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Original Article

COMPARATIVE EVALUATION OF THE EFFICACY OF LIGNOCAINE AND BENZOCAINE PATCHES FOR VARIOUS DENTAL TREATMENTS IN CHILDREN

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Abstract :

This study was done to evaluate the clinical efficacy of lidocaine and benzocaine patches in various dental treatment in children. A total of 120 patients were divided into two groups ,i.e Group A and Group B. Group A, consisted of 60 children where lignocaine patches were placed and Group B where Benzocaine patches were placed. For each group, the onset of action was recorded after checking for symptoms of anesthesia ,subjective and objective pain assessment was evaluated by the VAS and the SEM scale. There was an earlier onset of action which was seen for Lignocaine compared to Benzocaine. But when each of the treatments were compared the anesthetic effect from patches kept the patient comfortable for minimally invasive procedures like band adaptation and was statistically significant .The VAS(Visual analogue scale) scores recorded were statistically significant for the pulpectomy procedure for Benzocaine group compared to Lignocaine. SEM (Sound eyes motor scale) scores were suggestive that the children were more comfortable with the Lignocaine patches when compared to Benzocaine patches.($p < 0.0001$).

The extraction procedures of only grade 3 mobile teeth, pulp therapy for non-vital teeth and band adaptation were clinically successful for both the groups. Our study concluded that, bioadhesive patches can be an alternative over infiltration anesthesia in minimally invasive dental procedures and also could be used successfully for reducing the pain of nerve blocks for children as well as adults which has to be administered in the case of more invasive procedures like pulp therapy.

Keywords : Topical anesthesia, Lidocaine, Benzocaine, patch

Introduction:

Fear related behavior is well recognized as the most difficult aspect of patient management and a barrier to good dental care.[1, 2] Several means exist , including pharmacological and psychologic strategies , to reduce pain and unpleasantness.[3] The pharmacological management includes a multitude of drugs administered by oral, parenteral or inhalational routes, each having its own advantages and disadvantages. Anxiety is one of the major issues in the dental treatment in children and the needle is the most anxiety provoking procedure for both children and adults.

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Studies showed that patients rated the feel of the injection needle penetrating the mucosa as the most fear-provoking stimuli in dentistry. While just the sight of the needle itself was ranked as the most fear –provoking.[1] Investigations have supported these negative connotations associated with dental needles and injections among patients. Fear of painful stimuli, such as needle penetration, appears to be learned and is thought to be a major contributor to the avoidance of routine dental care.[4, 5, 6]

There is a constant search for ways to avoid the invasive and often painful nature of administering local anesthesia and to find more comfortable and pleasant means for anesthesia before dental procedures. Topical anesthesia is

used in dentistry to reduce or eliminate the discomfort of needle penetration.[7] A number of clinical studies have been conducted regarding the effectiveness of such drugs, some showing the advantages of topical anesthetics and others showing that they are no more effective than a placebo.[8]

The development of bioadhesive patch represents a major advancement in the intra oral delivery of topical anesthesia. A topically applied patch has several advantages over the conventional delivery techniques. These have improved patient compliance, elimination of bleeding complications associated with injections in hematologically compromised patients and soft tissue lacerations and reduction in injuries caused to nerves by the insertion of needles.[9]

The anesthetic efficacy of Lidocaine bioadhesive 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 anesthesia during exodontia of mobile/ firm primary teeth than for pulpal therapy. The efficacy of the lidocaine bioadhesive patches were far more limited during pulpal therapy compared to extraction and restorative procedures.[1]

Lignocaine bio adhesive patches have been experimented which is evident from the large number of studies which have been conducted. In the present study, benzocaine was included as the drug of choice so as to widen the choice of availability of the local anesthetic patches in case of idiosyncratic reactions, local or untoward reactions towards lignocaine. Benzocaine has been implemented in ointments and creams as topical anesthetics but not in patches. Through the present study, the clinical efficacy of Lignocaine and Benzocaine patches for various dental procedures in children was studied.

Materials and methods:

120 children reporting to the Department of Pedodontics of A.B Shetty Institute of Dental Sciences between the age groups 6-14 years of both genders for various dental treatment were included in this study. Informed consent from the parents and ethical clearance from the teaching institution was obtained.

The study groups are:-

The selected children were divided into two groups, Group 1 &Group 2 of 60 each for Lignocaine & Benzocaine patch for various dental treatment.

In each of the groups, extraction of grade 1, grade 2 or grade 3 mobile teeth were performed on 25 children, pulpectomy on 30 children and band adaptation procedures on 5 children respectively for the primary teeth.

The onset and duration of action of these patches were recorded by superficial probing on the gingival mucosa and compared[10]. Any untoward reaction exhibited by the child following its administration was scored as a complication to the procedure. Visual analogue scale was also recorded as subjective symptoms and SEM scales was used to record the objective symptoms.[11, 12.] Each of the 40 mg Lidocaine patch was cut into 2 pieces of equal sizes and placed buccally and lingually/ palatally on either side of the tooth to be treated appropriately in the sulcus. After placement of the patch, objective signs were checked for the effect of anesthesia and treatment carried out. Pain assessment was done by using the Visual analogue scale & Sound, Eyes& Motor scale.

Results:

Of the 120 children, our present study enrolled 55.2% of males and 44.8% of females in Group 1 (Lignocaine) and in group 2 (Benzocaine), 51.7% of males and 48.3% of females, (Table 1)

For the extraction procedure, the use of patches were uneventful and clinically successful for grade 3 mobile teeth. For grade 2 and 1 mobile teeth , the procedures had to be performed following the conventional method of delivering Local anesthesia . Use of the patches were successful for pulpectomy procedures of non –vital teeth and had to be complimented with the conventional method of delivering local anesthesia irrespective of the

Keywords: Topical anesthesia, Lidocaine, Benzocaine, patch

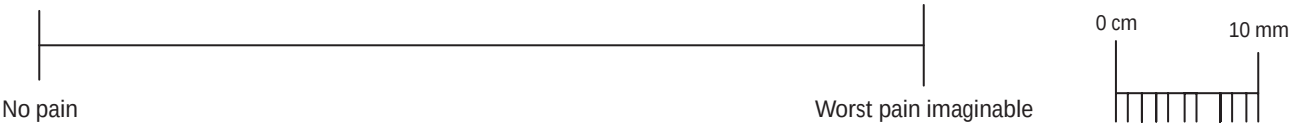
anesthetic agent used for the vital teeth. The comfort level of the patient was appreciable and children were cooperative, towards the conventional method of injections, post patch placement, which confirmed successful soft tissue anesthesia of patches. The band adaptation procedure was successfully performed with both the groups. (Table 2)

Lignocaine had an earlier onset of action for the non invasive procedure such as band adaptation compared to Benzocaine, which was statistically significant. (p= 0.055) (Table 3) (Bar diagram 1)

The subjective symptoms scored by the VAS scale were high for Benzocaine (Group 2) compared to Lignocaine(Group 1) which was statistically significant (p=.003). For extraction, the comparison of VAS scores between group1 and group 2 were statistically not significant. The VAS scores in group 2 was high for pulpectomy procedures compared to group 1, (p = .01) which was statistically significant. For band adaptation procedures, the comparison of VAS scores between group1 and group 2 was not statistically significant. (Table 4, 5) (Bar diagram 2)

The objective symptoms scored by the SEM scale showed that in Group 1, 11.7% of the patients and in group 2, 11.9% of the patients were given the SEM score of 2. 48.3% of the patients in group 1, 27.1 % of the patients in group 2, were given the SEM score of 3. In group 1, 40% of the patients and in group 2, 61% of the patients were given a SEM score of 4 and it showed that the test was statistically significant, p value being <.001.This infers that the patients were more comfortable with the lignocaine patches compared to benzocaine patches as the patients evidently displayed more discomfort with the benzocaine patches. (Table 6) (Bar diagram 3)

Visual Analogue Scale [11] :- Diagrammatic representation of VAS.



It is a line that represents a continuum of a particular experience , such as pain. The most common form used for pain is a 10 cm line , with perpendicular stops at the ends .The ends are anchored by " No pain" and " Worst pain imaginable"

1.SOUNDS ,EYES, MOTOR (SEM) SCALE)[12]:-

Table 1:- SEM scale

OBSERVATIONS	1 COMFORT	2 MILD DISCOMFORT	3 MODERATELY PAINFUL	4 PAINFUL
SOUNDS	No sounds indicating pain	Non specific sounds. Possible pain indication	Specific verbal complaints:- 'ow' raises voice.	Verbal complaint indicates pain. Eg:-scream
EYES	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 tenseness	Hand show some distress or tension, grasps chair due to discomfort, muscular tension.	Random movement of arms or body without aggressive intention of physical contact, grimace, twitch.	Movement of hands to make aggressive contacts. Eg:- Punching.

Table 2: Gender Distribution in Group 1 (Lignocaine) and Group 2 (Benzocaine)

			Group		Total
			Group I	Group II	
Gender	Male	Count %	32 55.2%	31 51.7%	63 53.4%
	Female	Count %	28 44.8%	29 48.3%	57 46.6%
Total		Count %	60 100.0%	60 100.0%	120 100.0%

Keywords: Topical anesthesia, Lidocaine, Benzocaine, patch

Table 3: Various dental procedures performed in both the groups.

Dental procedures performed	Group 1 (Lignocaine) (n=60)			Group 2 (Benzocaine) (n=60)			Procedures Performed successfully with patches	
Extraction (n=50)	(no= 25)			(no= 25)			Group1	Group 2
	grade 1	grade 2	grade3	grade 1	grade 2	grade3	10	8
	8 (32%)	7(28%)	10(40%)	9(36%)	8(32%)	8(32%)		
pulpectomy (n=60)	(no= 30)			(no= 30)				
	non-vital 9(30%)	vital 21(70%)		non-vital 8(26.6%)	vital 22 (73.4%)		9	8
band adaptation (n=10)	(no=5)			(no=5)			5	5
	5(100%)			(no=25)				

Table 4: Comparison of onset of action of 3 groups of treatment between Group 1(Lignocaine) and Group 2(Benzocaine).

	Group	N	Mean (mins)	Std. Deviation (±)	Std. Error Mean	p value
Extraction	GROUP 1	25	13.4615	2.35339	.46154	0.184
	GROUP 2	25	14.5652	3.34156	.69676	
Pulpectomy	GROUP 1	30	14.3103	3.46517	.64347	0.424
	GROUP 2	30	15.0000	3.16228	.56796	
Band adaptation	GROUP 1	5	10.0000	.00000	.00000	0.055
	GROUP 2	5	14.0000	4.18330	1.87083	

Table 5: Vas comparison between group 1 (Lignocaine) and group 2 (Benzocaine)

	Group 2	N	Mean	Std. Deviation(±)	Std. Error Mean	p value
Vas	GROUP 1	60	6.2712	1.78915	.23293	0.003
	GROUP 2	60	7.1500	1.32544	.17111	

Table 6 : Comparison of VAS scale for the various procedures done between the two groups i.e Lignocaine(Group 1) and Benzocaine(Group2)

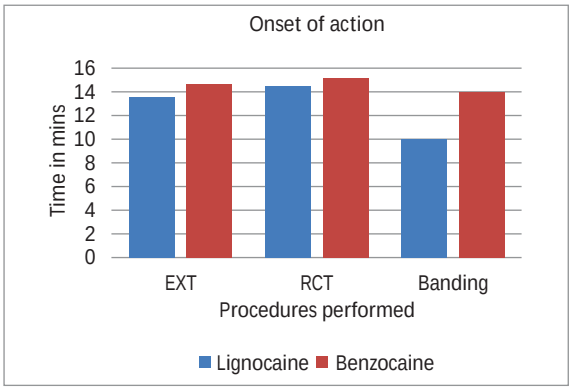
Group		N	Mean	Std. Deviation (±)	p value
Group II	Ext	25	6.2609	1.88818	
	pulpectomy	30	7.4194	.95827	0.01
	Band adaptation	5	5.4000	1.14018	
Group I	Ext	25	6.7586	1.66165	
	pulpectomy	30	6.9615	.87090	0.26
	Band adaptation	5	4.8000	.44721	

Table 7 : Comparison of the sound, eyes, motor scale between the Lignocaine and the Benzocaine group.

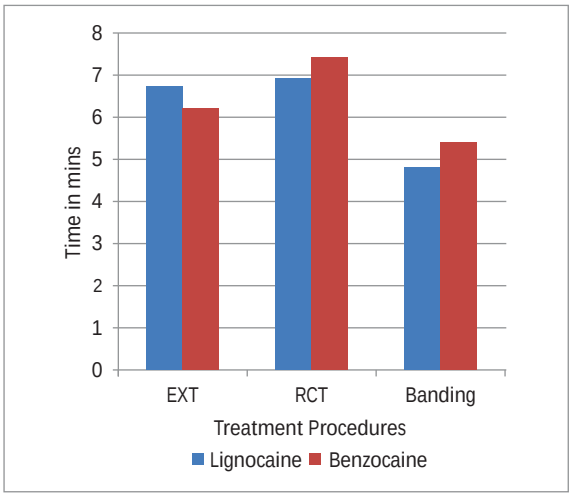
			group		Total
			Group II	Group I	
SEM	2.00	Count	7	7	14
		%	11.9%	11.7%	11.8%
	3.00	Count	17	29	46
		%	27.1%	48.3%	37.8%
	4.00	Count	36	24	60
		%	61.0%	40.0%	50.4%
Total		Count	60	60	120
		%	100.0%	100.0%	100.0%

	Value	Asymp. Sig. (2-sided)
Pearson Chi-Square	41.222	.000

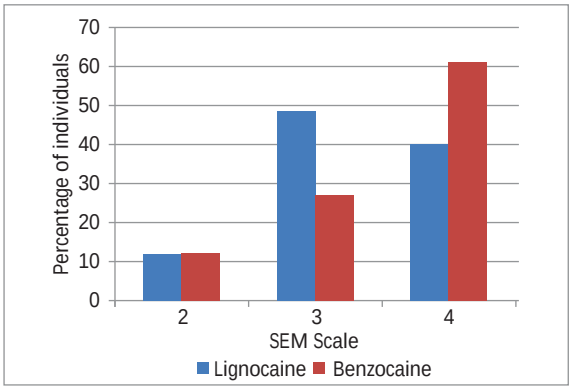
Bar diagram 1:- Comparison of the onset of action between Lignocaine and Benzocaine patches.



Bar diagram 2 : Comparison of VAS among the two groups.



Bar diagram 3 : Comparison of SEM scale between Lignocaine & Benzocaine.



Discussion :

Intraoral anesthetic procedure 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 injections cause the greatest amount of physiologic arousal during a dental appointment. The fear arising from particular stimuli, such as injection needles, plays a significant role in explaining why some individuals avoid regular dental care. Alleviation of belonephobia can make the dental experience pleasant & comfortable which is one of the goals of Pediatric Dentistry[13].

The development of the bioadhesive patch containing anesthetics represents an advancement and the choice of drugs in the bioadhesive patches will prove to be a bigger advantage in terms of efficacy and variable pharmacology of two different drugs.

Anesthetic agents, Lidocaine and Benzocaine used in the present study are most commonly used. Adrenaline was not incorporated in the bioadhesive patch as it might cause tissue necrosis due to its vasoconstrictive property, when applied to the mucosa. The amount of Lidocaine Hydrochloride contained in the patch was similar to that used for a single dental block or infiltration (2ml of 2% lidocaine Hcl).

The dosage is in concurrence with that used by Taware CP et al in their study of 49 dental extractions attempted using the bioadhesive patches. However, Harsh EV et al (1996) used concentration of 10% and 20% in the patches, which contained 23mg and 46mg respectively of the drug. The content of one cartridge of local anesthesia contain 1.8 ml of 2% lidocaine , which amounts to 36 mg of the drug .Therefore, they consider that even such significant amounts of the drug can be used in these bioadhesive patches[9].

In our study, it was observed that Lignocaine had an earlier onset of action compared to Benzocaine, and it was in concurrence with the study conducted by Fukayama H and Suzuki N[14]. The potency of the anesthetic patches were

sufficient for the minimally invasive procedures which was statistically significant for banding procedure performed (Table 4) compared to the invasive procedures such as pulpectomy and extraction.

The taste preferences observed was, better acceptance to Lignocaine than to Benzocaine which was in concurrence with the study performed by Kavitha et al.[15]

VAS was used in the present study for the subjective pain assessment because, it is easily understood and related on the scale by the patient. But pain perception varies from patient to patient, so SEM scale is also included. The pain response of the patient towards the two different anesthetic agents; lignocaine and benzocaine was assessed using the above scales.

When VAS was compared between the Lignocaine and Benzocaine for the different treatment procedures, the VAS scores were high for the pulpal therapy for the Benzocaine group (p = .01) which was statistically significant (Table 6). The patients evidently also showed more discomfort with Benzocaine compared to Lignocaine which was in concurrence with the study conducted by Fukayama H et al (Table 5). [14]

On comparison between Benzocaine and Lignocaine group, it was found that the SEM scores ranged between painful (3) and moderately painful (4) which was statistically significant for the Benzocaine group .The patient experienced more discomfort with the Benzocaine patches compared to the Lignocaine patches.(Table 7)

The extraction procedures were performed once the symptoms of anesthesia were achieved by superficial probing, deep probing and gingival retraction. The extraction procedures of grade 3 mobile teeth were clinically successful for both Lignocaine and Benzocaine patches. Grade 1and Grade 2 mobile teeth could not be extracted with help of both Lignocaine and Benzocaine patches and the VAS scale ranged between 6cm to 9 cm in Group 1 and 7cm to 10 cm in group 2 and however, concludes the limitation for both the Lignocaine and Benzocaine patches on extraction procedures for Grade 1 and grade 2 mobile teeth. The extraction procedures of Grade 1 and Grade 2 teeth, were later completed by the conventional method of delivering Local anesthesia and the patients were comfortable during the administration of the injection procedures. (Table 7)

The anesthetic potency of the bioadhesive patch in the current study could be justified for band adaptations as the patients were comfortable throughout the procedure with both the patches. Soft tissue procedures, performed in the subjects, in the present study evidently showed more comfort compared to the treatment procedures such as pulpectomy and extraction. The efficacy of Lidocaine and Benzocaine bioadhesive patches were far more limited during pulpal therapy where the subjective scoring for the Lignocaine group was between 70 mm and 100 mm and for Benzocaine group it was between 60mm to 100mm (Table 7).

The SEM scale had rated a score between moderately painful and painful for both Lignocaine and Benzocaine group. For the vital teeth , as the VAS recorded intense pain, the procedure had to be completed using conventional techniques of administering local anesthesia keeping in mind the drug dosage already administered based on body weight of the child. In non-vital teeth, the pulpectomy treatment could be done with the placement of the patches.

Lignocaine and Benzocaine were not effective for pulpectomy procedures as studies have reported that topical anesthesia is effective for the sensory nerve ending. The pulpectomy procedures for the vital teeth were later completed by the conventional method of delivering Local anesthesia and the patients were comfortable while receiving the injection procedures.

Local application of patches did not cause any allergic reactions, erythema, and ulcerations. odema, etc....in the patients during the procedure and post operatively for Lignocaine and Benzocaine patches.

Hence, bioadhesive patches can be considered as a viable

alternative over infiltration anesthesia in minimally invasive dental procedures and as an adjuvant for the invasive procedures because of better patient compliance & for alleviating their fears. However a larger sample size need to be carried out in future to establish the efficacy of the local anesthetic patches over the time tested conventional methods.

Conclusion :

The use of bioadhesive patches using Lidocaine & Benzocaine has given results which cannot be neglected. The results were appreciable in procedures such as band adaptation and grade 3 mobile teeth but was inadequate for pulpal therapies though the procedure was performed successfully in non vital teeth .The patches also were of limited use in performing the extraction of Grade 1 and Grade 2 mobile teeth. In case of pulpal therapy and extraction, improvements in the dosage form and usage of penetrating agents for increased depth of anesthesia could improve its efficacy.

Hence further studies should be conducted by increasing the dosage form for Benzocaine.. The patients showed more discomfort for Benzocaine compared to Lignocaine. The studies although limited by its treatment of fewer cases suggests that this new non-invasive technique of administering local anesthesia has the potential of gradually replacing infiltration anesthesia in pediatric dentistry successfully. Therefore, they could be useful as a good clinical adjunct for the anesthetic procedures in case of minimally invasive procedures

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