Effectiveness of Two Flavored Topical Anesthetic Agents in Reducing Injection Pain in Children: A Comparative Study

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Topical anesthesia is widely advocated in pediatric dentistry practice to reduce pain and anxiety produced by administration of local anesthesia. There are different combinations of topical anesthetic agents that are marketed worldwide. However, sparse literature reports exist regarding clinical efficacy of these agents. ***Aim:*** *To compare the clinical effectiveness of two strawberry flavored topical anesthetics viz. Precaine® (8% Lidocaine + 0.8% Dibucaine) and Precaine® B (20% Benzocaine) in children before intra oral local anesthetic injections and for extraction of mobile primary teeth.* ***Study Design:*** *This triple blind clinical study included sixty children divided equally under three techniques – palatal injections, inferior alveolar nerve block and extraction of mobile primary teeth. Both the products were used alternately using split mouth design in two visits and the child's pain response was assessed using VAS and SEM pain scale. The scores obtained were subjected to statistical analysis.* ***Results:*** *Precaine® has shown lower mean scores in all the techniques under both the pain scales, but were statistically insignificant. Gender wise comparison has also shown lower mean scores for Precaine® for both males and females, however these were statistically insignificant. On visit wise comparison, Precaine® B reported significant lower scores ($p<0.05$) in visit 2 compared to visit 1 for inferior alveolar nerve block and extraction of mobile primary teeth under SEM pain scale.* ***Conclusion:*** *Precaine® (8% Lidocaine + 0.8% Dibucaine) can be used as effectively as Precaine® B (20% Benzocaine).*

Keywords: *Topical anesthesia, Lidocaine, Benzocaine, VAS: Precaine, Dibucaine*
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INTRODUCTION

Intraoral local anesthesia is commonly used for children to control pain during several dental procedures. Paradoxically, administration of local anesthetic itself produces pain and anxiety that may cause subsequent unfavorable behavior.[1] In dentistry, topical anesthesia is commonly used to reduce the discomfort of intraoral local anesthetic injections. Additionally, topical agents also provide anesthesia for intraoral operative procedures, symptomatic relief from the pain of superficial mucosal lesions, toothache and post-extraction pain.[2] These anesthetics are produced in different formulations, with a variety of agents used to produce the anesthetic effect.[3]

The factors that influence the efficacy of topical anesthetics include the agent and its concentration, duration of application and site of application.[4] The benefits of topical anesthetics may not be entirely pharmacological, a psychological advantage may also accrue.[5] Topical anesthetics have a disadvantage of disagreeable taste; however with the introduction of various flavored preparations they have become more acceptable to children.[6]

Newer topical anesthetic combinations are in use intraorally which claims improved efficacy. These are marketed under different trade names, among which is Precaine® that contains lidocaine as well as dibucaine. 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.[7] 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® B (20% benzocaine) with

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Precaine® (8% lidocaine + 0.8% dibucaine) in reducing pain during intraoral procedures like palatal injections, inferior alveolar nerve block and extraction of mobile primary teeth in two different visits.

METHODOLOGY

The present triple blind clinical study included 60 patients (Males-30, Females-30) of age group 6-12 years, attending outpatient Department of Pediatric Dentistry who were selected based on non probability proportional quota sampling technique. Ethical clearance was obtained from Institutional Ethical Review Board (VDC/IERB/4136B/2009). Children with cooperative behavior and without any confounding medical history were only included in the study.

Informed consent was obtained from the parents or guardians of all the children who were included in the study. The selected children were involved under one of the following three techniques - Technique 1: Children requiring palatal injections, Technique 2: Children requiring inferior alveolar nerve block and Technique 3: Children requiring extraction of Grade-III mobile primary teeth.

The patients in each of the above mentioned techniques were tested for two different strawberry flavored topical anesthetic agents Product I, (Precaine® - 8% Lidocaine + 0.8% Dibucaine) and Product II (Precaine® B - 20% Benzocaine) using split mouth design. In the first visit, half of the children received Product I and the other half Product II. In the subsequent visit, children who received Product I in the first visit received product II on the contralateral side and vice versa.

The procedural details were explained to all the children according to the level of understanding and each child was apprised of Visual Analogue Scale (VAS). A single operator throughout the study performed all the procedures. The child as well as the operator was blinded of the type of product being used. Topical anesthetic agent of 0.5ml was applied on dried mucosa with moderate pressure with rubbing motion for 30 seconds using a cotton applicator tip. One minute after the application of topical agent in a confined area, excess agent was cleaned with gauze and administration of local anesthetic Xicaine® was carried out using single use syringe Dispovan®. Local anesthetic agent was delivered at a rate of 1ml/min with a needle size 0.55 X 25mm in the first two techniques. In technique 3, topical anesthetic was used alone without the administration of a local anesthetic agent.

The assessments of pain response were carried out soon after the needle prick for the first two techniques, however for technique 3; it is after the extraction of tooth. The child was instructed to mark his/her response to pain over the VAS as explained pre-operatively. A pre-trained well calibrated examiner standing at a distance of five feet from the operatory area in a well ventilated room assessed and recorded the child's pain reaction according to Sound Eyes Motor scale (SEM). Thus, obtained data from both the visits was subjected to statistical analysis without revealing the identity of the test products.

RESULTS

The scores obtained from VAS and SEM pain scales of sixty children were stored in an excel spread sheet (Microsoft, Inc., Redmond, Wash) and statistical analysis was carried out using statistical package for social sciences (SPSS, Inc., Chicago, I11). Inter-technique comparisons were made between both the test products using Kruskal-Wallis ANOVA. Mann-Whitney test was used to compare the products as well as pain responses in males and females. A visit wise comparison was also made between both the products using Wilcoxon's Rank Sum test.

Comparison between two test products in three techniques under VAS and SEM pain scales is depicted in Table 1. Higher mean scores have been obtained for Precaine® B (Product II) in palatal injections (1.28±0.9), inferior alveolar nerve block (1.02±0.9) as well as in extraction of mobile primary teeth (1.0±0.9) under VAS pain scale. The mean scores obtained for Precaine® B under SEM scale were also higher in palatal injections (3.8 ± 0.7), inferior alveolar nerve block (3.6 ± 0.8) as well as in extraction of mobile primary teeth (3.9 ± 0.7). However, these mean scores under both the pain scales were statistically insignificant (P > 0.05).

Gender wise comparison of two test products under VAS & SEM pain scale scores is shown in Table 2. Both boys and girls showed lower mean scores for Precaine® when compared to Precaine® B under VAS as well as SEM pain scale,

Table 1. Comparison of two test products under three techniques using VAS and SEM pain scale scores

Techniques	No. of children	VAS			SEM		
		Mean±SD		P – value **	Mean±SD		P – value **
		Product I	Product II	Pr. I v/s Pr. II	Product I	Product II	Pr. I v/s Pr.
T 1	20	0.90±0.06	1.28±0.9	P = 0.29, NS	3.5±0.5	3.8±0.7	P=0.29, NS
T 2	20	0.92±0.4	1.02±0.9	P = 0.51, NS	3.5±0.5	3.6±0.8	P=0.89, NS
T 3	20	0.86±0.7	1.0±0.9	P = 0.56, NS	3.6±0.6	3.9±0.7	P=0.24, NS
K – W ANOVA *		**H = 1.30, P= 0.52, NS**	**H = 1.66, P= 0.44, NS**	**—**	**H = 0.29 P = 0.87, NS**	**H = 2.36, P = 0.31, NS**	

Kruskal – wallis ANOVA: Inter-technique comparisons

* * Mann – whitney Test: Comparison between test Products

Table 2. Gender wise comparison between two test products using VAS and SEM pain scale scores

Variable	Gender	Mean±SD	
		Product I	Product II
VAS	Males	0.8±0.5	1.10±0.9
	Females	1.0±0.6	1.08±0.8
	M v/s F	P = 0.07, NS	P = 0.98, NS
SEM	Males	3.4±0.5	3.7±0.7
	Females	3.7±0.5	3.8±0.7
	M v/s F	P = 0.06, NS	P = 0.79, NS

M v/s F: Mann – whitney Test

but were statistically not significant. Females have reported higher mean scores for Precaine® when compared to males, however these scores were also statistically insignificant ($P > 0.05$).

Visit wise comparison of two test products for three techniques under VAS and SEM pain scale scores is reported in Table 3. Precaine® as well as Precaine® B have reported lower mean scores in visit 2 compared to their respective scores in visit 1 under both the pain scales for palatal injections, but these were statistically insignificant ($P > 0.05$). Precaine® B has reported significant lower scores in visit 2 compared to that of visit 1 for inferior alveolar nerve block (3.2 ± 0.4; 4.0 ± 0.9) and extraction of mobile primary teeth (3.6 ± 0.7; 4.3 ± 0.5) under SEM pain scale ($P < 0.05$).

DISCUSSION

The local anesthetics in routine clinical use today may be divided into two broad groups – agents containing an ester linkage like benzocaine and agents containing an amide linkage like lidocaine and dibucaine.[8] Lidocaine has faster onset and besides having excellent anesthetic efficacy, it has limited allergenicity.[9] Dibucaine is commonly used as a topical anesthetic agent in the field of dermatology. It has an advantage of longer duration of anesthesia in spite of delayed onset of action. Yamamura et al have reported pain relief of oral ulcers that lasted for 2–5 hours after application of the dibucaine film.[7] 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.[10] On the contrary, benzocaine is absorbed slowly due to its low aqueous solubility and it has also reported few localized allergic reactions.[2] Hence, this study has been planned to compare the effectiveness of a combination of 8% lidocaine and 0.8% dibucaine against 20% benzocaine.

Topical anesthetics exhibit pharmacological as well as psychological benefits. Pre-procedural explanation about the benefits of topical anesthetic agents was practiced in the present study. Pollack observed that patients who were given a verbal reinforcement about the effects of topical anesthesia reacted less severely to local anesthetic injection compared with those given no such information.[11]

The topical anesthetics in our 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 generally recommended to use a topical anesthetic agent for at least one minute.[12]

Measurement of pain is complicated as it is experienced on an individual level and is dependent on several physiological and psychological factors. Bayer CLV discussed on the children's self reports of pain intensity and stated that VAS has been extensively measured and show good sensitivity and validity for most children above 6 years of age. He also stated that these self reports when used in conjunction with observer reports of pain can provide a valuable indication of treatment outcome in both clinical and research contexts.[13] In the present study, VAS has been used to assess the subjective pain and SEM pain scale to record the objective pain as they have been shown to be reliable in children.

Table 3. Visit wise comparison of two test products under three techniques using VAS and SEM pain scale scores

Technique	Product	VAS				SEM			
		Visit 1	Visit 2	t *	P	Visit 1	Visit 2	t *	P
1	Product I	0.9 ± 0.6	0.8 ± 0.6	0.37	0.72	3.6 ± 0.5	3.4 ± 0.5	0.89	0.38
	Product II	1.6 ± 1.0	0.9 ± 0.6	1.9	0.07	3.9 ± 0.7	3.5 ± 0.7	1.28	0.22
2	Product I	0.8 ± 0.3	1.1 ± 0.6	0.61	0.55	3.4 ± 0.5	3.7 ± 0.5	1.34	0.2
	Product II	1.4 ± 1.2	0.7 ± 0.3	1.79	0.09	4.0 ± 0.9	3.2 ± 0.4	2.57	0.02 **
3	Product I	1.0 ± 0.9	0.6 ± 0.4	1.28	0.22	3.7 ± 0.7	3.5 ± 0.5	0.74	0.47
	Product II	1.1 ± 0.5	0.8 ± 0.9	0.92	0.37	4.3 ± 0.5	3.6 ± 0.7	2.6	0.018 **

** p value < 0.05

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 25 gauge needle.[14] Similarly, in our study when palatal injections were carried out there was no significant difference between both the products.

Whenever inferior alveolar nerve block was used, Precaine® has not shown any significant difference with Precaine® B. 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.[2] In our study though there was no statistical significance between the topical anesthetic agents, the mean pain scores observed for Precaine® under both the pain scales in all the three techniques were lower compared to Precaine® B. This difference could be attributed to the presence of dibucaine which has better penetration and duration of anesthesia.

With regard to dental anxiety in childhood, girls appear more secure than boys and exhibit more exploratory behavior.[15] However, Ram and Peretz[12] and Allen *et al* [16] reported no significant gender-specific difference in children's reaction to intraoral injection. These findings are in accordance with our 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.[15] They obtained the data from self reports completed by patients in the waiting room before the dental procedure. In our 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.

The order of injection had an effect on both anticipated and experienced pain intensity.[17] Significantly more pain is anticipated for the first injection than for the second. Bagesund and Tabrizi found that good pain control could reduce the patients' anxiety level at the second appointment.[6] However, in the present study only Precaine® B has reported significant lower mean pain scale scores in visit 2 compared to visit 1 in inferior alveolar nerve block and extraction of mobile primary teeth under objective pain scale (SEM). This variation between the products in both the visits could be attributed to varied pain threshold levels in children. This is in contrast to the findings of Martin *et al* who reported that second injections were more painful than first injections.[5] In their study second injection was given on the contra lateral side immediately after the first injection unlike the present study, in which the second injection was given in the subsequent visit.

Hence, lidocaine and dibucaine combination can be used as effectively as the commonly used 20% benzocaine with a short period of application thereby rendering pharmacological as well as psychological beneficial effects clinically along with minimizing the possible adverse effects.

CONCLUSION

The following conclusions have been obtained from the present study –

- Precaine® is equally as effective as Precaine® B.
- There is no gender specific difference between both the products.
- On visit wise comparison, Precaine® B has reported better efficacy in visit 2 with lower mean scores when compared to that of visit 1 in inferior alveolar nerve block and extraction of mobile primary teeth.

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