

COMPARATIVE EVALUATION OF PAIN PERCEPTION AND COMFORT OF THE CHILDREN FOLLOWING EXTRACTION OF GRADE III MOBILE TEETH USING LIGNOCAINE PATCH AND LIGNOCAINE GEL AS A TOPICAL ANAESTHETIC AGENT IN CHILDREN AGED 8-12 YEARS -A RANDOMIZED CONTROLLED TRIAL***¹Dr. Megha Gaded, ²Dr. Deepak B. M., ³Dr. Basappa N. and ⁴Dr. Chandrashekar Yavagal**¹Post Graduate Department of Pedodontics and Preventive Dentistry, Bapuji Dental College and Hospital Davangere.²Professor, Department of Pedodontics and Preventive Dentistry, Bapuji Dental College and Hospital Davangere.³Professor and Head of Department, Department of Pedodontics And Preventive Dentistry, Bapuji Dental College and Hospital Davangere.⁴Professor, Department of Pedodontics and Preventive Dentistry, Bapuji Dental College and Hospital Davangere.***Corresponding Author: Dr. Megha Gaded**

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ABSTRACT

Background: Pain management is critical aspect in pediatric dental care. In pediatric dentistry it is important to acknowledge that pain sensation is not necessarily dependent on tissue damage, it is generated by conditions like sound of drill, touch of needle during local anaesthetic injection. Exploring alternative, atraumatic methods will help us to improve the quality of dental care. Development of bioadhesive patch has major advancement in intraoral delivery of local anaesthesia which reduces injury caused by local anaesthetic injection and improves patient compliance. **Objectives:** To evaluate and compare pain perception and comfort of children following extraction of grade III mobile teeth using lignocaine patch and lignocaine gel. **Methodology:** 70 children aged between 8-12 years requiring grade III mobile teeth extraction were divided equally into Group I and group II. In group I: lignocaine patch was applied buccally and lingually or palatally on either side of oral mucosa, left for 5 minutes. In group II: lignocaine gel was applied in same manner using cotton swab, left for 5 minutes. After 5 minutes, Once symptoms of anaesthesia were achieved teeth was extracted using appropriate forceps. Each child completed FPS and SEM scale before and after procedure. **Results:** Lignocaine patch showed lower mean pain and comfort scores under both FPS and SEM Scale compared with lignocaine gel, results were statistically significant. **Conclusion:** Lignocaine patch had positive effect on reducing pain during extraction. It is more efficient and reliable technique to achieve topical anaesthesia.

KEYWORDS: Pain perception, Lignocaine patch, Lignocaine gel, Comfort, Extraction.**INTRODUCTION**

Pain is a highly complex and multidimensional defense mechanism that alerts the organism regardless of real or apparent tissue damage, to take action in relieving the presence of a potential stimulus.^[1]

Fear of pain related behaviors is the most difficult aspect of children supervision in dental office. Mota- Veloso et al in 2016, found that most children delay their dental visits because of fear of pain and injections which can negatively influence the patient's oral health and quality of life.^[2]

In pediatric dentistry, it is important to confess that the pain sensation is not necessarily dependant on tissue damage; it may also be generated by condition stimuli such as sound of the drill or of the touch of the needle during local anesthetic injections.^[1] Reduction of pain

during dental procedure can nurture the relationship of the child patient and dentist, building trust, allaying fear and anxiety and promoting a positive behavioral attitude, as well as help to provide overall comfort and well-being during the entire dental experience.^[3] Several means exist, including pharmacological and psychologic strategies, to reduce pain and unpleasantness.^[4]

The dentist must possess certain knowledge, readiness, and skill for the administration of painless anaesthesia. There are two important aspects in this context; the first is behaviour modification through communication and second is a technical procedure in order to ensure a non-traumatic experience for the child. For this reason topical anaesthesia has been in use in order to reduce pain to the patient.^[1]

Topical anesthesia is a fundamental part of local

anesthesia administration as it has both psychological and pharmacological impact. It is effective on surface tissues (2-3mm in depth) to lower painful needle penetration of the oral mucosa. Topical anaesthetics control pain perception and hence, alter the reaction to pain by blocking the transmission of signals from the terminal fibers of sensory nerves.^[3] and their effects are limited to the control of painful stimuli arising on or just beneath the mucosa.^[1]

The application of topical anesthetic can lower the discomfort of intraoral anesthetic injections; provide anesthesia for intraoral operative procedures, provide symptomatic repose of pain due to superficial mucosal lesions such as ulcers or even relieve toothache and postextraction pain.^[1,3] Various agents are financially available today for topical analgesia. While lignocaine serves as the gold standard, benzocaine is also known for its excellent surface anaesthetic properties. Lignocaine is known to have comparatively allergic reactions when compared with benzocaine. Commercially, topical anaesthetics are available in the forms of aerosols, gels, ointments, pastes, powder, and patches.^[5]

Lidocaine EP 5% medicated plaster (LIDOVALOR)

Beginning in 1990, Noven Pharmaceuticals, a founder and manufacturer of transdermal products, set out to develop a transmucosal delivery system for preinjection numbing so as to address the shared desire of patients and dentists for a better, less painful approach. Ideally, the product would block the injection pain and in case of less invasive procedures, actually remove the need for an injection altogether as this system can provide pain relief "to the bone" owing to rapid onset of <15 min after patch application and moderate duration of action of <30 min after removal.^[1]

The lidocaine patch is a transoral delivery system of lidocaine via a mucoadhesive base attached to the oral mucosa. The anesthetic agent is taken up by the mucosa and the reported onset of anesthetic effect is within 2 minutes of application and may last up to 30 minutes after removal. Indications for use include superficial mucosal and gingival procedures, and topical analgesia prior to injectable local anesthesia. Although the lidocaine patch is considered a good alternative to conventional topical agents by some authors.^[6]

The anaesthetic efficacy of Lidocaine bio-adhesive patches for various treatment procedures such as extraction of grade 2 and grade 3 mobile primary teeth, restorative treatments and pulpal therapies was evaluated in a study conducted and it provided superior anaesthesia during exodontia of mobile primary teeth than for pulpal therapy.^[2]

The purpose of this study is to evaluate and compare the pain perception and comfort of the children following the use of the lignocaine (lidovalor) patch versus the

lidocaine topical anaesthetic gel (septodont) for extraction of grade III mobile teeth.

MATERIALS AND METHODS

The materials required for procedures were.

- Mouth mirrors
- Straight Probe
- Kidney trays
- Cotton rolls
- Nasal mask
- 5% Lignocaine patch (LIDOVALOR)
- 5% Lignocaine gel (SEPTODENT)
- Extraction forceps
- Children aged between 8 to 12 years were selected from the outpatients required for the dental extraction from the department of paedodontics and preventive dentistry, Bapuji Dental College and Hospital, Davangere. A general examination of the selected children was done prior to the study, to assess if he/she fulfill the selection criteria. Informed consent was taken from the parent/guardian after explaining the entire treatment procedure and the assent form was obtained from the children and children were randomly distributed equally into two groups. Methodology was carried out according to the consort guidelines-2010 for randomised controlled trial.

EVALUATION OF TOOTH MOBILITY^[7]

Tooth mobility will be evaluated by holding the tooth between the two metallic instruments or one finger and one metallic instrument and effort is made to move the tooth in all directions.

Classification of mobility by Grace and Smales^[7]

GRADE	MOBILITY INTERPRETATION
Grade 0	No apparent mobility
Grade 1	Tooth mobility is perceptible, but less than 1 mm buccolingually
Grade 2	Mobility is between 1-2 mm
Grade 3	Mobility exceeds 2 mm buccolingually

CLINICAL PROCEDURE FOR APPLICATION OF LIGNOCAINE PATCH

Following case history and clinical examination, the procedure was explained to the child and parents in a simple terminology. Then a brief explanation was given to the child about FPS scale after which the child was asked to choose the face that best described his/ her feelings. This step was performed to determine baseline comfort before applying the topical anaesthetic to ensure the absence of any discomfort. If present, verbal communication was done. In order to avoid anxiety, no mention of any anticipated or expected pain during explanation of the scale or before the procedure was done. Both FPS and SEM scale score were recorded before starting procedure.^[6]

GROUP A: 5% LIGNOCAINE PATCH(LIDOVALOR)

The oral mucosa was dried with a cotton roll before application of the topical anaesthesia. Lignocaine patch (lidovalor) was cut into two pieces of equal sizes. Then lignocaine patch was shown to the child after removing the protective liner. Patch were placed buccally and lingually or palatally on either side of the oral mucosa using firm pressure and informing them that it will put their teeth into sleep. The lignocaine patch was left undisturbed for 5 minutes at the target site. After 5 minutes, the patch was removed, and the anaesthetic effect was evaluated by probing at the target site using a sterile probe. The extraction procedure was performed once the symptoms of anaesthesia were achieved by superficial probing, deep probing. Teeth was then extracted using appropriate forceps.^[3]

Subjective symptoms were assessed by asking the participants to rate their pain using the Wong-Baker Faces pain scale (FPS) at the completion of the procedure. And the objective symptoms were also recorded using the Sound, Eye, Motor scale (SEM) after the procedure.^[1,3]

CLINICAL PROCEDURE FOR APPLICATION OF LIGNOCAINE GEL

Following case history and clinical examination, the procedure was explained to the child and parents in a simple terminology. Then a brief explanation was given to the child about FPS scale after which the child was asked to choose the face that best described his/ her feelings. This step was performed to determine baseline comfort before applying the topical anaesthetic to ensure the absence of any discomfort. If present, verbal communication was done. In order to avoid anxiety, no mention of any anticipated or expected pain during explanation of the scale or before the procedure was done. Both FPS and SEM scale score were recorded before starting procedure.^[6]

GROUP B: 5% LIGNOCAINE GEL (SEPTODONT)

The oral mucosa was dried with a cotton roll before application of the topical anaesthesia. Lignocaine gel was applied on both buccal and lingual or palatal site on the oral mucosa using sterile cotton swab. and informing them that it will put their teeth into sleep. The lignocaine gel was left undisturbed for 5 minutes at the target site. After 5 minutes, the anaesthetic effect was evaluated by

probing at the target site using a sterile probe. The extraction procedure was performed once the symptoms of anaesthesia were achieved by superficial probing, deep probing. Teeth was then extracted using appropriate forceps.^[3]

Subjective symptoms were assessed by asking the participants to rate their pain using the Wong-Baker Faces pain scale (FPS) at the completion of the procedure. And the objective symptoms were also recorded using the Sound, Eye, Motor scale (SEM) after the procedure.^[3]

EVALUATION CRITERIA

1. SUBJECTIVE METHOD

1. Pain perception: FPS^[1]

Wong-Baker faces pain rating scale (FPS) which is a subjective scale to assess the pain perception. The child was shown a set of six cartoon faces with varying facial expressions ranging from a very smiling face to a very sad face. A brief explanation was given to the child about each face after which the child was asked to choose the face that best described his/her feelings before and after the procedure.^[1]



The FPS measured the unpleasantness and dimension of a child's pain experience.

2. OBJECTIVE METHOD

1. Child comfort

SEM SCALE: SOUND, EYE, MOTOR SCALE.^[1,6]

The Sounds, eyes, and motor (SEM) scale was used to measure the comfort and observed pain. It is divided into two categories of comfort and discomfort. The discomfort response is further divided into three subscales: mild discomfort, moderate discomfort, and severe. taking into account SEM components of the children response to stimulation. The score in each category of the scale ranges from 1 (no physical response to pain) to 4 (intense reaction to pain).

PARAMETER	COMFORT LEVEL			
GRADE	1- COMFORT	2-MILD DISCOMFORT	3-MODERATE DISCOMFORT	4- SEVERE DISCOMFORT
Sound	No sounds indicating pain	Nonspecific sounds. Possible indication of pain.	Specific verbal complaints (such as "OW"), raises voice	Verbal complaint indicate intense pain (such as screaming, sobbing)
Eye	No eye signs of discomfort	Eyes wide, show of concern, no tears	Watery eyes, eyes flinching	Crying tears running down face
Motor	Hands relaxed;	Hands showing	Random movement	Movement of hands to

	no apparent body tension	some distress or tension; grasping of chair owing to discomfort, muscular tension	of arms or body without aggressive intention of physical contact, grimacing, twitch.	make aggressive physical contact (such as pushing, pulling head away)
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The obtained responses from both scales were subjected to statistical analysis without revealing the identity of the products.

RESULTS

There was a statistically significant difference between the lignocaine patch and the gel group. ($P < 0.011$) with

respect to FPS score given by the children (Table 5, Graph 1). Similarly, with respect to SEM scale, there was a statistically significant difference between the patch and the gel groups ($P < 0.019$) (Table 6, Graph 2). Lignocaine patch application showed increased comfort and less mean pains score in children compared to lignocaine gel group.

Table 1: Descriptive statistics showing FPS scores before and after intervention in the lignocaine gel and lignocaine patch group.

FPS Scale	Lignocaine Gel		Lignocaine Patch	
	Before intervention	After intervention	Before intervention	After intervention
Score 0: Does not hurt	35 (100%)	23(65.7%)	35 (100%)	31 (88.6%)
Score 2: Hurts a little bit	0	9(25.7%)	0	4 (11.4)
Score 4: Hurts a little more	0	2 (5.7%)	0	0
Score 6: Hurts even more	0	1 (2.9%)	0	0
Score 8: Hurts whole lot	0	0	0	0
Score 10: Hurts worst	0	0	0	0
Median Score	0	0	0	0

Table 2: Descriptive statistics showing SEM scores before and after intervention in the lignocaine gel and lignocaine patch group.

SEM SCALE	Lignocaine Gel		Lignocaine Patch	
	Before intervention	After intervention	Before intervention	After intervention
Score 1-comfort	35 (100%)	29 (82.9%)	35 (100%)	35 (100%)
Score 2- mild discomfort	0	5 (14.3%)	0	0
Score 3- moderately discomfort	0	1 (2.9%)	0	0
Score 4- severe discomfort	0	0	0	0
Median Score	1	1	1	1

Table 3: Comparison of FPS and SEM scores before and after intervention in lignocaine gel group using Wilcoxon signed-rank test.

		N	Mean Rank	Sum of Ranks	Z	p value
FPS scores	Negative Ranks	0	0.00	0.00	-3.213	0.001*
	Positive Ranks	12	6.50	78.00		
	Ties	23				
SEM scores	Negative Ranks	0	0.00	0.00	-2.333	0.020*
	Positive Ranks	6	3.50	21.00		
	Ties	29				

Table 4: Comparison of FPS and SEM scores before and after intervention in lignocaine patch group using Wilcoxon signed-rank test.

		N	Mean Rank	Sum of Ranks	Z	p value
FPS scores	Negative Ranks	0	0.00	0.00	-2.000	0.046
	Positive Ranks	4	2.50	10.00		
	Ties	31				
SEM scores	Negative Ranks	0	0.00	0.00	0.000	1.000
	Positive Ranks	0	0.00	0.00		
	Ties	35				

Table 5: Comparison of post intervention FPS scores between lignocaine gel and lignocaine patch group using Man Whitney U test.

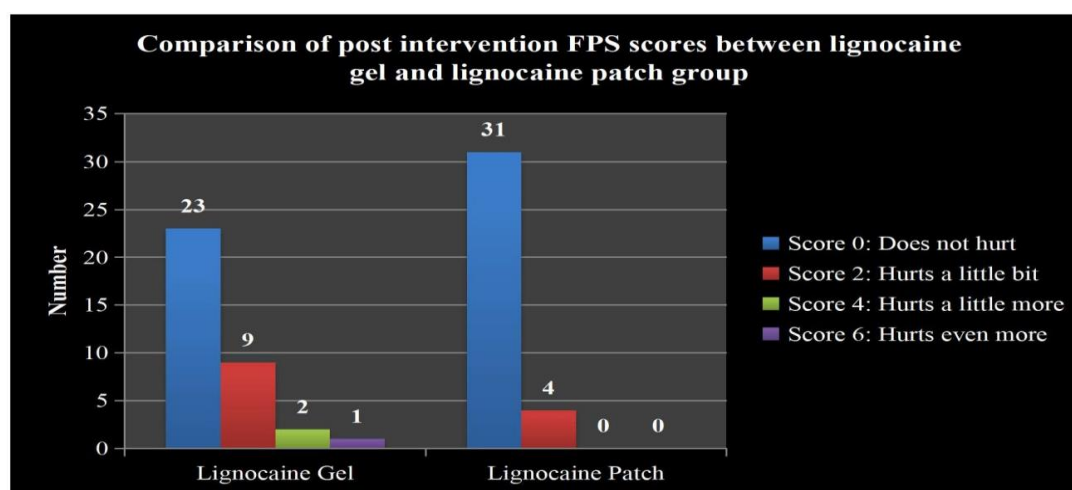
FPS scores	N	Mean Rank	Sum of Ranks	Mann-Whitney U	Z	p value
Lignocaine gel	35	38.50	1347.50	507.500	-2.542	0.011*
Lignocaine patch	35	32.50	1137.50			

Table 6: Comparison of post intervention SEM scores between lignocaine gel and lignocaine patch group using Man Whitney U test.

SEM scores	N	Mean Rank	Sum of Ranks	Mann-Whitney U	Z	p value
Lignocaine gel	35	39.67	1388.50	466.500	-2.345	0.019*
Lignocaine patch	35	31.33	1096.50			

Table 7: Wong Baker Faces Pain Rating Scale.**Table 8: Sound, Eye, Motor Scale for the assessment of child's comfort.**

PARAMETER	COMFORT LEVEL			
GRADE	1-COMFORT	2-MILD DISCOMFORT	3-MODERATE DISCOMFORT	4- SEVERE DISCOMFORT
Sound	No sounds indicating pain	Nonspecific sounds. Possible indication of pain.	Specific verbal complaints (such as "OW"), raises voice	Verbal complaint indicate intense pain (such as screaming, sobbing)
Eye	No eye signs of discomfort	Eyes wide, show of concern, no tears	Watery eyes, eyes flinching	Crying tears running down face
Motor	Hands relaxed; no apparent body tension	Hands showing some distress or tension; grasping of chair owing to discomfort, muscular tension	Random movement of arms or body without aggressive intention of physical contact, grimacing, twitch.	Movement of hands to make aggressive physical contact (such as pushing, pulling head away)

**Figure 1: Comparison of post intervention FPS scores between lignocaine gel and lignocaine patch group.**

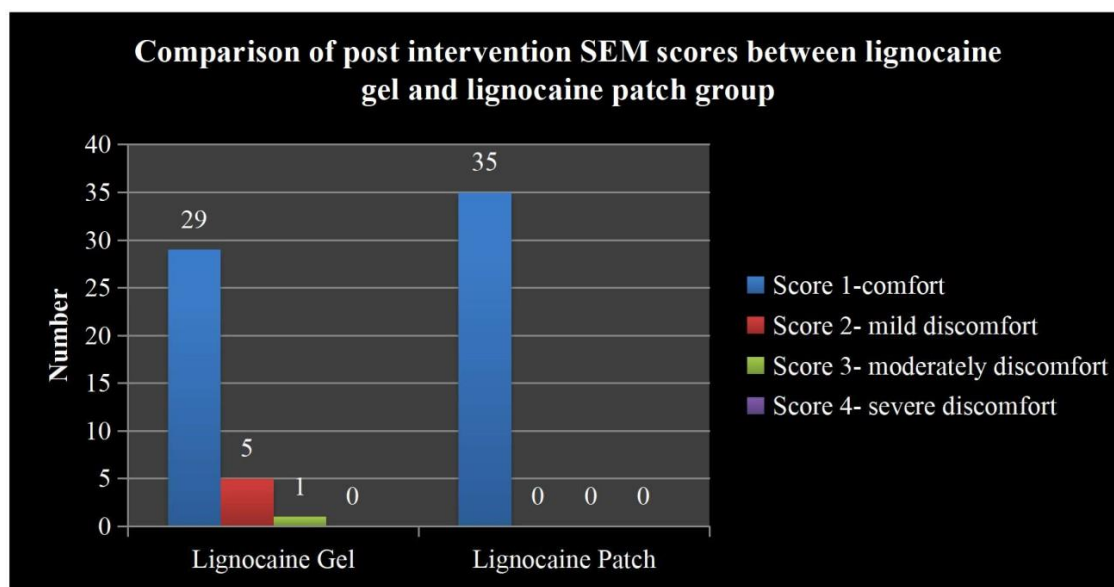


Figure 2: Comparison of post intervention SEM scores between lignocaine gel and lignocaine patch group.

DISCUSSION

New methods have been introduced to facilitate dental procedures, but the administration of local anesthetic is still necessary to perform pain control during several dental procedures. The thought and performance of local anesthetic injection often provoke feelings of discomfort for the patient and have been described as one of the most anxiety-provoking procedures in dentistry.^[8] Therefore, any procedure that significantly reduces the unpleasantness of dental injection could serve as a positive reinforce toward obtaining dental care.^[1]

Topical anesthetics are frequently used in dentistry in order to reduce or eliminate pain during an injection procedure.^[9] Therefore, The present study was conducted among 70 children in the age range of 8-12 years (This age was selected because children of this age range would possess sufficient verbal and cognitive skills to communicate well and understand the instructions and explanation given about the treatment) to evaluate the pain perception and comfort of the children following the use of two lidocaine based delivery systems- the lidocaine patch 5% (LIDOVALOR) versus the lidocaine topical anesthetic gel 5% (SEPTODONT) as a topical anaesthetic agent for extraction of grade III mobile teeth.

The topical anesthetic gels that are frequently used lack bio adhesiveness to the oral mucosa, making them relatively ineffective.^[1] Therefore, the Lidovalor patch system was used to overcome this problem and ensure contact with the oral mucosa.

It is clinically important to note that uncooperative children can give imperfect pain assessment, all the children selected for this study were cooperative (positive or definitely positive according to the Frankel's Behavior rating scale.^[1] Children with previous painful dental experiences were excluded as negative experience can affect the degree of response to painful stimuli.

Children who came to the clinic in need of emergency treatment were also excluded as their reaction to the painful procedures would not have been reliable. Besides, some of them were on medications or analgesics that could have distressed the outcome.^[10]

Pain thresholds and physical reactions to stimuli vary among children; pain is extremely difficult to quantify in children, therefore, one scale may not quantify the pain of a child. For better outcomes of the present study, two different scales (subjective and objective) were used to assess pain. The SEM scale used is an objective scale that measures pain or discomfort considering the SEM components of child's response to stimulation. Moreover, this scale has a 90% inter-rater reliability. The subjective scale used was FPS scale which measures the degree of unpleasantness or effective dimension of child's pain experience especially in children aged from 3 to 17 years. According to Lindsay et al., the FPS scale has been translated to over 30 languages and showed good construct validity as self-report pain measure.^[8]

The bio-adhesive patches used in this study were of size 14 cm × 10 cm and contains: lidocaine EP 5 % w/w. Each medicated patch contains adhesive material impregnated with 700 mg lidocaine EP (50 mg/g adhesive) in an aqueous base. It has been recently approved by the FDA. The maximum safe dose of Lidocaine without adrenaline is 3 mg/kg body weight.^[11]

CONCLUSION

The following conclusions can be drawn from the study

- The Lignocaine patch (LIDOVALOR) was perceived to be significantly more effective in reducing pain than the lignocaine gel in children.
- The lignocaine patch proved to be a more efficient and reliable technique to achieve topical anaesthesia in children

- Lignocaine patch application showed increased comfort in children.
- Hence, bioadhesive patches can be considered as a viable substitute in the future over infiltration anaesthesia for various minor oral surgical procedures of the soft tissue, thus overcoming the pain and anxiety associated with injections particularly in children.

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