Prog* 35:121-123 1988

12. Agarwal M, Das U M. Dental anxiety prediction using Venham Picture test: A preliminary cross-sectional study. *J Indian Soc Pedod Prev Dent* [serial online] 2013 [cited 2020 Jan 20]; 31:22-4.
13. Makade C S, Shenoi P R, Gunwal M K. Comparison of acceptance, preference and efficacy between pressure anesthesia and classical needle infiltration anesthesia for dental restorative procedures in adult patients. *J Conserv Dent*. Mar-Apr; 17(2): 169–174; 2014.
14. Munshi AK, Hegde A. Clinical evaluation of the efficacy of anesthesia and patient preference using the needle-less jet syringe in pediatric dental practice. *J Clin Pediatr Dent*. 25(2):131-6; 2001.
15. Dugal, M.S, Curzon, M.E.J., Fayle, S.A., Pollard, M.A. and Robertson, A.J. Local anesthesia in Restorative Techniques in Paediatric Dentistry. pp.11–26; 1995.
16. Sixou JL, Marie-Cousin A, Huet A, Hingant B & Robert JC. Pain assessment by children and adolescents during intraosseous anaesthesia using a computerized system (Quick Sleeper). *Int J Paed Dent*; 19: 360-366. 2009.
17. Valasingam Sandeep, Manikya Kumar, P. Jyostna, and Vijay Duggi. Evaluation of 2-Stage Injection Technique in Children ISSN 0003-3006/16 \_ 2016 by the American Dental Society of Anesthesiology SSDI 0003-3006(16); 2016
18. Kincheloe JE, Mealiea WL Jr, Mattison GD, Seib K. Psychophysical measurement on pain perception after administration of a topical anesthetic. *Quintessence Int*. Apr;22(4): 311-315; 1991
19. Von Baeyer CL. Children's self-reports of pain intensity: Scale selection, limitations and interpretation. *Pain Res Management*, 11(3): 157–62, 2006.
20. Goodenough, B., Addicoat, L., Champion, G.D., McInerney, M., Young, B., Juniper, K. and Ziegler, J.B.: Pain in 4- to 6-year-old children receiving intra-mascular injections: A comparison of the Faces Pain Scale with other self-report and behavior measures. *The clinic J of Pain* 13: 60–73, 1997.
21. Kuscu O O, Sandalli N, Caglar E, Meechan J G. Use of Pre-Injection Diffusion of Local Anesthetics a means of reducing needle penetration discomfort. *Acta Stomatol Croat*. Sep; 48(3); 193-198; 2014.
22. Kale TR, Momin M. Needlefree Injection technology – An overview. *eInov Pharm*.5(1),148; 2014
23. Lee HS. Recent advance in topical anesthesia. *J dent Anesth Pain Med*; Dec,16(4):237-244; 2016.

