Research Article

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Comparison of Anxiety in A 5-8 Years Old Children with and Without Novel Syringe Masking Carpule During Local Anesthesia Administration

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ABSTRACT

Background: Despite the skill and art of the operator and care with which the injection is administered, fear of injection and anxiety that comes with it continues to plague the profession of pediatric dentist.

Aim: To assess the efficacy of novel syringe carpule to reduce the anxiety while administrating local anesthesia and To assess & compare the level of anxiety in children with or without alligator sleeves using Venham's picture test (VPT), Venham's clinical rating scale (VCRS) and physiologic parameters.

Materials and Method: Total 40 children aged 5-8 years were divided into two equal groups of 20 children in each group. Group A-conventional syringe group and Group B-with alligator syringe sleeves. Measurement of anxiety before and after the administration of local anesthesia with or without angie angelus alligator syringe cover was done with VPT & VCR scales. Pulse rate and oxygen saturation were recorded, as physiological indicator of anxiety response.

Result: Comparing mean difference of both group A to group B using VPT, VCRS, and pulse rate group B was statistically significant.

Conclusion: Angie angelus alligator syringe sleeves can be considered as an effective measure to reduce injection related anxiety in children.

Keywords: Dental anxiety, local anesthesia, novel syringe.

INTRODUCTION

In spite of new scientific and technologic advancements, dental treatment still is not pleasant for most people and visiting the dentist regularly generates a big deal of anxiety and stress to the patients[1]. Psychological and physiological parameters characterized by somatic, emotional, cognitive and behavioral components is termed anxiety[2]. The word anxiety means 'to vex or trouble'; either in the absence or presence of psychological stress. Anxiety can develop feelings of fear, worry, uneasiness[3]. There is a strong correlation between a child's dental anxiety with pain and also successful dental treatment[4]. Painful dental operations always lead to fear, while fear and anxiety increases the amount of pain to be perceived[5].

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Fig 1: Angie angelus syringe cover.

Fig 2: Injecting local anesthesia in a child with Angie alligator syringe sleeves.

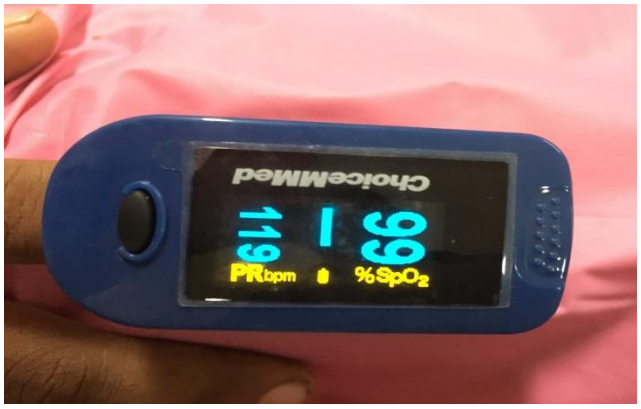

Fig 3: Pulse oximeter (OxyWatch-MD300C2)

0 = Relaxed: smiling, willing, able to converse, displays behavior desired by the dentist
1 = Uneasy: concerned, may protest briefly to indicate discomfort, hands remain down or partially raised. Tense facial expression, 'high chest'. Capable of cooperating
2 = Tense: tone of voice, questions and answers reflect anxiety. During stressful procedure, verbal protest, crying, hands tense and raised, but not interfering very much. Protest more distracting and troublesome. Child still complies with request to cooperate.
3 = Reluctant: pronounced verbal protest, crying. Using hands to try to stop procedure. Treatment proceeds with difficulty.
4 = Interference: general crying, body movements sometimes needing physical restraint. Protest disrupts procedure
5 = Out of contact: hard loud swearing, screaming unable to listen, trying to escape. Physical restraint required

Fig 4: Venham's clinical rating scale.

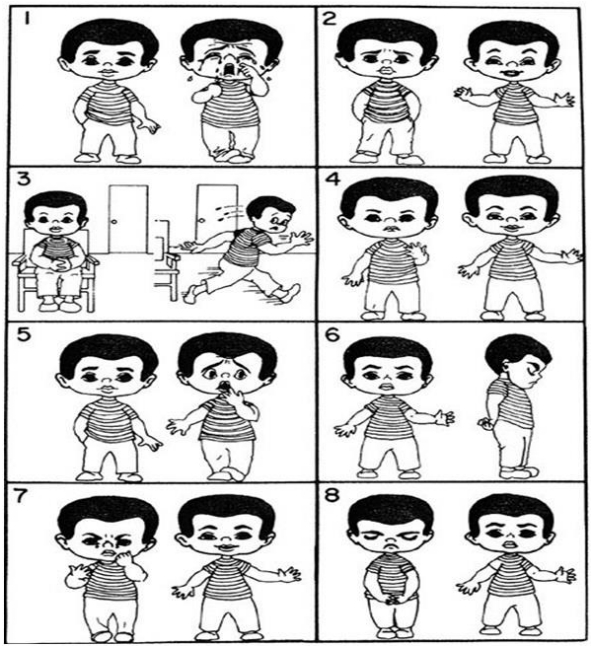

Fig 5: Venham's picture test.

The threatening appearance of dental syringes mostly contributes to provoke or increase fear, especially in dentally anxious children[6]. Fear or anxiety-related behavior has always been recognized as the most difficult aspect of patient management and can undermine an adequate dental care, especially in children[7].

AAPD has outlined a series of behavior management techniques to deal with the problem, ranging from voice control, to distraction, to physical restraint. When all else fails, sedation with drugs such as nitrous oxide has been advocated.[8] Other techniques that have been used are the application of topical anesthetic gel or patches prior to injection, or electronic computerized devices such as Wand (Milestone Scientific, Livingston, NJ, USA).[1]

Angie Angelus Alligator disposable syringe cover (Fig 1) was developed in an attempt to attenuate or overcome patients' fear and anxiety of local anesthesia required prior to invasive procedures According to the manufacturer, the "injection" most feared by children can have a friendlier face with the syringe sleeve in the shape of an alligator's body. With the angelus alligator, a child will see prior to receiving local anesthesia is a cartoon-looking device made of flexible rubber that fits over the needle and syringe, hiding them from young patients' eyes. Thus masking the threatening

Table 1: Mean anxiety scores according to venham's picture test and venham's clinical rating scale in group A using paired sample t-test.

	TREATMENT	Mean	N	Std. Deviation	Std. Error Mean	Mean Difference	P Value
VPT	Pretreatment	2.00	20	.86	.192		
	Post treatment	3.00	20	1.08	.242	1.00	.003
VCRS	Pretreatment	0.90	20	.86	.192	0.54	.002
	Postreatment	1.44	20	.79	.176		

Table 2: Mean anxiety scores according to venham's picture test and venham's clinical rating scale in group B using paired sample t-test.

Group B	Treatment	Mean	N	Std. Deviation	Std. Error Mean	Mean difference	P value
VPT	Pretreatment	1.90	20	.57	.128		
	Postreatment	2.32	20	.69	.153	0.42	0.43
VCRS	Pretreatment	.70	20	.80	.179	0.45	0.46
	Postreatment	1.15	20	.93	.209		

Table 3: Intergroup comparison of mean venham's picture test & venham's clinical rating scale using independent sample t test.

GROUP A vs GROUP B	Mean Difference	N	Std. Deviation	Std. Error Mean	P Value
VPT-Change From Pre to Post	0.58	20	0.67	0.150	<0.001
VCRS-change from Pre to P[ost	0.09	20	0.87	0.195	<0.001

Table 4: Mean anxiety scores according to physiologic parameter (pulse rate and oxygen saturation) in group A using paired sample t-test group.

GROUP-A	Mean	N	Std. Deviation	Std. Error Mean	Mean Difference	P Value
Pulse rate Pretreatment	100.50	20	4.85	1.085		
Pulse rate During treatment	112.00	20	5.49	1.227	10.60	<0.001
Pulse rate Pretreatment	100.50	20	4.85	1.085		
Pulse rate Posttreatment	110.60	20	5.32	1.189	10.10	<0.001
Pulse rate During treatment	112.00	20	5.49	1.227		
Pulse rate Posttreatment	110.60	20	5.32	1.189	-1.40	.041
Oxygen saturation Pretreatment	98.00	20	1.34	0.300		
Oxygen saturation During treatment	99.00	20	3.97	0.888	1.00	1.000
Oxygen saturation Pretreatment	98.00	20	1.34	0.300		
Oxygen saturation Posttreatment	98.00	20	3.85	0.862	0.00	1.000
Oxygen saturation During treatment	99.00	20	3.97	0.888		
Oxygen saturation Posttreatment	98.00	20	3.85	0.862	0.00	1.000

Table 5: Mean anxiety scores according to physiologic parameter (pulse rate and oxygen saturation) in group B using paired sample t-test group.

GROUP B	Mean	N	Std. Deviation	Std. Error Mean	Mean Difference	P Value
Pulse rate Pretreatment	100.00	20	5.71	1.277		
Pulse rate During treatment	102.50	20	6.79	1.518	2.50	.040
Pulse rate Pretreatment	100.00	20	5.71	1.277		
Pulse rate Posttreatment	102.00	20	7.02	1.569	2.00	.036
Pulse rate During treatment	102.50	20	6.79	1.518		
Pulse rate Posttreatment	102.00	20	7.02	1.569	-0.50	.047
Oxygen saturation Pretreatment	98.00	20	1.20	0.268		
Oxygen saturation During treatment	99.00	20	1.23	0.275	1.00	.104
Oxygen saturation Pretreatment	98.00	20	1.20	0.268		
Oxygen saturation Posttreatment	99.00	20	7.89	4.000	1.00	.411
Oxygen saturation During treatment	99.00	20	1.23	0.275		
Oxygen saturation Posttreatment	99.00	20	7.89	4.000	0.00	.356

Table 6: Intergroup comparison of mean physiologic parameter (pulse rate and oxygen saturation) using independent t test.

Group a vs group b	Mean Difference	N	Std. Deviation	Std. Error Mean	P Value
a) Pulse rate	5.10	20	3.23	0.722	<0.001
B) Oxygen saturation	0.34	20	2.67	0.597	0.754

appearance as with conventional syringe.[9] Hence the following study was conducted with an aim to assess the efficacy of angie angelus alligator sleeves in reducing anxiety related to local anesthesia administration.

MATERIALS AND METHOD

The interventional cross sectional study was conducted in the department of pedodontics and preventive dentistry at Karnavati school of dentistry, Gandhinagar. Ethical clearance was obtained from the institutional ethical committee board. Prior written permission and consent was obtained from the participant's parents. After considering inclusion and exclusion criteria a total sample size of 40 healthy children aged 5-8 years were selected & divided into two groups. Depending upon the results of coin toss method 20 children in each group were automatically assigned without alligator sleeves (Group A) or with alligator sleeves (Group B).

Children having congenital malformation, attending school classes not compatible with their age, diagnosed and treated for neurological and/or psychological disorders, systemic diseases and having previous dental experience were excluded from the study. The children should be in good general health with at least requiring local anesthesia in the maxilla to be treated, no history of previous dental injection and only positive rating children according to the frankl's behavior rating scale at the time of oral examination were included in the study.

Only infiltrative maxillary anesthesia was administered on the teeth to be treated and the entire content of an anesthetic cartridge (1.8 ml), both for the conventional and with the stainless-steel syringe (masked by the carpule) was delivered. Before administering the local anesthesia, lignocaine hydrochloride gel I.P. (LOX-2%) was applied at the site of L.A. administration for 2

minutes (according to giddon 1975 for soft tissue analgesia) for standardization. Local anesthesia xicaine (2% with adrenaline 1:80,000) was used for the conventional method and lignospan special septodent vial (1: 80,000) was used for the alligator sleeves syringe.

For the Group A, syringe was used with a sterile disposable 25 mm gauge needle. The mucosa was gently pulled for better visualization at the puncture site and infiltration started with minimum penetration of the needle. Tissue penetration was at the free gingival mucosa. The needle was advanced until reaching the desired depth and then the remaining anesthetic solution was delivered.

In Group B the syringe with cartridge and needle (after removing the needle cap) were prepared by inserting syringe in the sleeve so that the needle was not in contact with internal wall of the sleeve and care was taken that the cartridge was clearly visible at the lower opening of sleeve. The index and middle fingers were positioned on the rear feet of the alligator sleeve and thumb was placed on the plunger. The needle was hidden inside the mouth of the alligator. The mounted assembly was placed into the area of the mouth to receive anesthesia. The lower part of the alligator was positioned upwards; which allowed the cartridge to be seen by the dentist so that the flow of the anesthetic solution and any resultant bleeding could be checked. The patient was only being able to see the rear part of the sleeve. The rear feet of the alligator sleeve were pressed with the index and middle finger to expose the needle and proceed with the injection of the anesthetic solution. After completing the injection, rear feet of the sleeve (which will hide the needle again) was released and the entire assembly was removed from the patient's mouth (fig 2).

The children were evaluated individually before, during and immediately after each type of anesthesia by pulse rate and oxygen saturation, as a physiological indicator of anxiety response using a pulse oximeter (OxyWatch-MD300C2). It was placed on the patient's index finger of the left hand, oxygen saturation and pulse rate was recorded continuously during the treatment sessions (fig 3). Measurement of anxiety before and after the administration of local anesthesia with or without alligator syringe cover was done with Venham's picture test (VPT) and Venham's clinical rating scale (VCRS).

The two trained observers scored the subjects before and after the procedure using the Venham's clinical rating scale [Venham et al, 1977][10]. The VCR scale rates a child's behavioural and physiological parameters on a scale from 0-5 (6-point scale) with a score of 0 corresponding to a relaxed, smiling child and a score of 5 corresponding to a screaming child actively involved in escape behavior (fig. 4)

The Venham's picture test (fig. 5) was scored by showing eight cards, with two pictures in each card, one "anxious" figure and one "non-anxious" figure. The child was asked to point the picture they felt most like at that moment. All the cards were shown in their numbered order, if the child pointed at the "anxious" figure, a score of one was recorded, if the child pointed at the "non anxious" figure, a score of zero was recorded[11].

RESULTS

Paired sample t test was used to find out the mean difference between two groups at 5 % level of significance by SPSS 20. Independent sample t test was used to compare group A and group B to find out which group was more significant in VPT, VCR and physiologic parameter (pulse oximeter). P value of Group A in VPT was 0.003 & in VCR was 0.002 which was significant (Table 1). But P value of Group B in VPT was 0.43 & in VCR was 0.46 which was not significant (Table 2). While comparing the mean difference of VPT (group A-1, group B-0.42) and VCR (group A-0.54, group B-0.45), group B mean difference was lower than the group A so group B was better in accordance with VPT (0.58), VCR (0.09) as shown in Table 3.

Elevation in pulse rate during injection without sleeves was significant (Table 4). But in group B no or slight elevation in pulse rate as compared with group A was observed (Table 5). In post injection the pulse rate decreased or remained constant as it was found in both the groups. Comparing the mean difference from group B to group A, the group B was better than the group A shown in Table 6 (5.10).

Measuring the oxygen saturation in pre, during and post in both the groups showed no or minimal change (Table 4 & Table 5). No significant mean difference (0.34) was obtained by comparing from group A to group B (Table 6).

DISCUSSION

Dental anxiety is a wide spread phenomenon throughout the world[12]. It causes long term avoidance of dental treatment resulting in a deterioration of oral health state, ultimately leading to pain and distress, and negative effects on social life[13]. The resulting prospects of potentially invasive treatments may reinforce existing avoidance behavior, thus instigating a vicious cycle of avoidance behavior, anticipatory anxiety, and suffering[14]. In addition, dentists identify treating nervous patients as a major source of stress, which may compromise their performance. Managing dental anxiety is therefore recognized as an important issue in dental practice[15]. Helping patients overcome their apprehensions can reduce the incidents of delayed or missed dental visits and the negative repercussions from avoidance of needed care, can decrease their perception of pain and may ultimately improve their quality of life[16].

Next to fear of pain, cognitive perceptions and past traumatic dental experiences, the sights (needles, air turbine drills), sounds (drilling, screaming), smells (eugenol, cut dentine), and sensations (high frequency vibrations) in the dental setting are a major cause of dental anxiety[17]. Removing or masking these four major sensory triggers for dental anxiety may mitigate anxiety[18]. According to Al-Harasi et al (2010), Dionne et al (2006), Feck and Goodchild (2005), Leitch and Macpherson (2007) the behavioural approaches and other treatments like anxiolytic drugs are contextually relevant[19,20,21,22].

The Venham's picture test which has been used in the study is suggested to be valid and reliable scale and has demonstrated the reliability in assessing self reported anxiety among children. To eliminate the subjective variation, Venham's clinical rating scale was also taken with Venham's picture test. The objective measure of anxiety was done by measuring pulse rate and oxygen saturation with the help of a pulse oximeter[18].

In the present study, p value for group A in accordance with VPT and VCRS was statistically significant, whereas p value for group B-VPT and VCRS was statistically non significant. In group B there was no change or slight change in anxiety level from pretreatment to postreatment. So the VPT & VCRS was an effective measure of emotional state of the child at that particular instance. This observation was similar to the earlier observation made by Venham et al[11].

Our results are comparable to those found by Aminabadi (2010), where in there was a significant decrease in state anxiety scores with the use of virtual reality eye glasses during dental treatment[23], Additionally, there was an agreement with the findings of Frere (2001), who investigated the effect of audiovisual eyeglasses distraction on anxiety during dental prophylaxis in adult patients and found that decrease in anxiety and discomfort were reported when using the audiovisual eyeglasses[24].

S Nuvvula (2014) reported the use of video-eyewear promoted the control of physiological signs of anxiety[25]. Where as Marwah N (2005) concluded that the audio distraction did decrease the anxiety level in pediatric dental patients, but not to a very significant level[26]. The pulse rate is governed by the nervous system, especially the autonomic nervous system (ANS) which reflects negative emotions in terms of physiologic parameters such as heart rate, respirations and body temperature. Therefore, physiological response of the ANS are the indicator used to tell if a person is under stress or relaxation.

Statistically significant results were observed with the pulse rate measured when both the group were compared, the increase of the anxiety level for group B was less than the group A. Our findings were partially concurrent with the study of prabhakar et al., in which audio distraction was slight better in managing the anxiety, though not statistically significant level[27].

Rayen et al (2006)[7], Shindova & Belchena (2013)[28], Dedeepya et al (2013)[29] stated that oxygen saturation remains unaltered, which was also seen in our study. On contrary Nishidha Tiwari et al (2015) showed variation in oxygen saturation rate explaning it might have occurred due to

hyperventilation in children as high anxiety may cause an increase in respiration rate[30].

Ujaoney et al (2013) concluded that the camouflage syringe was associated with improved outcomes related to dental fear and anxiety in children which is in accordance with our study outcome[31]. The advantage of the alligator syringe sleeve is that its very playful thus facilitates the dentist's work during anesthesia application. It also encourages the patient as a gracious gift after the treatment is done. Mostly it can be sterilized (Guarantee of Biosafety) as mentioned in the brochure.

Further studies using alligator sleeves are needed to better understand its role in diminishing fear and anxiety in pediatric patients.

LIMITATIONS

Parental attitude towards dental treatment and various environmental factors of dental clinic can influence the fear and anxiety of children.

CONCLUSION

Alligator syringe sleeves can be considered as an effective measure to reduce injection related anxiety in children.

CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

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