Original Article

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Dentistry Section

Effectiveness of Two Topical Anaesthetic Agents used along with Audio Visual Aids in Paediatric Dental Patients

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ABSTRACT

Introduction: Topical anaesthetic agents enable pain free intraoral procedures, symptomatic pain relief for toothache, superficial mucosal lesions and pain related to post extraction time. Most common anxiety provoking and fearful experience for children in dental operatory is administration of local anaesthesia because on seeing the needle, children usually become uncooperative. One of recent trend of behaviour management technique is using non-aversive techniques out of which audiovisual distraction has emerged as a very successful technique for managing children in dental settings. Audio visual distraction could decrease the procedure related anxiety of patients undergoing dental treatment and can be very relaxing for highly anxious patients.

Aim: The aim of the present study was to compare the efficacy of topical anaesthetics EMLA (Eutectic Mixture of Local Anaesthetics) cream and benzocaine (20%) jelly in reducing the pain during the needle insertion with and without the use of Audio Visual (AV) aids.

Materials and Methods: The study was conducted on 120 children, the age range of 3-14 years attending the outpatient department for their treatment. EMLA and benzocaine jelly (20%) were assessed for their effectiveness in reducing the pain on needle insertion during local anaesthesia administration. Based on the inclusion and the exclusion criteria, children requiring local anaesthesia for the dental treatment were randomly divided into four equal groups of 30 children based upon whether AV aids were used or not. AV aids were given using Sony Vaio laptop with earphones with nursery rhymes and cartoon movies DVD. The pain assessment was done by using the Visual Analogue Scale (VAS) scale and measurement of the physiological responses of pulse rate and oxygen saturation were done by pulse oximeter.

Results: There was a statistically significant difference in the mean pain score, pulse rate and mean oxygen saturation rate when it was compared between the four groups. EMLA with AV aids was found to be a better topical anaesthestic agent as compared to other three groups.

Conclusion: EMLA with AV aids was better when compared with EMLA without AV aids followed by benzocaine with AV aids. Benzocaine topical anaesthetic agent without AV aids was least effective in reducing the pain scores and improving the oxygen saturation rate.

Keywords: Ache, Conduction blocking anaesthetics, Dental phobia, Visual aids

INTRODUCTION

Fear is "an unpleasant emotional condition involving psychosomatic and psycho-physiological reaction to a realistic external threat that includes anxiety, apprehension and mobilization of alarmed response" [1]. It is one of the primary emotions acquired soon after birth to protect the individual from harm and self destruction. The majority of fears evident in children may have been acquired either objectively or subjectively. Objective fears are those which are produced by direct stimulation of sense organs and they don't have any parental origin. Subjective fears are the ones based on feelings and attitudes that have been suggested to the child by others mostly through parents or acquaintances [2].

The anaesthesia for various intraoral procedures like symptomatic relief from the pain of superficial mucosal lesions, toothache and post extraction pain is provided by topical anaesthetic agents. These agents act by blocking the terminal fibres of sensory nerve endings thus controlling painful stimulation during needle insertion [3]. When it comes to dental treatment children are usually lot more anxious and it's very normal for the children to be afraid of new and potentially threatening situations. Most common anxiety provoking and fearful experience for children in dental operatory is administration of local anaesthesia because on seeing the needle, children usually become uncooperative. There is a strong relationship between a child's dental anxiety and successful dental treatment, and also between anxiety and pain [4]. The painful situations like needle insertion can result in fear; while fear and anxiety during dental treatment might amplify the amount of perceived pain. The haemodynamic changes like alteration in pulse rate and oxygen saturation of a patient can also be induced by the pain caused during dental procedure [5]. Management of a fearful child is important because behaviour management of a paediatric dental patient is very crucial in successful outcome of dental treatment.

Behaviour management includes non-pharmacological methods along with the pharmacological means. The present trend is towards using non-aversive techniques out of which AV distraction has also emerged as a very successful technique for managing children in dental settings. The anxiety of patients undergoing dental treatment can be reduced by AV distraction technique and it can be extremely relaxing for fearful patients [6]. Therefore, the present study was undertaken to compare the efficacy of topical anaesthetics EMLA cream and benzocaine (20%) jelly in reducing the pain during the needle insertion with and without the use of AV aids.

MATERIALS AND METHODS

The present randomized controlled clinical study was carried out in Department of Paedodontics and Preventive Dentistry and approved by the institutional ethics committee. The study was conducted on 120 children (60 male and 60 female) in the age range of three to 14 years, irrespective of sex, attending the departmental outpatient department for their treatment. The sample size for each group was calculated based on the mean values obtained in the pilot study to have 80% power and 95% confidence interval. At the mean difference of 2.28, the sample size required for each group was 28 which were rounded off to 30 children, hence making a total sample

size of 120. The children well oriented to surroundings, requiring local anaesthesia for dental treatment with no previous dental experience were included in the present study. The children allergic to any of the components of the topical anaesthetic agents used in the study, medically compromised or the disabled children, children with any dentofacial anomaly and syndrome were excluded from the present study. Written informed consent was obtained from the parents after explaining them the procedure and confirming their participation in the study.

EMLA (lidocaine 2.5% and prilocaine 2.5%) and benzocaine jelly (20%) were assessed for their effectiveness in reducing the pain on needle insertion during local anaesthesia administration. AV aids were given using Sony Vaio laptop with earphones and DVD used were nursery rhymes and cartoon movies. The pain assessment was done by using the VAS scale and measurement of the physiological responses of heart rate and oxygen saturation were done by pulse oximeter (OMRON).

Based on the inclusion and the exclusion criteria, children requiring local anaesthesia for the dental treatment were selected for the study and randomly divided into two equal groups of 60 children which were further subdivided into two equal subgroups of 30 children each based upon whether AV aids were used or not. Thus, the final grouping was as follows:

1) EMLA cream group without AV aids (n=30);
2) EMLA cream group with AV aids (n=30);
3) Benzocaine jelly without AV aids (n=30);
4) Benzocaine jelly with AV aids (n=30).

The vital statistics were recorded for each patient and the child and the parents were made to fill the proforma while they were waiting in the play area. The complete treatment of the patient was done in a single visit. A single examiner checked the patient and carried out the study to rule out any operator bias in recording the scores. Evaluation of the patient was done in four stages in a single visit.

Stage I: Baseline reading: After the patient was seated on the dental chair but prior to any treatment, the pulse oximeter was attached to the patient and the pulse rate and the oxygen saturation were recorded by the examiner.

Stage II: The child was allotted either Group A or Group B consecutively. The site of local anaesthesia delivery was identified, cleaned with sterile gauge piece and dried and the respective topical agent was applied. Pulse rate and oxygen saturation were continuously monitored. The highest pulse rate and at the same time oxygen saturation were recorded for the patient.

Stage III: When the baseline heart rate was attained, the local anaesthetic solution was deposited by the injection. In the experimental group AV aids were used for distraction during needle insertion. In the control groups, no AV aids were used. The video was selected on the basis of the child's age. The younger children were shown nursery rhymes whereas the older children were given the choice of a cartoon movie. The highest pulse rate and the oxygen saturation post injection were recorded. When heart rate returned to base line, the patient was made to complete the VAS for that injection. Once the injection was given the study portion of the appointment was complete and the necessary treatment was then done for the child.

Stage IV: After completion of treatment procedure, the pulse rate and oxygen saturation were again recorded. The patient was sent after the baseline readings were attained. Necessary postoperative instructions were given to the parents and child verbally.

Comparisons were made between the groups and the results obtained were subjected to statistical analysis. The data was analyzed using the SPSS version 19.0 software. The descriptive analysis included mean and standard deviation. The intragroup comparison was done using the one-way ANOVA test and intergroup comparison between the groups was done using the Post-hoc Bonferroni test. The level of significance for the present study was 0.05.

RESULTS

The study population consisted of 120 children with the mean age of 8.8 years. The comparison among the four groups with respect to mean pain scores, mean pulse rate and mean oxygen saturation rate are as follows:

1. Comparison of Mean Pain Scores

The mean pain score in the EMLA group without and with AV aids were 5.7±0.93 and 4.73±1.14 respectively, while in benzocaine group with and without audiovisual aids were 5.86±0.77 and 7.36±0.71 respectively. The comparison between four groups was found to be statistically significant (p<0.001) as shown in [Table/Fig-1].

2. Comparison of Mean Pulse Rates

The mean pulse rate in the EMLA group without and with AV aids were 74.16±2.97 and 72.36±2.38 respectively, while in benzocaine group with and without audiovisual aids were 78.19±3.14 and 80.19±2.14 respectively. The comparison between four groups was found to be statistically significant (p<0.001) as shown in [Table/Fig-2].

3. Comparison of Mean Oxygen saturation rate

The mean oxygen saturation rate in the EMLA group without and with audiovisual aids were 98.36±2.09 and 99.47±2.02 respectively, while in benzocaine group with and without audiovisual aids were 98.31±2.62 and 97.19±2.34 respectively.

Groups		Mean	SD	F-value	p-value
1	EMLA Group (Without AV aid)	5.70	0.93218	23.45	<0.001
2	EMLA Group (With AV aid)	4.73	1.14269		
3	Benzocaine Group (Without AV aid)	7.36	0.71840		
4	Benzocaine Group (With AV aid)	5.86	0.77608		

[Table/Fig-1]: Comparison of mean pain scores among all the groups.
One-way ANOVA test

Groups		Mean (in beats/ min)	SD	F-value	p-value
1	EMLA Group (Without AV aid)	74.16	2.97	22.47	<0.001
2	EMLA Group (With AV aid)	72.36	2.38		
3	Benzocaine Group (Without AV aid)	80.19	2.14		
4	Benzocaine Group (With AV aid)	78.19	3.14		

[Table/Fig-2]: Comparison of mean pulse rates among all the groups.
One-way ANOVA test

Groups		Mean (in %)	SD	F-value	p-value
1	EMLA Group (Without AV aid)	98.36	2.09	22.92	<0.001
2	EMLA Group (With AV aid)	99.47	2.02		
3	Benzocaine Group (Without AV aid)	97.19	2.34		
4	Benzocaine Group (With AV aid)	98.31	2.62		

[Table/Fig-3]: Comparison of mean oxygen saturation rates among all the groups.
One-way ANOVA test

Group	Group	Mean pain score		Mean pulse rate		Mean oxygen saturation rate	
		Mean diff	p-value	Mean diff	p-value	Mean diff	p-value
1	2	0.97	0.048	1.8	0.089	-1.11	0.010
	3	-2.26	0.002	-6.03	<0.001	1.17	0.005
	4	-0.76	0.067	-4.03	0.006	0.05	0.072
2	3	-2.63	<0.001	-7.83	<0.001	2.28	<0.001
	4	-1.13	0.036	-5.83	0.003	1.16	0.004
3	4	1.5	0.024	2.00	0.063	-1.12	0.012

[Table/Fig-4]: Intergroup comparison of mean pain score, pulse rate and oxygen saturation rate.
Post-hoc Bonferroni test, p-value <0.05-significant, p-value <0.001-highly significant

The comparison between four groups was found to be statistically significant (p<0.001) as shown in [Table/Fig-3]. The intergroup comparison among the four groups was found to be statistically significant as shown in [Table/Fig-4].

The pulse rate did not show any significant difference with respect to use of AV aids with any of the anaesthetic agent as shown by Post-hoc results [Table/Fig-4].

Post-hoc results show that EMLA with AV aids was found to have statistically significant difference than EMLA without AV aids. Similar results were seen with the benzocaine group [Table/Fig-4].

DISCUSSION

Fear of the needle is one of the most common anxiety provoking stimuli especially in small children who are probably undergoing their first experience in a dental clinic. Intraoral local anaesthesia is commonly used for children to control pain during dental procedures. Paradoxically, local anaesthetic administration itself produces pain and anxiety that may possibly result in a negative behaviour during dental treatment [3]. Eradication of this fear and anxiety encompasses a major aspect of behaviour management in the field of paediatric dentistry. To develop a cooperative and positive attitude in a child is a critical and desirable outcome of any dental procedure.

Topical anaesthetic agents may be applied prior to needle insertion to reduce the pain due to intraoral local anaesthetic injections. They produce anaesthesia by the direct application of the drug to abraded skin or mucous membrane surface by anaesthetizing their superficial nerve endings. Topical anaesthesia is effective only 2 to 3 mm deep into the surface tissues. However, this surface anaesthesia is sufficient for painless needle penetration during local anaesthetic administration [3].

Benzocaine is the ethyl ester of p-Aminobenzoic Acid (PABA). This agent is effective only on surface tissues; however tissues deep to the area of application are poorly anaesthetized. It is one of the commonly used anaesthetic agents used in paediatric dentistry, due to its characteristics of rapid onset of action (30 sec), acceptable taste, effectiveness and lack of systemic absorption [7]. Lidocaine, chemically is 2-diethylaminoethyl-4-amino-2-propoxybenzoate hydrochloride. Lidocaine hydrochloride tends to penetrate tissues more proficiently than lidocaine base which in turn also makes it more toxic due to the greater possibility of systemic absorption. To overcome this fact various formulations of lidocaine are prepared and one of those preparations is EMLA. EMLA is an oil-in-water emulsion of 2.5% lidocaine and 2.5% prilocaine and when these agents are combined in eutectic form, it results in the formation of polyoxyethylene fatty acid emulsifiers at mouth temperature (37^{0}C) which consequently facilitates its absorption. It was specifically formulated to provide anaesthesia of intact skin surface and is effective when used principally before painful events like venipuncture or needle insertion [8]. Furthermore, research has reported that a five minute topical application of EMLA cream significantly reduces pain that happens during needle insertion of dental anaesthetic agents [9]. The advantages of EMLA are its longer duration of action approximately 60 minutes, thereby making the procedure completely painless [10]. Benefits of these topical anaesthetics are not only pharmacological but also psychological, as they reduce the needle prick pain. This might help in diminishing the anxiety levels which consequently results in better cooperation from the patient.

One of the well accepted means of behaviour modification of uncooperative children is by distraction through AV aids. Distraction is a non pharmacological intervention that breaks one's attention from a non noxious stimulus through passive redirection of the subject's attention or by actively engaging the subject in performing the diversion task. This technique encompasses the method of visual distraction by counting objects or watching TV, vocal distraction by listening to music, touch motion distraction by slow regular breathing and purposive distraction by playing with toys [11]. Of all these distraction methods used among children AV distraction is most effective, because in this type of distraction child listens to music with the earphones as well as sees the cartoon movie on the screen. For this purpose either laptop or television screens could be used. Children with different age groups prefer different distraction movies like younger age group prefer watching nursery rhymes or cartoon movies whereas older age group prefer to watch movies and listening music. Kaur B et al., have reported that there is an effect of AV distraction technique on human emotional and physiological responses like pulse rate [12].

The alteration in the physiological parameters can be very well assessed by the use of pulse oximeter. It is a medical apparatus which monitors the pulse rate and indirectly measures the oxygen saturation rate of a patient's blood [13]. The main physiological indicators of anxiety and pain perception considered are pulse rate and oxygen saturation levels [14]. Thus, considering these factors, the efficacy of two topical anaesthetic agents viz., EMLA and benzocaine (20%) was compared for reducing pain due to needle insertion with or without the use of AV aids. Pain was assessed using VAS and further correlated with the physiological parameters of pulse rate and oxygen saturation.

When the mean pain scores were compared within the EMLA group, it was seen that pain score was significantly lower when AV aids were used. The pulse rate was comparatively lower and oxygen saturation higher when AV aids were used for distraction at the time of needle penetration. Similar results were obtained in the benzocaine group suggesting that when both the topical anaesthetic agents were used separately, the changes in pain score; pulse rate and oxygen saturation were observed when AV methods were used. These results are in accordance to Kaur B et al., and Prabhakar AR et al., who found in their study that audiovisual distraction certainly reduces the pain perception and distress in children during intravenous injection and concluded that AV distraction was more effective in managing anxious paediatric patients in terms of heart rate and oxygen saturation level [12,15]. However, Aitken JC et al., reported that there was no significant difference in heart rate and consequently pain and anxiety in children when music distraction is used [16]. Farrokhnia M et al., investigated the role of cognitive involvement on decrease in pain intensity, heart rate change as well as level of oxygen saturation during lumbar puncture or intrathecal injection and observed that cognitive involvements were competent in plummeting the pain intensity, reducing heart rate and increasing oxygen saturation levels [17]. Another study evaluated the audio and AV distraction technique in the managing of anxious paediatric dental patients and reported that AV distraction technique was more proficient as compared to audio distraction technique alone [15]. Results indicate that there was a decrease in oxygen saturation as pulse rate increased though the difference was not statistically significant. Our findings

regarding the efficiency of AV distraction in reducing pain intensity and changing heart rate and oxygen saturation level are consistent with those of the previous studies. Studies by Tousignant-Laflamme Y et al., have demonstrated the relationship between pain and physiological parameters [18]. Anxiety and discomfort resulting from acute pain releases corticosteroids, glucagon, catecholamines and growth hormone. This increases the heart rate on the one hand, and constricts the vessels on the other, overall compromising the tissue perfusion and oxygenation. In response to pain, heart rate elevates and blood oxygen saturation levels fall. The autonomous nervous system prepares a person for fighting or escaping if a danger or threat is perceived. Children undergoing painful medical procedures manifest similar responses indicating mental pressure. Distracting the child may reduce the physiological changes by diminishing his or her anxiety and discomfort [17].

In the present study, it was seen that the mean pain scores, pulse rate were found to be higher and the oxygen saturation level lower with the use of EMLA (5%) in comparison to benzocaine (20%) both without and with the use of AV aids. The difference was seen to be statistically significant. These results are in agreement with that of Nayak R et al., Dhawan P et al., Primosch ER et al., Dabagh RA et al., Roghani S et al., who all reported that among local anaesthetic agents, EMLA was effective in reducing pain [9,10,19-21]. However, contrary to our findings, Leyda AM et al., concluded that there were no significant differences between these two agents in reduction pain response to needle puncture [7]. These findings are reported when these researchers have used these topical anaesthetic agents without any AV aids.

However, in the present study when these anaesthetic agents were used in conjunction with the AV aids, EMLA was seen to be significantly better than benzocaine. No other study have been reported in dental literature when both EMLA and benzocaine topical anaesthetic agents were compared for pain reduction in combination with AV aids. These results suggest that there might be a synergistic effect of AV aids and the topical anaesthetic agents which helped in the reduction of pain scores in children and consequently lowered the pulse rate and improve the oxygen saturation rate. When all four groups were compared, our findings suggested that the reduction of pain score and increase in oxygen saturation rate was superior in EMLA when used with or without AV aids as compared to benzocaine. EMLA has high water content and is lipophilic making it more permeable which could be the reason for greater pain reduction as compared with benzocaine. This shows that the composition and properties of EMLA are superior to benzocaine in reducing pain when used in combination with AV distraction technique.

The present study indicated a definite positive effectiveness of AV distraction technique in managing dental anxiety in children. The better results obtained with the AV aids can be explained by the fact that AV distraction allowed the children to use two of their senses, becoming more engaged and thereby distracting their attention from the anxiety resulting from the local anaesthesia administration. One of the limitations of the present study was that the study design did not used the split mouth design which would have given more accurate interpretation of the parameters involved in the present study. To conclude, the AV distraction system may be a useful adjunct in paediatric dental clinic to help in reducing anxiety and discomfort associated with the dental procedures. Therefore, there should be widespread and regular use of the AV aids along with other well recognized behaviour management techniques in paediatric dental practice.

CONCLUSION

Within the limitations of this study it can be concluded that EMLA with AV aids was better when compared with EMLA without AV aids followed by benzocaine with AV aids. Benzocaine topical anaesthetic agent without AV aids was least effective in reducing the pain scores and improving the oxygen saturation rate.

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