

Comparing Conventional Syringe with Camouflage Syringe by Evaluating Behavior and Anxiety in 6 -10 Year Old Children While Administering Local Anaesthesia – A Cross Over Trial with Split Mouth Study Design.

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Abstract

Introduction: Achieving profound local anaesthesia (LA) is critical for providing positive dental experiences to the child. Ironically the procedural intervention with needles and syringes for administering local anaesthesia by itself is a painful and anxiety provoking procedure. The child visually and psychologically perceives the needle to be a threat. Hence camouflaging the needle is a viable and pragmatic approach to defy anxiety.

Materials and methods: A group of 20 children aged 6-10 years were randomly divided into two groups. Both the groups received local anaesthesia using camouflaged syringes and conventional syringes in two different appointments as per the order of intervention allotted in the cross over trial. The heart rates were measured using pulse oximeter and behavioural assessment was done using Faces, Leg, Activity, Cry, Consolability (FLACC) scale. The data was statistically analyzed keeping p value at 5%.

Results: The difference in the heart rate increase was lower with camouflaged syringes and was also found to be statistically significant ($p=0.001$). The mean FLACC scores were more for conventional syringe than

camouflaged syringe, but no statistically significant differences were obtained.

Conclusion: Camouflaged needles can better reduce anxiety levels when compared to the conventional syringes. The sleeve design employed in the present study is a user-friendly, customizable and extremely cost-effective alternative to camouflage needles and diminish anxiety levels during LA administration.

Keywords: Camouflage syringe; Dental Anxiety; Local anaesthesia; Needle; Syringe sleeve.

Introduction

Administration of Local Anaesthesia (LA) to children is an exquisitely challenging procedure.^[1] The achievement of profound anaesthesia is critical and imperative for successful co-operation of the child throughout the dental treatment.^[2,3,4] Ironically administration of LA involves procedural intervention with needles and syringes which by themselves are anxiety provoking stimuli.^[5] The very sight of needle deters the patient's co-operative behaviour in the dental operatory. Paediatric patients visually and psychologically discern the needles to be a threatening instrument.^[6] Perception of pain levels can get altered to be felt as more intense and for longer duration when

anxiety levels elevate.^[7] Hence camouflaging the needle can be a pragmatic approach to combat anxiety to a certain extent while administering LA in paediatric dental operatory.

Camouflage syringe systems that already exist in the literature include the Angelus syringe sleeve, cold cure syringe covers and the hydrosooter needle cover syringe. All these systems have shown effect on reducing dental anxiety.^[6,8-9] However certain limitations are present with each of these systems. In an attempt to overcome those limitations a simpler, user friendly and Do It Yourself (DIY) breed of camouflage syringe sleeves were designed to be employed in the current study. The DIY trend in the health care segment has led to the emergence of myriad of consumer affable products.^[10] Herein the consumers refer to clinicians or paediatric dentists in particular who can devise their own syringe sleeve that can be used to camouflage the needle.

The sleeve was constructed with the aim of providing a cost-effective, appealing, customizable product which can be self-made by the dentists themselves at the chairside too. The syringe sleeves constructed and employed in the study were made of different cartoons as preferred and picked by the patient. Further the sleeves were designed to be detached from the syringe to be used as positive reinforcement rewards for the child. The syringe sleeves were hence constructed with the aim of providing a user friendly experience for the clinicians particularly general dentists who are not acquainted with necessary behaviour management skill set to manage a child efficiently during LA administration. Therefore the effectiveness of this syringe sleeve in reducing anxiety levels during delivery of local anaesthesia to children was studied. Thus the aim of the current study was to assess the effectiveness of DIY camouflaged syringes by comparing it with that of conventional syringes through evaluation of behaviour and

dental anxiety in 6-10 year old children while administering LA.

Materials and Methods

The study was designed as a randomized controlled cross over clinical trial with a split mouth study design to compare the effectiveness of conventional syringe with camouflage syringe by evaluating behaviour and anxiety in 6-10 year old children while administering LA. After obtaining the clearance from the ethical committee and Institutional Review Board, and the trial was registered with the clinical trial registry of India (CTRI/2018/10/016198). Sample size was calculated using the G-power software after taking mean values from previous studies with heart rate as primary outcome. Keeping confidence at 95% and power to be at 80%, a total sample of 20 was arrived at for this cross over trial. The subjects were recruited and enrolled only if the child had no past dental history, had no underlying medical conditions, required dental treatment under LA in two different quadrants, belonged to Frankel's positive or negative ranks according to Frankel's behaviour rating scale, belonging to the age group of 6 – 10 years and were willing to participate after getting the parent's consent. Children with special health care needs and those who required treatment under LA in only one quadrant were excluded from the study. Written informed consent was obtained from the parents of children involved in the study after elaborating the details and purpose of the study.

The camouflage syringe sleeve consisted of colour prints of different cartoon characters mounted on a foam board with a loop attached from behind (Fig. 1A). The foam board is flexible and therefore can be bent around the syringe barrel if the clinician finds it bulky to handle. The syringe can be slid through the loop and the needle will get placed behind the sleeve thus getting camouflaged (Fig. 1B). On rotating the syringe, the barrel will be

visible to the clinician for monitoring the amount of drug delivered.

The sleeve was designed to be detachable and hence after the procedure, can be given to the child as a finger puppet for positive reinforcement (Fig. 1C). The twenty subjects recruited were randomly divided into two arms of ten subjects each using the lottery method by the trial coordinator. Participants were randomized in a ratio of 1:1 to receive both the interventions in a specific order. The order in which interventions were administered to each group was determined by flipping a coin.

Prior to the commencement of the study, the participants were allowed to pick their favourite cartoon character from a selection kit which was later used to camouflage their needle (Dispovan 0.55 * 25 mm / 24 g, Hindustan Syringes & Medical Devices LTD., Faridabad, Haryana, India) during LA (Lignox 2% with Adrenaline in 1:80,000. INDOCO REMEDIES LTD., Mumbai, Maharashtra, India) administration. In the first appointment Group A received LA through camouflage syringe while B received through conventional syringe (Fig. 2A). Baseline values of heart rate were collected using a pulse oximeter (Lotus 700, Upkar Healthcare India Pvt. Ltd., Varanasi, Uthar Pradesh, India) 15 minutes prior to the procedure. A single paediatric dentist alone administered LA to all the participants using conventional or camouflaged needle as per the allocation with routine behaviour management techniques. All patients received only Inferior alveolar nerve block with buccal infiltration. The LA was administered at a rate of 1ml / minute for all participants for an average duration of 2 minutes. A total of 1.8 ml of the 2% Lignocaine with 1:80,000 adrenaline drug was uniformly used for each participant. Heart rate values were recorded during LA administration and 1 minute post-intervention. The Faces, Leg, Activity, Cry and Consolability (FLACC) scores were recorded during

the procedure from a video recording of the event. Heart rate was considered to be the primary outcome and FLACC scores to be the secondary outcome. In the second appointment the above procedures were repeated except that group A participants received LA through conventional syringe and group B through camouflage syringe (Fig. 2B).

All the above allocation assignments were concealed by using third party assignment mechanism to avoid selection bias. The appointments were spaced one week apart for all the subjects. The outcome values were recorded by a separate investigator who was blinded to the type of intervention employed. Photos of the values displayed on the pulse oximeter monitor were taken and handed over to the blinded investigator for entering it into the data sheet. Data collected were tabulated in Microsoft Excel 2007 and were subjected to statistical tests using SPSS software version 20. The statistician was also blinded to the intervention and order of allocation for each group. One sample Kolmogorov-Smirnov test was used to assess the normal distribution of the variables. Heart rate values were normally distributed and hence a Paired t Tests was used for intra-group comparisons. Average values for FLACC scores were obtained as they were count data. These scores were further categorized into mild, moderate or severe and hence Chi square tests were employed for inter-group comparisons. The confidence levels were set at 95%, ($p=0.05$).

Results

All the subjects completed the trial with good compliance and no untoward incidents were reported. Fig. 3 gives details on exclusion criteria and depicts the randomized cross over study design. Table 1 shows the inter-group comparisons for heart rate and FLACC scores between conventional and camouflage syringes.

The mean FLACC score were 1.1 with camouflage syringe group and 1.75 with conventional syringe. FLACC scores were more with conventional syringe indicating that camouflage syringes are effective in reducing anxiety. However this difference was not found to be statistically significant ($p=0.430$). Normality tests run for base line heart rates between the two groups showed no significant difference with respect to the subjects' age ($p=0.2$). Fig. 4 graphically depicts the mean increase in heart rate for both the groups. Heart rate values increased in both groups but the magnitude of the rise in value was found to be more with conventional syringes. The mean increase in heart rate for camouflage group was found to be 1.5 ± 9.02 bpm and that of conventional group was 5.2 ± 5.88 bpm. The increase in the mean heart rate was more with use of conventional syringe than camouflage syringes and the difference was also found to be statistically significant ($p=0.001$).

Discussion

Despite advancements in the field of modern dentistry, fear and anxiety have been relatively constant all along in the paediatric population.^[11-15] About 14% of 4 – 11 year old children experience anxiety when attending a dental clinic and their strongest fears are associated with injections.^[2] Failure to adequately address the fear or anxiety of the child will lead to a vicious cycle of cumulative anxiety and increased avoidance of dental care.^[16,17] Fear of potentially painful or invasive procedures hoist up anxiety levels in children. The most common cause for this is attributed to the “needles and syringes”.^[18] Pain control by administration of local anaesthesia is vital for successful dental treatment and for bringing out a positive dental experience for the child.^[19-22] Several behaviour management methods are hence employed while carrying out anxiety provoking dental procedures. The concept of hiding the needle which is

seen as a visual threat by the child is a practical approach to reduce anxiety levels during administration of LA. The camouflage component also can act as a source of distraction for the child.^[9] Hence in the current study the effectiveness of Camouflage syringe on anxiety was compared to that of conventional syringes.

Different types of camouflage syringe systems have been compared in the previous studies. These include the commercially obtainable Angelus syringe sleeve that consists of a toy alligator camouflaging the syringe and needle. This system is compatible only with metal cartridge syringes.^[6] Cold cure based syringe camouflage systems are another kind which were prototyped and patented in the form of toys like butterfly, jet engine, fish and dolls. These systems consisted of three parts viz the head, body and tail. The head contain bristles which are intended to be used for applying topical anesthetic. The cold cure based camouflage systems are compatible with disposable syringes but are not commercially available yet. Further this system fails to conceal the needle; rather it circumferentially camouflages the body of the disposable syringes.^[8] One more camouflage type of syringe is the Hydroshooter needle cover syringes constructed using propylene and silicone. These were designed to obscure the needle part and also have an auto-cap mechanism. The toy shaped silicone syringe sleeve automatically moves forward to cover the needle back. This silicone sleeve is again found to be compatible only with metal cartridge syringes.^[9] Hence in the present study a new type of camouflage syringe sleeve was constructed to be used with disposable syringes.

In the present study camouflage sleeve containing different cartoon characters according to the child's preference was used. The presence of toy like tool or a cartoon as a camouflage component by itself serves to be a distraction. Hence in this study a syringe sleeve was

constructed with a simple slide-in design. The sleeve is easy to construct, cost effective and can be constructed by the dentist themselves in a short span of time. Although the camouflage syringe constructed and used in this study does not employ any sophisticated design framework, the results of the study show that it has some effects in reducing anxiety.

Babaji et al.^[23] in their cross-sectional study concluded that children of younger age group (6 – 10 years) preferred camouflaged syringes. Hence the current study was carried out among children of 6 – 10 year age group. Heart rate has been widely accepted as an objective measure of anxiety.^[24] Therefore heart rate values were recorded to objectively measure anxiety. The FLACC is one of the most commonly used behavioural observation pain scale and hence was used in the present study to assess the child's behaviour during LA administration.^[25,26] The current study was carried out as a crossover trial with split mouth design to bring down internal variability among cases and controls.

The results of the current study showed that the baseline heart rates had no significant differences with respect to the different ages in the study group. There was a rise in the heart rate values from the baseline for both the groups. However these increases in values were more for the conventional syringe group than the camouflage group and the difference was statistically significant ($p=0.001$). This finding is in harmony with the study of Melwani et al.^[6] However the mean difference in the heart rates were much higher when compared to the present study. They obtained an average difference of 16.67bpm and 8.27bpm for conventional and camouflage syringes respectively in the 6-8year old age group. However the results were not statistically significant in their study.

The results of the present study revealed that the FLACC scores were lower with camouflage syringes but were not

statistically significant between the two interventions. This result is in accordance with that of Melwani et al.^[6] who also did not arrive at any statistically significant differences when comparing Angelus syringes with conventional ones. Ismail et al.^[9] in their cross-sectional study showed that 90% children preferred the hydrosooter camouflage syringes and agreed that it reduced anxiety levels. Ujaoney et al.^[8] in their study compared the cold cure based camouflage systems with conventional syringes. They employed the Venham's Clinical Rating (VCR) for assessing the outcome and concluded that with the use of Camouflage syringes, improvement was observed in all the four domains of VCR.

The concept of camouflaging the needle during administration of LA has been well received by children. However the use of camouflage sleeves has its own limitations when it comes to the maneuverability of the syringe while administering LA. The syringe sleeve constructed in this study also exhibited some challenges while administering LA due to the larger size of the sleeve. Also the sleeves employed in this study camouflaged the needle in one dimension only as opposed to all other systems existing in the literature. However the ease of construction and extremely low cost involved in producing this paper mounted on foam type camouflage sleeves can be considered an advantage.

Conclusion

Within the limitations of the present study, it can be concluded that using a camouflaged needle can reduce anxiety levels when compared to the conventional syringes. The use of any syringe sleeve to camouflage the needle will assist clinicians in effectively managing the child in the dental office and provide them with a positive experience. The sleeve design employed in the present study is a user-friendly, customizable and extremely cost-

effective alternative to camouflage needles and diminish anxiety levels during LA administration.

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Table 1: Inter-group comparisons between Conventional syringe and Camouflage syringe

Outcome measure	Conventional Syringe		Camouflage syringe		P value
	Pre-intervention	Post – intervention	Pre-intervention	Post - intervention	
Mean Heart rate (bpm)	93.65±8.4	98.85±9.5	100.15±13.8	101.7±12.5	0.001*
FLACC scores (Mean)	1.75		1.1		0.430

*Significant at 1%level

Figure 1: (A) Camouflage syringe (B) Sleeve Camouflaging the needle (C) Sleeve used as Finger puppet



(A)



(B)



(C)

Figure 2: (A) LA administered using Conventional syringe in first appointment for one patient (B) LA administered using Camouflaged syringe in second appointment for the same patient



(A)



(B)

Figure 3: CONSORT flow Diagram

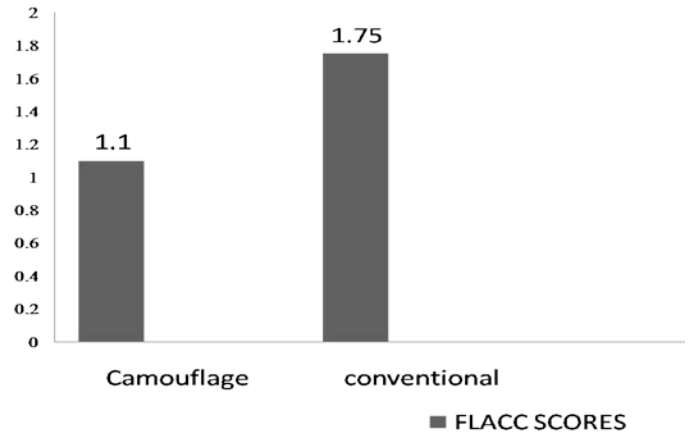
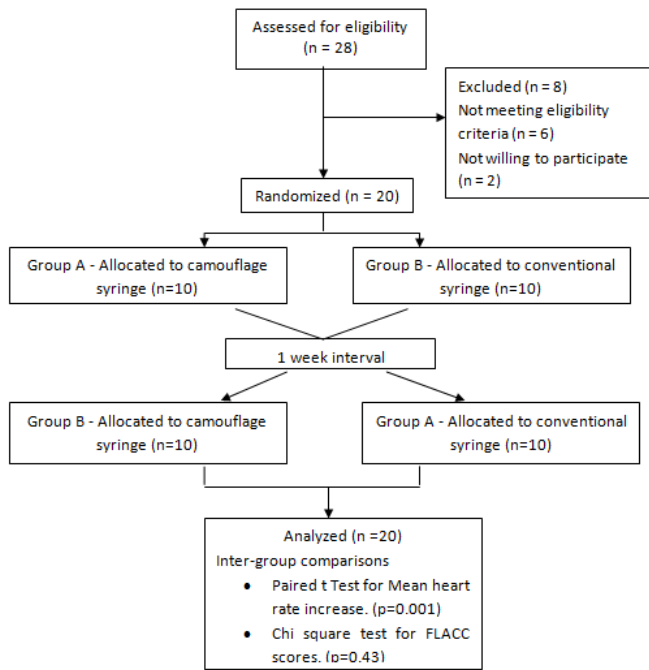


Figure 4A: Difference in the Mean increase in heart rates between conventional and camouflage syringes pre and post-intervention.

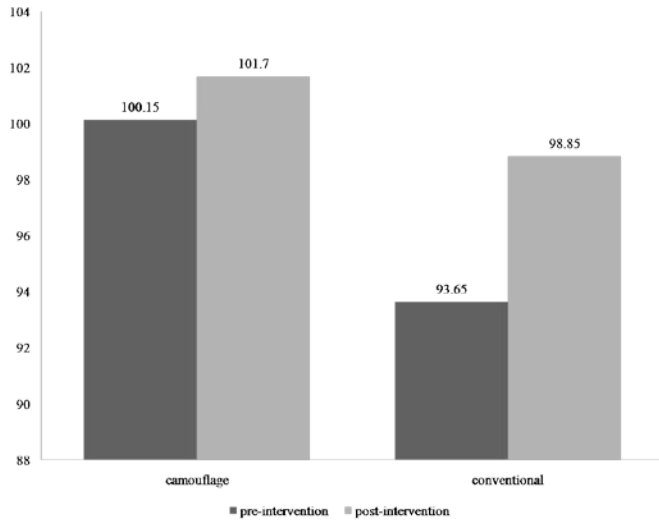


Figure 4B: Difference in the FLACC scores between conventional and camouflage syringes