

## **Evaluation and comparison of Clinical effectiveness of two topical anesthetic agents Precaine® against Precaine® B – in vivo study.**

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### ABSTRACT

Topical anesthetics are widely used in pediatric dentistry practice to reduce pain and anxiety produced during administration of local anesthesia. There are different combinations of topical anesthetic agents available worldwide. However, there is sparse literature report exist regarding clinical efficacy of these agent. Aim-To compare the clinical effectiveness of two topical anesthetic viz. Precaine® (8% Lidocaine +0.8 Dibucaine) and Precaine®B(20% benzocaine) in children before local anesthetic injections. Study design- This is double blind clinical study included forty children divided equally under two techniques- palatal injections, inferior alveolar nerve block. Both the product were used alternatively with split mouth design in two visits and child's pain response was assessed after local anesthetic injection using Wong baker scale and Taddoi's modified behavioural pain scale. The scores obtained were subjected to statistical analysis. Result- Precaine® has shown lower mean score compare to Precaine® B for both the technique and pain scale. Gender wise comparison was not significant between Precaine® and Precaine® B. On visit wise comparison, there is no specific difference observed for Precaine®, where as Precaine® B in palatal injection showed significant pain reduction for the second visit. Conclusion - Precaine® can be used more effectively as compare to Precaine® B.

### **Introduction**

There is one constant symptom dentists see when treating children and that symptom is pain. It is often difficult for children to convey their feelings of pain due to its subjective nature and be able to separate it from other symptoms like fear, anxiety, or fatigue. Therefore, it is generally accepted that one of the most important aspect of pediatric behaviour management in dental practice is pain control.

Intraoral local anesthesia is commonly used for children to control pain during several dental procedures. It is well recognized that avoidance of routine dental care by some patients specially, children

occurs because of the negative thoughts associated with local anaesthetic injections. Administration of local anaesthetic itself produces pain, anxiety and fear that may cause subsequent unfavourable behaviour.

There are several factors that influence dental injection pain. A variety of techniques are used to overcome this discomfort. These include suggestion, alteration of factors related to the injected solution such as pH and temperature, and reduced speed of injection. Another method is to prepare the surface tissue before needle penetration, method of surface analgesia include



Fig -1 Armamentarium required for the study



Fig -2 Wong Baker scale



Fig- 3 0.5 gm topical anesthesia



Fig-4 Application of topical anesthesia



Fig - 5 Administration of local anesthesia



Fig-6 Childs pain reaction during administration of local anesthesia

refrigeration, transcutaneous electronic nerve stimulation, and topical analgesia.<sup>1</sup>

In pediatric dentistry, topical anesthesia is commonly used to reduce the discomfort of intraoral local anesthetic injections. Topical anesthetics have a disadvantage of disagreeable taste; however with the introduction of various flavoured preparations they have become more acceptable to children.<sup>1</sup>

Dibucaine is used topically in medical field to treat pain and itching caused by minor burns, insect bites, hemorrhoids, sunburn, or other minor skin irritations. Clinical reports about the use of topical application of dibucaine in dentistry are scarce.<sup>2</sup> There is scope for further clinical research in children to compare combination of topical anesthetic agents that can

achieve faster onset of action and prolonged anesthesia. Thus, the main aim of conducting the present clinical study is to compare the effectiveness of Precaine<sup>®</sup> B (20% benzocaine) with Precaine<sup>®</sup> (8% lidocaine + 0.8% dibucaine) in reducing pain during intraoral procedures like palatal injections, inferior alveolar nerve block in two different visits.

### Material and method

#### Materials used:

- 1) Precaine<sup>®</sup> B [(benzocaine 20%) (Pascal international Inc. U.S Washinton) {fig.2}]
- 2) Precaine<sup>®</sup> [(8% lidocaine + 0.8% dibucaine) (Pascal international Inc. U.S.Washinton){fig.1}]

#### Armamentarium used: (fig.1).

- 1) Disposable gloves and syringe (2ml).
- 2) Mouth Mask

- 3) Needle – i) 0.45 x 38 mm for inferior alveolar nerve block.
- ii) 0.45 x12 mm for palatal infiltration injection.
- 5) Cotton applicator tip
- 6) Digital video device (Nikon-P600)
- 7) Weighing machine
- 8) Local anaesthesia Xicaine
- 9) Cotton rolls

#### **Pain rating scale:**

- 1) Wong Baker scale (fig. 2)
- 2) Taddio's modified behavioral pain scale.

#### **Methodology**

A double blind clinical study was conducted in 40 patients (20: males; 20: females) of 6-12 years old who reported to the department of Pedodontics And Preventive Dentistry, Bharati Vidyapeeth Dental College & Hospital Pune, fulfilling the inclusion criteria. After Explanation of the procedure an informed consent was obtained from parent/guardian/caretaker.

#### **Inclusion criteria:**

- 1) Age groups of 6-12years.
- 2) Children with definitely positive behaviour according to Frankel's behaviour rating scale.
- 3) Who requires intra-arch local anaesthetic administration on both right and leftside.

#### **Exclusion criteria:**

- 1) Mentally and physically challenged children who are unable to follow the instruction in condition such as autism, down syndrome ,epilepsy.
- 2) Patients who are medically compromised.
- 3) Patients allergic to ester linkage topical anestheticagent like benzocaine.

- 4) Patients allergic to amide linkage topical anesthetics agent like lidocaine and dibucaine.

Selected 40 patients were divided in two groups as follows.

Group-A –Patient requiring palatal infiltration Injection

(N= 20; 10 male, 10 female)

Group-B- patients requiring inferior alveolar Nerve block.

(N=20; 10 male ,10 female)

Each patient was assigned to receive topical anesthetic agent either Agent A (Precaine<sup>®</sup>) or Agent B (Precaine<sup>®</sup> B) for the first visit. If the patient received Agent A (Precaine<sup>®</sup>) in the first visit, then he will receive Agent B (Precaine<sup>®</sup> B) on the contralateral side on the second visit, which would be schedule after 15 days following first visit and vice-versa.

Procedure was explained to all children according to their level of understanding Child was apprised of Wong Baker scale. A single operator throughout the study performed all the procedures. The child as well as operator was blinded to the type of product being used. Isolation was done. After isolation, selected topical anesthetic agent [(approximately 0.5gm) (fig. 3) was applied on dried mucosa with moderate pressure with rubbing motion for 30 seconds using a cotton applicator tip.(fig-4)

Excess topical anesthetic agent was clean with gauze. After 1 min administration of local anesthetic was carried out using single use syringe (fig.5). Local anesthetic agent was delivered at rate of 1ml/ min with

<i>Mean ± SD for Group A ( N=20)</i>		
	<i>Precaine<sup>®</sup></i>	<i>Precaine<sup>®</sup> B</i>
<i>Wong Baker</i>	<i>0.7±1.4</i>	<i>1.6±2.3</i>
<i>Taddio's Modified</i>	<i>2.35±0.8</i>	<i>2.8±0.8</i>

Table 1 - Mean of Wong Baker scale and Taddio's modified behavioral pain scale for patient in Group A.

<i>Mean ± SD for Group B ( N=20)</i>		
	<i>Precaine<sup>®</sup></i>	<i>Precaine<sup>®</sup> B</i>
<i>Wong Baker</i>	<i>1.3±1.6</i>	<i>1.8±2.0</i>
<i>Taddio's modified</i>	<i>2.3±0.8</i>	<i>2.5±0.6</i>

Table 2 - Mean of Wong Baker scale and Taddio's modified behavioral pain scale for patient in Group B

needle size 0.45x12 mm for palatal injection and 0.45x38 mm for inferior alveolar nerve block.

Childs pain reaction during administration of local anesthetic were recorded using a digital video-camera by a pretrained assistance standing at distance from operative area (fig-6). The child was asked to choose the face on Wong Baker scale that best describes amount of pain he / she experienced at that particular moment. Recorded child's pain reactions were assessed by Taddio's modified behavioral pain scale by same operator.

## Results

The scores obtained from Wong Baker scale and Taddio's modified behavioral pain scale of forty children was statistically analysed using statistical package for social science (SPSS) version 17.0.

Inter-technique comparisons (IANB and Palatal infiltration) were made between both the test products using Wilcoxon Signed Rank Test. For comparison of Precaine<sup>®</sup> and Precaine<sup>®</sup> B Mann-Whitney U test was used to compare the products as well as pain responses in males and females.

Comparison between two test products in two different techniques under Wong Baker scale and Taddio's modified behavioral pain scale is depicted in Table 3

P-Value of Precaine<sup>®</sup> and Precaine<sup>®</sup> B shows a significant result.

For Visit wise comparison we used Wilcoxon signed rank test and Mann Whitney U test, P-Values more than 0.05, statistically insignificant difference observed in two visits.

In Palatal infiltration (Group A) Wong Baker for Precaine<sup>®</sup> B shows visit wise as P- Value is 0.03. All other comparison doesn't show any significant difference visit wise.

For comparison between gender we used Mann Whitney U test,

P-Value of Precaine<sup>®</sup> and Precaine<sup>®</sup> B for group A and group B was statically insignificant. which is depicted in table -5.

## Discussion

Pain control is important part of pediatric dentistry. Intraoral anesthetic injection is one of the procedures that invoke pain, anxiety and negative response in pediatric patients. This anxiety is more often manifested as a behavioural problem. Likewise, dental

Table 3- Comparison between two test products in two different technique under Wong Baker scale and Taddio's modified behavioral pain scale.

	N	IANB (Group B)			Palatal (Group A)		
		Wong Baker	Taddio's Modified	P-Value	Wong Baker	Taddio's Modified	P-Value
Precaine®	20	1.3±1.6	2.3±0.8	0.003**	0.7±1.4	2.35±0.8	0**
Precaine® B	20	1.8±2.0	2.5±0.6	0.011**	1.6±2.3	2.8±0.8	0.004**

Table 4 - Visit wise comparison of two test products under two techniques using Wong Baker scale and Taddio's modified behavioral pain scale

	IANB				Palatal			
	Visit 1	Visit 2	Wilcoxon 'W'	P	Visit 1	Visit 2	Wilcoxon 'W'	P
Wong Baker	1.2±1.3	1.4±1.8	104.5	0.967	0.6±1.8	0.8±1.0	92	0.194
Taddio's Modified	2.5±1.08	2.1±0.3	99	0.466	2.2±0.6	2.5±1.0	99.5	0.503
Wong Baker	2.2±2.2	1.4±1.8	93.5	0.344	2.8±2.8	0.4±0.8	81	0.03
Taddio's Modified	2.7±0.6	2.3±0.6	87	0.118	3±1.0	2.6±0.6	95	0.416

injections cause the greatest amount of physiologic arousal during a dental appointment. Because of this Pediatric dentists are constantly searching for tools which may provide a more comfortable dental procedure.<sup>3</sup> Alleviation of belonephobia can make the dental experience pleasant & comfortable which is one of the goals of Pediatric Dentistry.

Yamamura et al have reported pain relief of oral ulcers that lasted for 2–5 hours after application of the dibucaine film.<sup>2</sup> Adriani et al studied a number of different topical anesthetics by electrical stimulation of the mucous membrane and reported that drugs like dibucaine were the longest acting.<sup>4</sup> On the contrary, benzocaine is absorbed slowly due to its low aqueous solubility and it has also reported few localized allergic reactions.<sup>5</sup> Nayak et al., Jelvehgari

et al. Stated that Benzocaine has low dissociation constant (pKa= 3.4) and penetrates through mucosa, exerting its anesthetic effect and providing intimate contact between dosage form and absorbing tissue which may result in high drug concentration in local area and high drug flux through the absorbing tissue.<sup>6</sup> Hence, this study has been planned to compare the effectiveness of a combination of 8% lidocaine and 0.8% dibucaine against 20% benzocaine.

The topical anesthetics in this study were applied with moderate pressure with rubbing motion for 30 seconds and left for one minute to increase the depth of penetration which is based on the principle that the duration of application of the anesthetic influences the amount of penetration. To minimize the sensation of pain from the injection it was

Variable	Gender	Mean±SD	
		Precaine®	Precaine® B
IANB	Males	1.65±1.4	1.75±1.4
	Females	1.95±1.3	2.55±1.5
	M Vs F	0.493	0.102
Palatal	Males	1.35±1.3	1.95±1.9
	Females	1.7±1.6	2.45±1.7
	M Vs F	0.458	0.162

Table -5 Gender wise comparison between two test products using Wong Baker scale and Taddio's modified behavioral pain scale

generally recommended to use a topical anesthetic agent for at least one minute.<sup>7</sup>

Wong Baker scale has been used for pain assessment in children above 3 years of age. Due to the improved cognitive ability of children above 6 years the inclusion criteria was set as 6 to 12 years of age. Taddio's modified behavioral pain scale (MBPS) in this child is evaluated during and after the procedure. It is based on three Parameters: facial expression, cry movements. Modified behavioral pain scale recorded as sum of all 3 parameters Interpretate as minimum score: 0 maximum score: 10.<sup>8</sup> In the present study, Wong baker scale has been used to assess the subjective pain and Taddio's modified behavioral pain scale to record the objective pain as they have been shown to be reliable in children.

Deepika et al. compared 20% benzocaine and 8% lidocaine + 0.8% dibucaine combination. She reported lower mean scores for lidocaine - dibucaine combination but the difference was not found to be significant for palatal as well as inferior alveolar block injections.<sup>9</sup> G Suma et al. Compared 20% benzocaine and 8% lidocaine + 0.8% dibucaine combination. She reported the result of study shows significantly lower

pain score after application of lidocaine and dibucaine combination gel.<sup>3</sup>

Similarly, the result of present study shows that there is significant difference observed with Precaine® and Precaine® B, in reducing injection pain in two techniques, Inferior alveolar nerve block and Palatal injection. Precaine® more significant in reducing Palatal injection and Inferior alveolar nerve block injection pain in children than Precaine® B.

Giddon et al compared topical anesthetics in different application and dosage forms and reported that there was no difference among 20% benzocaine, 5% lidocaine and placebo when applied for 30 seconds on palate using 25gauge needle.<sup>10</sup> Nakanishi et al also reported no difference between 20% benzocaine and placebo even after application for 4 minutes in the pterygotemporal region when the injection was carried out.<sup>5</sup> Better results shown by lidocaine and dibucaine combination (Precaine®) could be related to the dibucaine component of the gel which has better penetration ability and longer duration of action.<sup>9</sup> There is significant difference between both the products is seen in the present study.

Ram and Peretz<sup>7</sup> Allen et al reported no significant gender-specific difference in children's reaction to intraoral injection. Both scale shows similar findings where in girls are more comfortable than boys in present study. In contrast, Peretz reported significantly higher pain scores in girls than in boys with respect to dental anxiety in general and fear of needle. They obtained the data from self reports completed by patients in the waiting room before the dental procedure<sup>11</sup>. In present study, children had good communication with the operator and possible explanation of the benefits of topical anesthesia prior

to the dental procedure could have minimized the influence of dental anxiety on pain scores.

Martin et al. reported the second injection given on contralateral side in the same appointment immediately after first was perceived as more painful.<sup>12</sup> However, according to Bågesund and Tabrizi good pain control in the first appointment could decrease patient's anxiety in the second appointment.<sup>13</sup> G Suma et al study concluded that, no significant difference was seen in pain reduction between the two appointments.<sup>3</sup> Similarly, present study shows no significant difference was seen in pain reduction between the two appointments for Precaine<sup>®</sup> while Precaine<sup>®</sup>B shows there is significant pain reduction in second visit for palatal infiltration injection. However, Deepika et al. reported significant lower mean scores of pain in visit 2 under SEM pain scale in inferior alveolar nerve block, and extraction of mobile teeth when 20% benzocaine was used as topical anesthetic.<sup>9</sup> The difference could be attributed to the different levels pain threshold among the participants for anxiety reduction carried out during the procedure could have reduced the anxiety difference between boys and girls.

Hence, present study indicates that the combination of 8% lidocaine + 0.8% dibucaine (Precaine<sup>®</sup>) topical anesthetic gel is more effective in reducing injection pain than 20% benzocaine (Precaine<sup>®</sup>B). This combination has the advantage of better penetration, longer duration of action, thereby rendering pharmacological as well as psychological beneficial effects clinically along with minimizing the possible adverse effects.

### Conclusion

The resultant conclusions strictly within the scope of study are as follows-

- Precaine<sup>®</sup> is more effective anesthetic gel than Precaine<sup>®</sup> B.
- Precaine<sup>®</sup> is more effective in reducing injection pain in both technique i.e. ( palatal injection and Inferior alveolar nerve block) than precaine<sup>®</sup> B.
- There is no gender specific difference between Precaine<sup>®</sup> and precaine<sup>®</sup> B
- On visit wise comparison, there is no specific difference observed for Precaine<sup>®</sup>, where as precaine<sup>®</sup> B in palatal injection showed significant pain reduction for the second visit.

The present study depicts Precaine<sup>®</sup> been more effective than Precaine<sup>®</sup> B, the same however needs to be extensively studied with a larger sample size and other variables to reinforce above conclusions.

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