

Comparative evaluation of pricking pain response, behavioural response, heart rate and blood pressure response to prilido cream and lignocad gel prior to local anesthesia administration in children

Dr. Pawan Joshi¹, Dr. Sudhindra Baliga², Dr. Nilesh Rathi³, Dr. Nilima Thosar⁴

¹Department of Pedodontics and Preventive Dentistry, Sharad Pawar Dental College, Sawangi (Meghe), Wardha, India

²Department of Pedodontics and Preventive Dentistry, Sharad Pawar Dental College, Sawangi (Meghe), Wardha, India

³Department of Pedodontics and Preventive Dentistry, Sharad Pawar Dental College, Sawangi (Meghe), Wardha, India

⁴Department of Pedodontics and Preventive Dentistry, Sharad Pawar Dental College, Sawangi (Meghe), Wardha, India

Abstract: Pain is an unpleasant sensory and emotional experience associated with actual and potential damage. Local anesthesia is an important procedure for the control of pain and discomfort during dental treatment but fear associated with local anesthesia injection has been reported to be a factor especially in children prior to dental treatment. It is necessary to seek alternatives to reduce discomfort during administration of local anesthesia in children. So the aim of the present study was to evaluate and compare the effectiveness of topical anesthetics, prilido cream and 2% lignocad gel prior to administration of nerve blocks and infiltrations in children. Method: Study consisted of forty children, (age group 7 – 13 years) in which prior to administration of local anaesthesia, 20 patients were treated with prilido cream and 20 other patients were treated with 2% lignocad. The assessment of pain was done by independent interpreter with a customised form of Visual analogue scale (VAS) and sound eye motor (SEM) scale. Pulse rate and blood pressure changes were also monitored during the procedure. Result: Visual analogue scale (VAS) and Sound eye motor (SEM) scales have shown that Prilido is more effective than Lignocad. However, pulse rate changes and blood pressure were significantly lower in the Prilido cream group as compared to Lignocad group. **Conclusion:** Prilido cream has been found to be more effective in reducing pain as compared to lignocad gel prior to local anesthesia administration in children

Keywords: Dental pain, 5% Prilido cream, 2% Lignocad gel, VAS scale, SEM scale

I. Introduction

Behavior management in pediatric dentistry encompasses various elements for creating a “pain-free” environment for acceptance of treatment by a child [1]. Pain is an unpleasant sensory and emotional experience associated with actual and potential damage. The neonates, infants and children experience pain and considerable stress responses to dental procedures which causes fear, anxiety and distress. Elimination of pain and suffering, whenever possible is an important responsibility for clinicians as unmanaged pain can result in psychological stress and a variety of negative long term consequences [2,3]. Pain control during dental procedures is essential in children to maintain a positive relationship and to built trust between the child and dentist and allaying fear and anxiety. Fear of syringes and needles has been reported as one of the major causes of apprehension and anxiety in dental patients. So pediatric dentists are on a constant search of tools for painless administration of local anaesthesia via topical anesthetic [4].

Local anesthesia is an important tool for the control of pain during dental treatment, but fear associated with local anesthesia injection has been reported to be a factor especially in children prior to dental treatment [5,6]. The majority of local anesthesia procedures in pediatric dentistry involve traditional methods of infiltration or nerve block techniques with a dental syringe, disposable cartridges, and needles. Inferior alveolar nerve block (IANB) is the most common technique for providing local anesthesia before restorative and surgical procedures of the mandibular teeth and it is reported to be most painful technique than any other block. So it is very much necessary to seek alternative techniques to minimize the complications of such procedures in the care of patients, especially in children [7].

Prilido cream is a 1:1 oil/water emulsion of a eutectic mixture of 2.5% lidocaine and 2.5% prilocaine. It has a property similar to EMLA i.e; having a lower melting point above 16°C, as compared to lidocaine (66°C) and prilocaine (36°C) alone. This physical property allows it to become liquid in the oral environment and aids

in rapid transmucosal absorption of the bases [8]. So, the aim of the present study was to evaluate and compare the effectiveness of topical applied anesthetic agents i.e; 5% prilido cream and 2% lignocad gel prior to administration of nerve blocks and infiltrations in children.

II. Materials And Methods

Ethical approval was obtained from institutional ethical committee. Forty children ,(age group 7-13 years) who reported to dental clinic for restorative, endodontic and extraction treatment were randomly divided into two groups, Group A and Group B. Group A consisted of 20 children who were treated with Prilido cream [Ethinext pharmaceuticals] Group B consisted of 20 children who were treated with 2% Lignocad gel [Cadila pharmaceuticals] (figure 1)

Children who showed positive or definitively positive behavior before application of topical anesthesia agents, Prilido cream and lignocad gel were included in the study. Children requiring emergency treatment for abscess, cellulitis or infections, children with past traumatic dental experience, allergens, systemic diseases, children and parents unwilling to participate and those with any psychotic disorders were excluded from the study. The parents were informed about the treatment procedure and an informed written consent was obtained from parents.

In group A, 20 children were treated with prilido cream. prilido cream is a topical anesthetic agent consisting of 2.5% prilocaïne and 2.5% lidocaine. In group B, 20 children were treated with 2% lignocad gel. Lignocad gel is a topical anesthetic agent consisting of 2% lidocaine-hydrochloride. In both the groups the procedure was application of topical anesthetic agents over the dried mucosa using a cotton applicator.

Prilido cream (2.5% lidocaine and 2.5% prilocaïne) was applied over the dried mucosa using a cotton applicator. Child was randomly pricked for nerve blocks or infiltrations for the extractions,restorative and endodontic procedure unilaterally. The needle was penetrated 3 minutes after application of prilido cream. The procedure was performed with a 30 G sterile disposable dental needle with a volume of 2 ml disposable syringe. The procedure was carried out for 20 patients. Topical lignocad 2% (lidocaine hydrochloride) gel was applied over the dried mucosa using a cotton applicator and rest of the procedure was same.

Pain perceptions of each child were evaluated by using sound, eye and motor (SEM) scale (figure 2). The gradings for sound, eye symptoms and body movements have been shown in Table 1 and children were evaluated from 1.5 m distance from the dental unit by two trained observers. Before application of topical anesthetic agent i.e.; prilido cream and lignocad gel, B.P cuff was attached to either of the arm of child and blood pressure as well as heart rate was recorded by means of blood pressure monitor (Omron healthcare ltd). Blood pressure and pulse rate for each child was recorded before the procedure and at the time of needle penetration during administration of anesthesia. Before administration of the local anesthesia, visual analog scale (VAS) was shown and explained to children for subjective pain assessment. Child was asked to point out the appropriate facial expression as on the scale. After obtaining the ratings based on VAS and SEM scale values were recorded for both the groups. The statistical analysis was done using SPSS (Statistical Package for Social Sciences) Version 15.0 statistical analysis software.

III. Results

Comparison of parameters i.e.; sound eye motor scale, was determined using systolic blood pressure, diastolic blood pressure, VAS scale Analysis of variance(ANOVA), student 't' test, Wilcoxon test were performed to know effect of each variable and statistical significance.

1.1 Comparison of sound eye motor scale and visual analogue scale

The observation for sound eye motor movements was in the form of grade 1 i.e.; comfort, grade 2 i.e.; mild discomfort, grade 3 i.e.; moderate discomfort, grade 4 severe discomfort as shown in table 1 and figure 2. Comparison of pain based on VAS and SEM scale in both the groups showed statistically significant association (0.000) with p value < 0.05 (Table 2)

1.2 Systolic blood pressure:

Systolic blood pressure was compared in both the groups before and after treatment. 5% prilido cream and 2% lignocad gel is shown in table 3. The comparison of systolic blood pressure in both the groups before treatment was not statistically significant (0.18) showing P value 0.05, but when systolic blood pressure was compared with both the groups after treatment, the values were found to be statistically significant(0.001) with P value 0.05. Association of Systolic blood pressure after application of 5% prilido cream as well as 2% lignocad gel before and after treatment showed statistically significant relation with p value >0.05 in both the groups. (Table 3)

1.3 Diastolic blood pressure:

Diastolic blood pressure was compared in both the groups before and after treatment. 5% prilido cream and 2% lignocad gel as shown in table 4. The comparison of diastolic blood pressure in both the groups before treatment was not statistically significant (0.015) showing P value < 0.05 but when diastolic blood pressure was compared with both the groups after treatment, the values were found to be statistically significant (0.000) with P value < 0.05 . Association of Diastolic blood pressure after application of 5% prilido cream as well as 2% lignocad gel before and after treatment showed statistically significant relation with p value < 0.05 in both the groups. (Table 4)

1.4 Heart rate

Comparison of heart rate in both the groups has been shown in table 5. The values for heart rate before treatment with 5% prilido cream and 2% lignocad gel were not statistically significant (0.068) with P value > 0.05 . Comparison of heart rate in both groups after treatment showed statistically significant association (0.000) with p value (p <0.05). (Table 5)

IV. Discussion

Pain control is an integral part of modern dentistry. Prevention of pain during routine dental procedures can help to develop the relationship of the patient and dentist. Hence, a painless method of administering local anesthesia in a pediatric patient is an important consideration in their behavior guidance [5, 6].

Local anesthetic agents can be injected or can be topically applied. Though the actual efficacy of topical anesthesia in reducing pain associated with the intraoral injection of local anesthesia is in dispute, its routine use is still strongly advocated. Acute pain can be influenced by psychological factors, such as anxiety, fear, trust, and perceived control over the stimulus, which may well account for the equivocal findings of dental topical anesthesia efficacy [5]. Martin and co-workers concluded that the widespread belief among patients that topical anesthetics are effective at reducing injection pain may serve to reduce the anticipatory anxiety associated with an impending dental injection, thus making the injection painless. Their results supported the contention that the intensity of the injection pain experienced was significantly less than anticipated by the patient and the injection site location also plays a role in pain perception [9].

5% EMLA cream, a topical anesthetic agent which is a eutectic mixture of 2.5 % lignocaine and of 2.5 % prilocaine was introduced and approved for medical applications by Holst and Evers [10]. The cream has been studied extensively and found to have early analgesic effect due to its rapid absorption. 5% Prilido cream has got acceptable taste and it is cost effective so it was selected over other commercially available topical anesthetic products. 5% Prilido cream is one of new advances in the field of topical anesthetic agents having the same combination as that of EMLA. As the active drugs in the eutectic mixture are in liquid phase, the release rate is favorable. Thus, ideal circumstances for skin penetration by the active base are achieved with the Prilido preparation having high concentration gradient, small micro droplet size and a satisfactory release rate. Another reason for low grade of pain perception of Prilido cream could be attributed to its high pH of 9.6, which increases the potency of the topical anesthetic agents [8]. The lack in efficacy and subject preference, the extended duration of time i.e.; 5 minutes required for onset of action in lignocad gel had given favorable results for 5% Prilido cream. When the groups of children were evaluated for pain perception the results inferred that eutectic mixture of local anesthetic 5%, Prilido cream, had low grade of pain perception when compared to lignocad gel. During dental anesthesia, trained observers assessed children's pain reaction according to the sound, eye and motor scale (SEM).

The facial pain scale has been used frequently to evaluate the pain associated with therapeutic regimens and, in this study was used to measure discomfort. The Facial pain scale provides quantitative ratings to represent a child's pain, such that the numerical values represent the magnitude of pain from a child's perspective. Visual analogue scales (VAS) such as the FPS are regarded as the most sensitive measurements of pain experience in adults. Huskisson et al [11] reported good agreement between VAS and a verbal scale in assessing pain experience in children. The SEM scale was used in this study to record pain reactions since it is considered a sensitive scale recording detailed levels of eye, sound or motor reactions. One of the vital signs used in the present study was the heart rate change in the children which is said to be an effective parameter in assessment of pain response. Testing of the results through VAS, SEM, blood pressure assessment and pulse rate made this study, more accurate and precise in terms of results and observations. Findings of the present study were in agreement with the findings of Sonia Lim, Kell Julliard 2004 [12], the efficacy of EMLA (eutectic mixture of local anesthetics, 2.5% lidocaine and 2.5% prilocaine) cream in reducing discomfort from pressure applied by rubber dam clamp on first permanent molars on opposite sides of the mouth and found significantly lower scores on facial pain scale (FPS) in EMLA as compared to those obtained on placebo application which was suggestive of its better efficacy in reducing discomfort caused by the dental dam clamp and also Singh et al, 2012,[13] who evaluated the efficacy, safety, patient acceptability of topical application of EMLA cream in

patients undergoing radiofrequency ablation of warts from intact skin and found significantly higher scores on VAS and verbal rating scale as compared to those obtained after lignocaine infiltration which was suggestive of its better efficacy than lignocaine infiltration. Therefore, prior topical application of Prilido cream may be advantageous in providing painless injection of local anesthesia in children.

V. Figures And Tables

Table: 1 Sound, Eye, Motor (SEM) Scale

Parameters	Comfort (Grade 1)	Mild discomfort (Grade 2)	Moderate discomfort (Grade 3)	Severe discomfort (Grade 4)
Sound	No sound	Non-specific sound	Verbal complaint, louder sound	Verbal complaint shouting, crying
Eye	No sign	Dilated eye without tear (anxiety sign)	Tears, sudden eye movements	Crying, tars all over the face
Motor	Relaxed body and hand status	Muscular contraction, contraction of hands	Sudden body and hand movements	Hand movements for defense, turning the head to the opposite site

Table 2: Comparison of pain based on VAS and SEM scale in both the groups

Parameters	5% Prilido Cream	2% Lignocad Gel	t-value	p-value
Pain on VAS	0.35±0.58	2.00±0.56	9.07	0.000,S p<0.05
SEM Scale	0.55±0.60	1.80±0.61	6.47	0.000,S p<0.05

Table 3: Comparison of Systolic blood pressure (SBP) in both the groups

SBP	5% Prilido Cream	2 % Lignocad Gel	t-value	p-value
Before treatment	106.40±6.91	109.30±6.53	1.36	0.18, NS P>0.05
After treatment	112.20±6.74	119.60±5.89	3.69	0.001, S P<0.05
t-value	12.10	12.84		
p-value	0.000 S, P<0.05	0.000 S, P<0.05		

S: Significant, NS: Not significant

Table 4: Comparison of Diastolic blood pressure (DBP) in both the groups

DBP	5% Prilido Cream	2% Lignocad Gel	t-value	p-value
Before treatment	67.10±5.48	72.70±8.03	2.57	0.015, S P<0.05
After treatment	72.70±5.32	81.80±6.83	4.69	0.000, S P<0.05
t-value	8.30	9.73		
p-value	0.000 S, P<0.05	0.000 S, P<0.05		

S: Significant

Table 5: Comparison of Heart Rate in both the groups

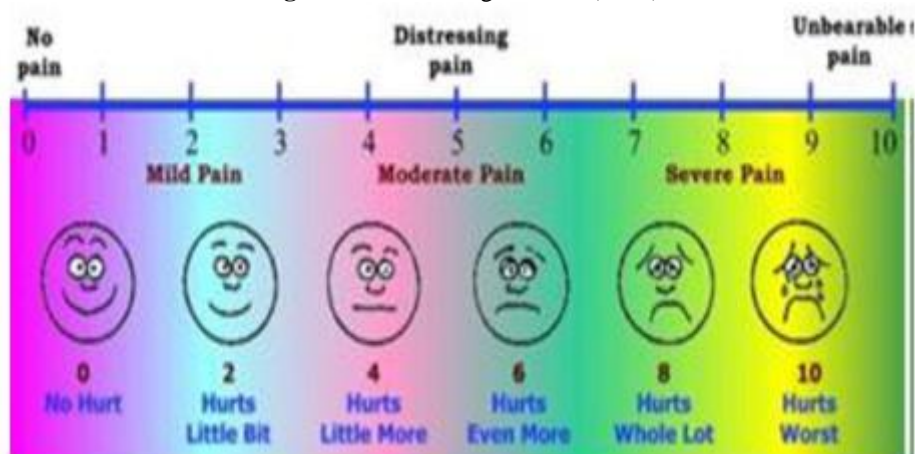
Heart Rate	5% Prilido Cream	2% Lignocad Gel	t-value	p-value
Before treatmentt	69.80±3.83	74.50±10.29	1.91	0.068, NS P>0.05
After treatment	76.50±4.44	89.80±10.97	5.02	0.000, S P<0.05
t-value	9.57	12.49		
p-value	0.000 S, p<0.05	0.000 S,p<0.05		

S: Significant, NS: Not significant

Fig 1: prilido cream and lignocad gel



Fig 2: Visual Analogue Scale (VAS)



VI. Conclusion

Prilido cream provides effective local pain control with a minimal anesthetic agent and could be suggested as an alternative method especially for fearful children during pricking of needle.

References

- [1]. Wu SJ, Julliard K, Children's Preference of Benzocaine Gel Versus the Lidocaine Patch, *Pediatric Dentistry*, 25(4), 2003, 401-05.
- [2]. Sixou JL, Marie-Cousin A, Huet A, Hingant B, Robert JC, Pain assessment by children and adolescents during intraosseous anaesthesia using a computerized system, *Int J Paediatr Dent*, 19(5), 2009, 360-6.
- [3]. Kaufman E, Epstein JB, Naveh E, Gorsky M, Gross A, Cohen G, A Survey of pain, pressure, and discomfort induced by commonly used oral local anesthesia injections, *Anesth Prog*, 52(4), 2005, 122-7.
- [4]. Nayak R, Sudha P, Evaluation of three topical anesthetic agents against pain: A clinical study, *Indian Journal of Dental Research*, 17(4), 2006, 155-60.
- [5]. American Academy on Pediatric Dentistry Council on Clinical Affairs. Guideline on appropriate use of local anesthesia for pediatric dental patients, *Pediatr Dent*, 30(7), 2008-2009, 134-9.
- [6]. Aminabadi NA, Farahani RM, Oskouei SG, Site-specificity of pain sensitivity to intraoral anesthetic injections in children, *J Oral Sci*, 51(2), 2009, 239-43.
- [7]. Ashkenazi M, Blumer S, Eli I, Effectiveness of computerized delivery of intrasulcular anesthetic in primary molars, *J Am Dent Assoc*, 13(6), 2005, 1418-1425.
- [8]. Gajraj NM, Pennant JH, Watcha MF, Eutectic Mixture of Local Anesthetics (EMLA) Cream, *Anaesthesia Analgesia*, 78, 1994, 574-83.
- [9]. Ciocatto E, First Italian Studies on a New Local Anesthetic: Xylocaine, *Current Researchers in Anaesthesia and Analgesia*, 78, 1950, 353-55.
- [10]. Holst A, Evers H, Experimental studies of new topical anesthetics on the oral mucosa, *Swed Dent J*, 9, 1985, 185-191.
- [11]. Huskisson EC, Measurement of pain, *Lancet*. 2 (7889), 1974, 1127-1131.
- [12]. Sonia Lim, Kell Julliard, Evaluating the efficacy of EMLA topical anesthetic in sealant placement with rubber dam, *Pediatr Dent*, 26, 2004, 497-500.
- [13]. Singh S, Singh R, Singh JP, Anesthetic Potential of Lignocaine/ Prilocaine Cream (EMLA) Versus Lignocaine infiltration for radiofrequency ablation of warts, *International Journal of Pharmaceutical Sciences and Research*, 3(3), 2012, 858-62.