
**COMPARATIVE EVALUATION OF ANXIETY LEVELS
AND PAIN PERCEPTION DURING LOCAL ANAESTHESIA
ADMINISTRATION USING CONVENTIONAL AND
CAMOUFLAGED SYRINGES IN 6–11 YEAR OLD
CHILDREN: AN IN VIVO STUDY.**

By

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2018-2021

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LIST OF ABBREVIATIONS

1.	FPS	Faces Pain Rating Scale
2.	VPT	Venham Picture Test
3.	DFA	Dental Fear and Anxiety
4.	LA	Local Anesthesia
5.	VAS	Visual Analogue Scale
6.	RCT	Randomized Control Trial
7.	MCDAS(f)	Modified Child Dental Anxiety Scale-faces version
8.	FLACC	Faces, Legs, Activity, Cry and Consolability
9.	TSD	Tell- Show- Do
10.	UK	United Kingdom
11.	USA	United States of America
12.	WITAU	Writing In The Air Using Leg
13.	TPPPS	Toddler- Preschooler Post-operative Pain Scale
14.	<	Less than
15.	>	Greater than
16.	=	Equals to
17.	3D AV	Three-Dimensional Audio-Visual
18.	MVARS	Modified Venham Scale
19.	SEM	Sound, Eye, Motor scale
20.	VBA	Vibrational Anaesthesia
21.	CCLAD	Computer-Controlled Local Anaesthesia Delivery
22.	M : F	Male to Female Ratio

ABSTRACT

AIM: To evaluate and compare the anxiety level and pain perception using conventional and camouflaged syringes during local anesthesia administration in children 6-11 years of age.

METHOD: The present study was a concurrent parallel arm randomized control trial. Sixty two children with treatment need in the maxillary arch requiring local anesthesia procedure and fulfilling inclusion and exclusion criteria were selected.(n=62)The children were randomly allocated to either conventional syringe group (Group A, n=31) or camouflaged syringe group (Group B, n=31). After taking proper consent and assent, preoperative Venham Picture Test score and baseline anxiety were recorded. The children were then subjected local anesthesia procedure using either camouflaged syringe or conventional syringe. Pulse rate during the procedure was noted. The post-operative Venham Picture Test score was noted. Post-operative pain perception was analysed using Faces Pain Rating Scale.

RESULTS: The collected data was statistically analysed. The Pulse rate was seen to follow a normal distribution, and hence parametric tests like independent and dependent t-test were used. The comparative difference in before and after pulse rate in Group A and B was analysed by independent t test which were statistically insignificant ($p=0.5169$). When intergroup analysis was done by Wilcoxon Matched Pairs analysis to assess Venham Picture test, there was statistically significant change seen in individual groups ; $p=0.0006$ and $p=0.0095$ in control and experimental group respectively, but not in intergroup analysis. The mean pain perception in Group A was 4.58 and in Group B was 5.03. The difference in the pain perception in two groups was not statistically significant. ($p=0.5449$). In both groups, it was seen that there was

a significant correlation between pain perception and post injection anxiety score. (p=0.0015; p=0.0064).

CONCLUSION: The anxiety increases during local anesthetic procedure. But there was no significant difference between preoperative and postoperative anxiety levels with and without camouflaged sleeve. There was no statistically significant difference in pain perception during the delivery of anesthesia, using conventional and camouflaged syringes. In spite of this, the head control was better attained in the camouflaged syringe group as compared to conventional syringe group.

KEYWORDS: Anxiety, Camouflaged Sleeve, Local Anesthesia, Pain perception, Pediatric Dentistry

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INTRODUCTION

“Camouflage is the most interesting form of art” - Rishi Mandal

Pain is a protective mechanism against injury to the body. So intense is this sensation that historically, Homer thought this to be due to arrows shot by God. Aristotle went on to describe pain as “passion of the soul”. It was in the 19th century that the concept of pain was scientifically defined, after the development in the field of neurology.¹ It is hypothesized, pain potentially breeds anxiety.² The difficulty in tackling the issue of anxiety and pain perception lies in its inherent diverse nature. Anxiety in itself involves a variety of cognitive, emotional, neurobiological and behavioral responses to a variety of potentially threatening stimuli.³

The Subcommittee on Taxonomy of International Association for Study of Pain defines pain as, “An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.”⁴ Modified definition by Stedman TL too has defined pain in the following way, “An unpleasant sensation associated with actual or potential tissue damage and mediated by specific nerve fibres to the brain, where its conscious appreciation may be modified to various factors.”⁵

So the puzzling question remains as to why nature has provided these to humans? The answer to this is the tale of humankind wherein early in evolution the body developed a mechanism to protect itself from potential threat in the way of autonomic response. In present day this can be a potentially unhelpful situation to a pediatric dentist, who means no actual harm to the child. Ironically, the tool intended

to diminish anxiety and pain throughout dental procedures, the local anesthesia is the culprit in initiating most anxiety due to the bodily response to sharp objects.

The pain and anxiety of the patient may be recorded physically or physiologically, which is collectively termed as pain behavior and can be measured using various scales. Faces pain rating scale is a self-reported measure of pain intensity developed for children.⁶ The more objective analysis of children's reaction to dental treatment is by assessing their physiological responses. The main physiological signs which are monitored are perspiration and pulse rate. It is seen that there is an increase in pulse rate with increase in apprehension.⁷ This can be documented by a photoelectric device or Finger pulse oximeter.⁷ The Venham Picture Test which measures situational anxiety in an age appropriate way is a gold standard used in gauging anxiety.⁸ Anxiety is measured via a picture selection task which can be rapidly administered and readily understood and accepted by the child.

Pediatric dentistry includes several behavior management techniques like non-pharmacological and pharmacological behavior management techniques. Physical restraints or pharmacological management techniques may present a potential health hazard.⁸ Local anesthesia is amply used in the field of pediatric dentistry and a painless administration of injection would in turn lead to good behavior from the patient in the future.⁹ Distraction is a strategy using cognitive and behavioral aspects that draws a child's attention away from the noxious stimuli. Distraction is a psychological strategy which helps children to cope with brief stressors.^{10,11} It is safe, efficient and inexpensive way of behavior management.

Viewing of the dental injection can cause anxiety in children.¹² Camouflaging the injection apparatus can be an effective distraction tool.¹³ The Syringe Sleeve makes it possible to disguise the threatening metal syringe using an autoclavable

plastic in the shape of a toy alligator. Interestingly, it has been sensed that the degree of pain perception and anxiety patients experience may not be related to the amount of tissue injury.¹⁴ It has been observed that the intensity of pain usually relates to the attention given at that time, and hence, if one's attention is distracted even at the time of injury, no pain may be felt.¹⁵ Nevertheless, this concept has not been proved adequately. Whether the appearance of noxious stimulus can be altered to alter the pain perception is a question vexing many in the scientific community. Furthermore, if truly anxiety causes increased pain perception, it can be scrutinized if camouflaging the threatening stimulus will ease anxiety and consecutively the pain perception.

Development of anxiety may have various complications such as avoidant behavior, disruptive behavior and development of future phobias.¹⁶ It has been perceived that children having high anxiety associated with dental treatment will evolve into adults having high caries index.¹⁷ Dental negligence can be mainly due to two contributory factors: 1) Improper Perceptions and 2) Inherent anxiety. In this sense, it becomes a responsibility of the pediatric dentist to tackle the anxiety and pain perception in the patient. Inability to do so will lead to a nasty succession of anxiety and evasion. Moreover, in accordance to Davey's latent inhibition hypothesis, dental anxiety is seen to be more within children who experience pain and anxiety early in treatment course.¹⁸

We observed that this intervention may be of ample clinical relevance, but there is scanty reliable literature where syringes have been camouflaged resulting in entire injection apparatus being hidden from the sight of children. Therefore this study was directed at evaluating the effects of distraction on anxiety and pain perception in children through camouflaging the injection using conventional syringe as control.

AIM AND OBJECTIVES

AIM:

To Compare and Evaluate Anxiety Levels and Pain Perception during Local Anaesthesia Administration Using Conventional and Camouflaged Syringes in 6–11 Year Old Children

OBJECTIVES:

1. To evaluate the change in anxiety level before and during local anaesthesia administration via conventional and camouflaged syringe in patients 6-11 years of age.
2. To evaluate pain perception during local anaesthesia administration with conventional and camouflaged syringe in patients 6-11 years of age.
3. To compare change in anxiety level before and during local anaesthesia administration using conventional and camouflaged syringe in patients 6-11 years of age.
4. To compare pain perception during local anaesthesia administration using conventional and camouflaged syringe in patients 6-11 years of age.

RESEARCH HYPOTHESIS

NULL HYPOTHESIS:

There is no difference between the anxiety level and pain perception while using conventional and camouflaged syringe during administration of local anesthesia in children.

ALTERNATIVE HYPOTHESIS:

There is a difference between the anxiety level and pain perception while using conventional and camouflaged syringe during administration of local anesthesia in children.

REVIEW OF LITERATURE

Dental fear is a commonly encountered difficulty in a pediatric dental clinic. Children mainly have fear of unknown when approaching first dental experience. Due to this, treating children can be seen as a challenge by many dentists. In a study, different fear items were rated according to the fear levels they induced in Nigerian children. A short form of the dental subscale of the child fear survey schedule was used by the authors to assess the levels of fear in children for each aspect of dental treatment. The post-treatment fear increased for Local anesthesia injection signifying that children have a feeling of sustained fear towards this procedure.²

Literature in relation to different scales used to assess fear, anxiety and pain perception:

Assessment of anxiety and pain perception is an important component of research in behavioural studies. The scales for assessing pain perception can be broadly classified as:

1. Physiological
2. Self-reported
3. Behavioural

In a study done to assess the reliability of self-reported scales in comparison to behavioural scales, one verbal and two analogue scales were used. Self-reporting verbal and visual analogue scale and behaviour assessment scales were used. Retrospective assessment was done in 141 pediatric patients out of whom 82 patients were male and 59 patients female. Ages of the subjects ranged from 1.6 – 17 years.

Patients were divided into three groups and correlation of the pain rating scales was done. The study concluded that there is no statistical difference in the correlation coefficient of either of the scales used in various age groups as well as different sexes, when the patient has completely understood the scale.¹⁹

A study aimed at assessing which one among the Visual analogue scale or Wong Bakers faces pain rating scale is better. The authors collected data in children from 180 patients in 3-14 year age group. The data was collected post extraction in males and females alike. Even though all confounding factors were eliminated, it was observed in this study that there was a difference in anxiety levels when Visual Analogue scale was used in males and females. The authors mention the finding to be due to lack of vocalisation from the boys as compared to girls.²⁰

Various scales have been given to assess anxiety. In an effort to develop self-report measure for analysing situational anxiety in children, a picture selection task which could be easily perceived by children was developed. In this, a male cartoon figure with large head was drawn expressing emotions commonly seen in a pediatric dental clinic. The final version of this self-report measure consisted of an 8 item picture scale. Clinical experiments were carried out to assess the reliability.⁸In an observational study conducted on 105 pediatric patients aged from 3-14 years, Venhampicture test and Melamed Scale of Dental Anxiety were compared. In a 4 point scale rated by the practitioner, Venham scale was found to have a good patient and operator cooper ability.²¹

Another study assessed the comparative effectiveness of Facial Image Scale and Venham Picture Test. The aim of this study was to assess the reliability in children's anxiety level. In this experiment, 103 children between the ages of 3-18

years were chosen as subjects. Both the scales were shown to children in the waiting room. The correlation of the two scales was found to be high. The Venham scale finding showed that children showed anxious behaviour toward dentistry.⁶

When assessing the anxiety in patients, one of the question commonly faced is whether the scale used is effective. In a study aimed at evaluating two short term anxiety rating scales, Faces Image Scale and Venham picture test, fifty two Indian children were included. The age group of inclusion was 6-12 years. The children were assessed for their anxiety while they were sitting in the waiting area of the clinic. The results of the study did not reveal any statistically significant difference in the two anxiety scales to be compared. This experiment proved that Venham Picture Test and Faces Image Scale both were comparable as far as anxiety testing was involved.²²

To assess the physiological changes due to anxiety in children, pulse oximeter has been used in many studies. The effectiveness of this technique has been aptly given in a study conducted to assess finger pulse volume as a measure of anxiety. In this experiment, 32 males and 32 females were subjected to threatening and non-threatening stimuli and assessed. Using pulse oximeter finger volume pulse was noted whereas self-report of anxiety was collected using a questionnaire. The experiment yielded a statistically significant difference in pulse rate on subjecting the patients to threatening and non-threatening stimuli which inturn affected the subject's anxiety. This experiment proves that changes in anxiety will affect the pulse rate which will be shown using pulse oximeter.⁷

Literature in relation to anxiety, fear and pain perception:

In a review article aimed at discussing the effect of psychological state on pain perception in dental environment, the authors discussed various factors contributing to pain perception of a patient. They stated that pain perception has a complex mechanism and maybe dependent on more than one factor. The review concluded that distraction was based on psychologically sound principles and often proven by neuroimaging studies. They also discussed other factors like empathy, personality, negative attitude, placebos alter the pain perception in a human. They concluded that an overview of the studies shows that distraction technique is useful way to alter pain perception.²³

In an article discussing the psychology of pain, it has been mentioned that the pain processing takes place in the limbic system. The article also discusses the directly proportional relationship between anxiety and pain perception. One of the factors mentioned by the author involves converting the threatening stimuli to non-threatening stimuli which will in turn reduce the pain perception of the patient, for example preparing needle out of sight of the patient. The author concludes that psychological means should be used to evaluate and treat pain.²⁴

Literature in relation to needle and anxiety:

The main question regarding the use of needles is that whether the size of the needles matters in case of pain perception and anxiety of the patient. In a research aimed at researching whether the size of the needle matter, the researchers have compared the cross section of different guage needles. They are of opinion that the pain, anxiety and needle phobia makes the injection highly unpopular. The needle

guage appears to have a significant relation to pain as far as injection in the skin is considered. The authors mention that reducing the size of the needle will have a beneficial effect on the anxiety and pain perception of the patient. They conclude that fine needles of 31-32 guage have a greater acceptance of the operator as well as the patient.²⁵

In an attempt to assess the factors causing the fear of injection, a questionnaire study was conducted. The subjects, mostly adults were divided into two groups each 350, from two different localities. A 23 question questionnaire was made and distributed. The results of the study showed more than 25% of adults feared injections and at least one in 20 respondents showed avoidant behavior due to fear related to injection. In this study, four aspects of fear of injection were identified.

1. General fear of injection including pain of injection
2. Fears related to local anesthesia
3. Fear of acquired diseases
4. Fear of physical injury²⁶

Literature in relation to Distraction as a non-pharmacological intervention:

Distraction is a very commonly used non pharmacological behaviour management technique.

Four principles were stated according to McCaul and Mallot (1984) as follows:

Principle 1: distraction will reduce distress as compared with uninstructed and placebo control conditions.

Principle 2: distraction techniques that require more attentional capacity will be more effective.

Principle 3: distraction will have stronger effects on pain stimuli of low intensity.

Principle 4: distraction will be more effective than sensation redefinition for mild pain stimuli, but the reverse will be true for intense pain stimuli.¹⁵

The use of distraction in the field of Pediatric dentistry has its own share of controversies. Many studies have been conducted since the 1800s to evaluate the use of distraction during anxiety prone situations like dental anesthesia. A systematic review was conducted which aimed at comparing studies using different distraction techniques to determine whether they are useful in clinical practice to reduce anxiety and fear. A total of 20 randomized control trials were screened. Evidence of distraction using audio, audio-visual methods, instrument camouflage, biofeedback, dental operating microscope, toys was subjected to risk bias assessment. The results of this systematic review found a low certainty of evidence that distraction techniques could efficiently reduce dental anxiety and fear in children. The reviewers found many inconsistencies in the methodologies of the randomized control studies included in the review which may have been the cause of low quality evidence.¹³

The distraction techniques used in non-pharmacological behavior management are numerous. Widely, distraction techniques can be classified as active and passive. Active being the ones demanding some physical involvement of the children and passive being ones not involving physical involvement of the children. Other classification is audio distractors, visual distractors and audio-visual distractors.

Literature in relation to Camouflaged syringes to relieve anxiety and modify pain perception:

Distracting the children by hiding the needle by camouflaging it is one of the techniques used to reduce dental fear and anxiety which may then reduce the pain perception of the patient. The rationale of this is that lesser threatening object preferable to children. In a study in which child preference for dentist attire was assessed, children were asked their preference of dentist's attire. Results of this study showed that most of the children having preoperative anxiety preferred coloured clothed dentist who seemed non-threatening.²⁷

Another cross-sectional study was conducted to evaluate the preference of dentist's attire and kind of syringe (conventional or camouflage) among different age groups of children. A total of 750 children aged 4–14 years were included in the study. All the participants were subdivided into five major groups according to their age, i.e., 4–5 years, 6–7 years, 8–9 years, 10–11 years, and 12–14 years. A set of six photographs which included dentists in white-colored apron, pink-colored apron, green-colored apron, blue-colored apron, and gown with cartoon character and dentists without apron (formal attire) along with a camouflage syringe and a conventional syringe were provided to every child and was asked to give his/her preference looking at the six set of pictures. The preference of each child was recorded. Children's anxiety level during injections and dentist attire was assessed and recorded using two anxiety scales, i.e. the Modified Child Dental Anxiety Scale faces version and Facial Image Scale. Chi-square test were used to analyse the same. The results showed majority of participants in the 4–5-years age group preferred aprons with cartoon character, while 65.3% of the participants in the 12–14-years age

group selected white apron as the preferred choice. Regarding preference of the syringe type, it was observed that 82% of the younger age preferred camouflage syringe and 75% of the older age preferred conventional syringe. On comparison of both the scales, no significant differences were found. About 82% children in the older age group were reported to be non-anxious with white attire and only 14% were anxious with the conventional syringe type. The study hence concluded that the younger children have a greater preference of colorful attire of dentist and camouflage syringe over the conventional one when compared to older children.²⁸

In a study conducted aimed to assess the effect of camouflaged syringe on anxiety and behaviour in children between the ages 6-11 years. The rationale for this was converting visually threatening stimuli to visually non-threatening visual stimuli. In this randomized, crossover clinical pilot study conducted which included 30 children (15 boys and 15 girls), children were separated into two groups according to age group and assessed. Group 1 consisted of 15 children aged 6-8 years while group 2 consisted of 15 children aged 9-11 years. Among the participants, fifteen children were treated with camouflaged syringe in the first appointment and conventional syringe in the next appointment, and the other fifteen were treated with conventional in the first appointment followed by camouflaged syringe. The physiological parameter used was the finger pulse oximeter. Faces, legs, activity, cry and consolability (FLACC) scale was also used to assess the behaviour of the child undergoing anesthesia. Behaviour management techniques like Tell- Show- Do and Euphemisms were also used along with the control and intervention. One of the limitations of this study was that the patient was used as his own control and the washout time was not mentioned. The results of this study showed a lower mean change in pulse rate and FLACC scores in the camouflaged group, suggesting a

positive behaviour and lesser anxiety with camouflaged syringes than with conventional syringes. Conclusion of this study was that the use of camouflaged syringes for anaesthesia was demonstrated to be effective in improving the behaviour of children and decreasing their anxiety.²⁹

A similar study which was conducted using camouflage using toys made of acrylic resin showed a similar finding. The camouflaged syringe was made with a cold cure acrylic incorporated with various dyes. A sample size of 100 was achieved, and participants were randomly divided into two groups of 50 each. This was a concurrent parallel study as opposed to crossover in the previous trial. One group was treated using the camouflaged syringe whereas the other group using conventional syringe. Venham clinical rating scale was used to assess the pre and post anxiety score. Results showed that the overall behaviour score with the participants treated with camouflaged syringe was 97%. Hence this study concluded that the use of camouflaged syringe had improved outcomes related to dental fear and anxiety in children.³⁰

Anxiety and fear reduction using camouflaging technique was also assessed in a study conducted to assess anxiety and fear in different groups of children being administered local anesthetic (LA) using either conventional or camouflaged syringe. The injection was camouflaged using pictures of smiles, cars, cartoon characters, colorful fishes and sun. A sample size of 80 children aged 6-8 years was evaluated in the study. Inferior alveolar nerve block was administered in both the groups using the allocated type of syringes. Venham picture test and FLACC scales were used to assess the comparative anxiety levels. The study showed a higher mean score for Venham scale and FLACC scale for conventional syringe as compared to camouflaged syringe.

The study corroborated that the use of camouflaged syringe significantly decreased the anxiety in children during administration of local anesthesia.³¹

A clinical comparative study was done using camouflaged insulin syringe and conventional syringe for dental extractions in children. A total of 60 patients were selected between the ages of 10-14 years and were divided into two groups of 30 patients each. Group “A” patients were administered local anaesthesia by a conventional syringe and Group “B” by insulin syringes. The syringes were used to administer local infiltration anaesthesia. The pain, comfort and effectiveness were assessed by visual analogue scale and faces pain rating scale. The mean pain perception of conventional syringe was seen to be higher as compared to insulin syringe. Hence, the study concluded that the success rate of insulin syringe is more than conventional syringe.³²

In a pilot study done to assess the reaction of 5 and 6 year olds to dental injection after viewing the needle. The aim was to evaluate the practice of hiding the needle prior to dental anaesthesia administration to children. Fourteen 5 and 6 year olds received dental treatment in two sessions. The needle was shown in one session and hidden in the other. Eleven children were cooperative and three were uncooperative irrespective of approach. The children's behaviour correlated with fears expressed by the mothers. The initial findings did not support the practice of hiding the needle.³³

In a study published which aimed at comparing the anxiety and pain perception during maxillary anesthesia using camouflaged and conventional syringes. The anxiety was assessed using the Venham Picture scale and the pain perception was assessed using the Wong Bakers faces pain scale. Twenty four children were

randomly chosen and divided into two groups of Conventional and Camouflaged syringe. Only positive and definitely positive children were chosen for the study. After application of local anesthesia, local anesthesia was delivered using either conventional or camouflaged syringe after which pre and post anxiety was noted. Post treatment pain perception was also noted. The authors noted a significantly lower anxiety levels and levels of pain perception in children in camouflaged syringe group. They concluded that camouflaged syringe can be useful in children.³⁴

Literature in relation to other novel distraction techniques to relieve anxiety and modify pain perception during administration of Local Anesthesia:

A systematic review was conducted to check the acceptance of local anesthesia in children using various modalities. A total of 26 studies including 2435 children aged between 2 and 16 years were evaluated in this systematic review. These studies were conducted between 2002 and 2019 in dental clinics in the UK, USA, the Netherlands, Iran, India, France, Egypt, Saudi Arabia, Syria, Mexico, and Korea. Studies comparing the use of various equipment like audio-visual glasses or a computerised device for injection called the wand, or hypnosis, counter-stimulation/distraction, video modelling, to increase the acceptance of delivery of local anaesthetic were included. These novel interventions were compared with the usual conventional syringe. The reviewers could not come to a sound conclusion as they found the existing scientific evidence scanty.³⁵

Other than camouflaging the syringe, other efforts of distraction were also studied. In a randomized crossover split mouth study including 30 participants aged between 6-11 years, a novel vibrating device was used during administration of local anesthesia. The aim of this study was to compare and analyse the anxiety and pain

perception during Inferior alveolar nerve block with and without the vibrating device. The participants were divided into two groups according to age; group 1: 6-8 years and group 2: 9-11 years. During local anesthesia delivery on one side the device was used, whereas on local anesthesia delivery on the second side was done without the device. The baseline pulse rate and the pulse rate during the procedure were also noted by an independent observer. FLACC scale was also noted by the operator for comparative analysis. The mean baseline pulse rate and pulse rate during treatment using the conventional method were seen to have a greater difference when compared to children aged 9-11 years. The FLACC scores also showed reduced scores on using the distracting device. The study concluded that use of the novel vibrating device reduces the anxiety during administration of Inferior alveolar nerve block in children aged 6-11 years.³⁶

A study aimed at assessing the effect of an active and novel distraction technique using Writing In The Air Using Leg (WITAIL) during the administration of local anesthesia was conducted in 160 children aged between 4-10 years. The participants were divided into two groups of 80 patients each. During the administration of local anesthesia the children in the control group were made to relax by means of deep breathing and those in the intervention group were taught to use the WITAIL distraction technique. The behavior of the children aged 4 – 5 years was noted using the Modified Toddler- Preschooler Post operative Pain Scale (TPPPS) and that of children aged above 6 years was measured using the FACES Pain Scale– Revised. The results of the study was found to be statistically significant ($p < 0.0001$) when WITAIL technique was compared to the control method in serving as a distraction. Hence, the study concluded that distraction using WITAIL technique was effective during administration of local anesthesia.³⁷

In a randomized clinical trial aimed at assessing the effect of three-dimensional (3D) audiovisual (AV) distraction in reducing dental anxiety of children, 90 children (49 boys and 41 girls) aged between 7 and 10 years were chosen. The participants were randomly divided into three groups; control (basic behaviour guidance techniques without distraction), audio (basic techniques plus music) and AV (basic techniques plus 3D AV) distraction groups. All the children were subjected to LA administration with/ without distraction and the anxiety was assessed using a combination of measures: MCDAS(f) (self-report), pulse rate (physiological), behaviour (using Wright's modification of Franklbehaviour rating scale and Houpt scale) and preferences of children. The study showed a highly significant reduction in the anxiety of audiovisual group as reported by the MCDAS (f) values ($p > 0.001$) and Houpt scale ($p = 0.003$); whereas pulse rate showed statistically significant increase ($p > 0.001$) in all the three groups irrespective of distraction. The anxiety seemed to reduce with audiovisual distraction as compared to other techniques. The pulse rate was not found to differ in any of the three groups. Despite this, the children preferred 3D glasses over other distraction techniques.³⁸

A clinical study assessing the effectiveness of hypnosis in combination with conventional techniques of behavior management in anxiety/pain reduction during dental anesthetic infiltration was conducted in 40 healthy children (16 boys and 24 girls) aged 5 to 9 years. Patients who had never received dental treatment before were included in the study. Patients that met the inclusion criteria were randomly assigned to the experimental or control group (20 children in each). Standard conventional behavior management techniques were used with both groups. The experimental group was listed to a classic directive hypnosis intervention, while the control patients were told to use headphones to block out the dental drill's noise. No sound was transmitted

to the control group. The children in the experimental group were asked to listen to a recording that would teach them how their thoughts and breathing could help them feel more comfortable and relaxed. The hypnosis intervention procedure aimed at increasing the patients' focus, absorption, and concentration. In the intervention phase the hypnotic suggestions were aimed at modifying their perception of pain. Patients were asked to visualize a safe and special garden with a fountain in the middle. They were told the fountain water would make their mouth numb and relaxed, so they would feel completely comfortable and relaxed while the dentist "made their tooth feel better." They were then asked to raise their right arm when their mouth had gone completely numb. Once the audio recording finished, the dentist verified that the child was completely alert and continued cooperating with the dental procedure. FLACC scale was recorded. A marginal statistical difference ($p = 0.05$) was found in the heart rate between baseline and anesthetic moment, being lower in the hypnosis group. No statistically significant differences were found with the FLACC scale or in the skin conductance ($p > 0.05$). This study concluded that hypnosis combined with conventional behavior management techniques decreases heart rate during anesthetic infiltration showing that there may be an improvement in anxiety/pain control through hypnotic therapy.³⁹

In a randomized control trial aimed at assessing the effects of audiovisual distraction on children's behavior during dental treatment. The participants were aged between 7 and 9 years. The patients were divided randomly into two groups that received either AudioVisual distraction or no distraction. Coin toss method was used for randomization. The total samples included were 56. An audiovisual device was used in the experimental group for distraction. The patients underwent a dental examination in the first visit followed by acclimatization in the second visit and

restoration in the third visit which consisted of local anesthesia procedure, rubber dam application and restoration. Facial Image Scale, Modified Venham's Scale, Blood Pressure and Pulse Rate were used to monitor the anxiety and pain perception. Two observers who were blinded assessed the video tapes of the procedure. The results of this experiment showed significantly lower MVARs scores in audiovisual group when compared to the control-group ($p = 0.029$), and the scores decreased significantly during treatment in the AV-group ($p = 0.04$). Further, the pulse rate was significantly increased in the control-group during injection with local anaesthesia ($p = 0.02$), but not in the AV-group. The experiment concluded that audiovisual glasses are an effective tool in reducing anxiety in children during dental treatment.⁴⁰

Literature in relation to pain perception using computerized local anesthesia delivery:

Numerous studies were done to assess the conventional local anesthesia technique and computerized delivery. Local anesthesia experience can be unpleasant especially for children. In a study aimed at evaluating and comparing traditional and wand (computerized) method of delivering local anesthesia in children objectively and subjectively, pain perception in age group of 8-12 year old children were evaluated. A sample size of 100 subjects was split into two groups which received buccal and palatal anesthesia with wand and conventional local anesthesia delivery respectively. Visual Analogue scale was used for subjective assessment, Sound, Eye, Motor scale was used for objective analysis and pulse oximeter was used to assess the physiological parameters. The results of this study showed no statistically significant difference during the buccal infiltration using both techniques whereas during palatal injection, the wand technique showed less pain perception as compared to the

traditional technique. The experiment also concluded that gender had no effect on pain perception.⁴¹

The pain perception of children using computerized local anesthesia techniques have been evaluated in numerous studies. In a study aimed at comparing the pain perception in children using comfort control syringe and conventional injection technique during pediatric dental procedures. Comfort control syringe is a computer controlled local anesthetic delivery injection. Fifty children (31 boys and 19 girls) in the range of 6-14 years of age who required anesthesia in two quadrants were selected for the study. This study was a randomized crossover trial. The children were explained prior to the procedure with tell-show-do. Visual analogue scale, Faces rating scale, blood pressure, heart rate and temperature were noted before and after the procedure. The results were found to be statistically significant for the Visual analogue and faces rating scale, whereas there was no statistical difference between the physiologic parameters at various intervals of time. There was no difference in the males and females. The study concluded that comfort controlled syringe reduced the pain caused during the injection, but the physiological parameters remained the same.⁴²

A study conducted to evaluate the influence of different local anaesthetic techniques in pain, disruptive behaviour and anxiety in children's dental treatment gave a perspective regarding the use of conventional Local anesthetic technique in comparison to vibrational anaesthesia (VBA) and computer-controlled local anaesthesia delivery (CCLAD). This randomised clinical trial included a sample size of 105 children aged 5-8 years with comparable cognitive condition and chronological age, requiring restorative treatment in upper posterior teeth under local anesthesia.

The outcomes were self-perception of pain (Wong-Baker Faces Pain Rating Scale, Numerical Rating Scale, disruptive behaviour (Face, Leg, Activity, Cry, Consolability Scale – FLACC); anxiety (Corah’s Dental Anxiety Scale; modified Venham Picture Test) and physiological parameters (blood pressure – systolic and diastolic, heart rate, oxygen saturation , respiratory rate). The results obtained showed no statistically significant difference between any of the three modalities used. Hence, the authors concluded that different anaesthetic dental local techniques do not affect the levels of pain, disruptive behaviour, anxiety and physiological parameters in children aged 5–8 years old.⁴³

Innovations in hiding the needle (Patents):

In an effort to hide the needle from view, many patents have been acquired around the world. A needle hiding shield was invented for a dose metering syringe to hide the hypodermic needle from view. Two designs were proposed. In the first design, an inner anchoring sleeve which surrounded the medication cartridge was incorporated. In addition to this, an opaque outer sleeve was included which shielded the hypodermic syringe. This was arranged in such a way as to coaxially align both the sleeves connected by springs. The injection was administered when the outer sleeve was pulled distally before the medication was deposited.

In the second design, the needle hiding shield consists of an outer spring sleeve to shield the hypodermic needle. Injection will be administered by pulling the outer sleeve into the inner sleeve.⁴⁴ Another innovation in the field of needle related anxiety in children is a puncture depth controlling and needle hiding device. This design comprises housing and an inner sleeve. The inner sleeve is rotatable and is positioned in the housing. A spring is incorporated in the device which keeps the

inner sleeve at the same respective position but pushes the proximal end of the housing. When this happens, the local anesthetic is injected.⁴⁵

In an attempt to camouflage the needle, a syringe was designed where syringe holder was incorporated with a needle coupled with it. A plunger was mounted along with the syringe holder. The syringe holder and needle was fashioned in the form of a toy. It was designed such that the patient would not know it is a syringe prior to the injection.⁴⁶

A novel, simplified and children friendly camouflaging sleeve was made in India. It was designed as a toy in the shapes of butterfly, engine, fish and doll. It was made with cold cure acrylic and included various dyes for colour. It included a head, body and tail. An aspiration window was included and a fancy decoration notch made it more visually attractive. The innovator also included a tip through which the needle would emerge.³⁰

MATERIALS AND METHOD

The present in vivo study was designed to compare and evaluate the anxiety level and pain perception using conventional and camouflaged syringes during local anesthesia administration in children 6-11 years of age.

The study was conducted in the Department of Pediatric and Preventive Dentistry, KLE Academy of Higher Education and Research's, KLE VK Institute of Dental Sciences, Belagavi. Ethical clearance for the study was obtained from the Institutional review board(**AnnexureII**).

The following clinical armamentarium was used in the study [**Figure No. 1, Figure No. 2**]:-

MATERIALS AND ARMAMENTARIUM

- Camouflaged sleeve by Angelus®
- Metal syringe by Waldent
- Cartridge (2% lignocaine with 1: 80,000 adrenaline, Septodont)
- 27 Gauge Needle for metal syringe by Septoject
- Conventional syringe by UNOLOK, 2ml syringe cartridge
- BD Precision Glide Needle (27½ Gauge)
- Topical anesthetic gel (Lignocaine Hydrochloride gel IP , Xyocaine 2% Jelly)
- 2% lignocaine with 1: 80,000 adrenaline
- Pulse oximeter, CONTEC™
- Mouth mirror
- Probe
- Tweezer



Figure No.1: Photograph showing clinical armamentarium used in the study.



Figure No. 2 : Photograph showing camouflaged sleeve (Angelus®) used in the study

SOURCE OF DATA:-

The study was conducted on patients reporting to the outpatient department of the Department of Paediatric & Preventive Dentistry at KLE Academy of Higher Education and Research's KLE VK Institute of Dental Sciences, Belagavi.

The intervention was carried out under the supervision of the examiner. Informed written consent was obtained from the guardian/warden of the child (**Annexure IIIa, IIIb, IIIc**). Assent was obtained from all the children participating in the study (**Annexure IV**)

SAMPLE SIZE:-

The required sample size was calculated using the following formula⁴⁷:-

$$n = \frac{2(S^2)}{d^2} \{z_{\alpha/2} + z_{(1-\beta)}\}^2$$

- Where d = mean difference
- where $\alpha = 5\%$, $z_{\alpha/2} = 1.96$ and $\beta = 80\%$, $z_{(1-\beta)} = 1.037$,
- where $\alpha =$ type 1 error,
- $1-\beta =$ power of the study,
- S = standard deviation
- $S_1 = 2.1547$
- $S_2 = 1.658$

▪
$$S = \frac{S_1 + S_2}{2}$$

2

$$\frac{2.1547 + 1.658}{2} = 2.9837$$

2

- Confidence level was set to 80% and the probability to 0.05.
- So a total of 62 sample size were selected and divided into two study groups of thirty one each.

SELECTION OF SUBJECTS:-

62 children were selected according to the following inclusion and exclusion criteria:-

INCLUSION CRITERIA:

- Children who require infiltration anaesthesia in the maxillary arch for restorative, endodontic or extraction work.
- Children who have never experienced dental injection
- Children between the age group of 6-11 years.

EXCLUSION CRITERIA:

- Patients allergic to contents of local anesthesia
- Patients who require emergency treatment
- Patients with painful dental experience in past
- Patients with special health care needs
- Patients who do not want to participate in the study

METHOD OF COLLECTION OF DATA:-

A) Allocation:

Allocation was carried out using lottery method. Chits were prepared before the start of the experiment. An independent investigator asked the patient to pick up one chit containing the printed name of the intervention-conventional or camouflaged. In accordance to this, the patient would belong to one of the following groups (**Figure No. 3,4**):

1. Group A (Conventional)
2. Group B (Camouflaged)



Figure No. 3: Photo showing allocation by Lottery system in a patient

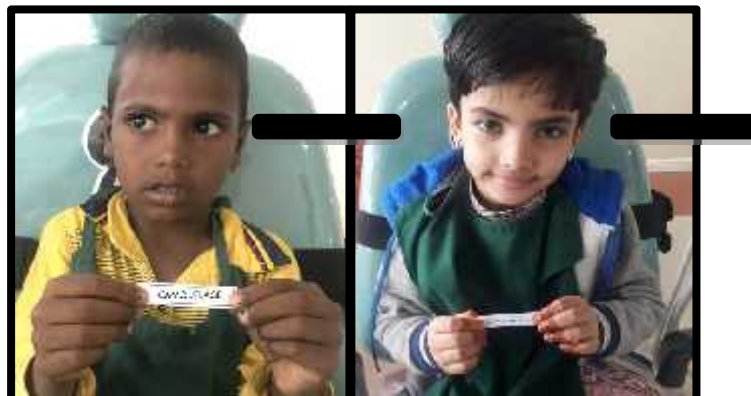


Figure No. 4: Photo showing the child holding the chit

B) Selection of case and recording of case history

After comfortably seating the patient on dental chair, the procedure was completely explained to the parents as well as children using standard operating protocol. Consent forms and Assent forms were given to the parent/Guardian and Patient to be filled and duly signed. (**Annexure IIIa, IIIb, IIIc, IV**)

A standardized case history format was used to record the demographic data, and relevant data comprising of details of the chief complaint, preliminary history, etc. After recording the preliminary information, clinical examination was carried out on a dental chair. (**Annexure V**)

C) Procedure of recording pre-operative anxiety through self-report

Venham Picture Test (VPT) and Pulse Oximeter:

Venham Picture Test was used to record the preoperative anxiety levels in the patient. A trained Investigator was appointed to administer the test in the language the child was fluent in to avoid errors due to lack of understanding. Patient was asked to select the pictures on the Venham Picture Test that he/she could correlate the most at that given point in the Dental Clinic. Anxiety score was the sum of the anxious pictures pointed at by the child. When the child pointed to an anxious picture, a score of 1 was given, non-anxious pictures were scored 0. The total score was given from 0-8. (**Figure No. 5a, 5b**)

Pulse Oximeter, CONTEC™, was used to record the preoperative baseline pulse rate of the patient. (**Figure No. 6**)



Figure No. 5a: Photograph showing Venham Picture Scale



Figure No. 5b: Photograph showing recording of Pre-operative Venham Picture Scale in a patient



Figure No. 6: Photograph showing recording of Baseline Pulse Rate in a patient

D) Explanation of the procedure to the child:

During our Literature Review, the importance of imparting information of the procedure to the patient as a part of the anaesthesia procedure came into picture. Hence, in accordance to the age group, we framed sentences which excluded threatening words. The sentences explaining the procedure were kept same for all the children. Euphemisms were used eg: “Your tooth will be put to sleep with magic water” or “This toy will help your tooth to sleep with magic water”

E) Precooling the site before administration of anaesthesia

Topical anaesthesia (Lignocaine Hydrochloride gel IP (Xylocaine 2% Jelly)) was applied at the site of injection and the site was precooled for about 3 minutes before injecting anaesthesia. **(Figure No. 7)**



Figure No. 7: Photograph showing precooling of injection site with topical anaesthesia.

F) Procedure of administration of local anaesthesia

A single trained Investigator (PI) was allocated to administer local anaesthesia.

Group A (Conventional syringe group):

- The syringe was loaded with local anaesthesia (2% lignocaine with 1: 80,000 adrenaline)
- After precooling of the site, retraction of the mucosa was done and needle was advanced into the tissue. **(Figure No. 8)**
- Pulse rate was noted at this point by the independent investigator as pulse rate during anaesthesia and local anaesthesia was slowly injected over one minute.
- The needle was retracted and inserted into the safety cover.



Figure No. 8: Photograph showing the local anaesthesia administration using Conventional syringe

Group B (Camouflaged syringe group):

- The metal syringe was loaded with local anaesthesia cartridge (Septodont 2% lignocaine with 1: 80,000 adrenaline) and syringe (27 Gauge Needle for metal syringe, Septoject) was attached to the apparatus at the nurse station.
- After precooling of the site, retraction of the mucosa was done and the camouflaged syringe advanced into the oral cavity.
- The alligator sleeve was retracted when the apparatus was completely out of view of the child and the syringe inserted into the tissue. **(Figure No. 9)**

- Pulse rate was noted at this point by the independent investigator as pulse rate during anaesthesia.
- Local anaesthesia was slowly injected over one minute.
- The needle was retracted.
- The apparatus was then safely disposed. Alligator sleeve and metal syringe were cleaned and autoclaved.



Figure No. 9: Photograph showing local anesthesia procedure being conducted using Camouflaged syringe

G) Procedure of recording post-operative anxiety through self-report

Venham Picture Test (VPT):

Venham Picture Test was used once more to record the post-operative anxiety levels in the patient. The trained Investigator administered the test once again in the language the child was fluent in to avoid errors due to lack of understanding. Patient was asked to select the pictures on the Venham Picture Test that he/she could correlate the most at that given point. Anxiety score was the sum of the anxious pictures pointed at by the child. The score was given from 0-8.(Figure No. 10)



Figure No. 10 : Photograph showing recording of post-operative anxiety through self-report Venham Picture Test (VPT)

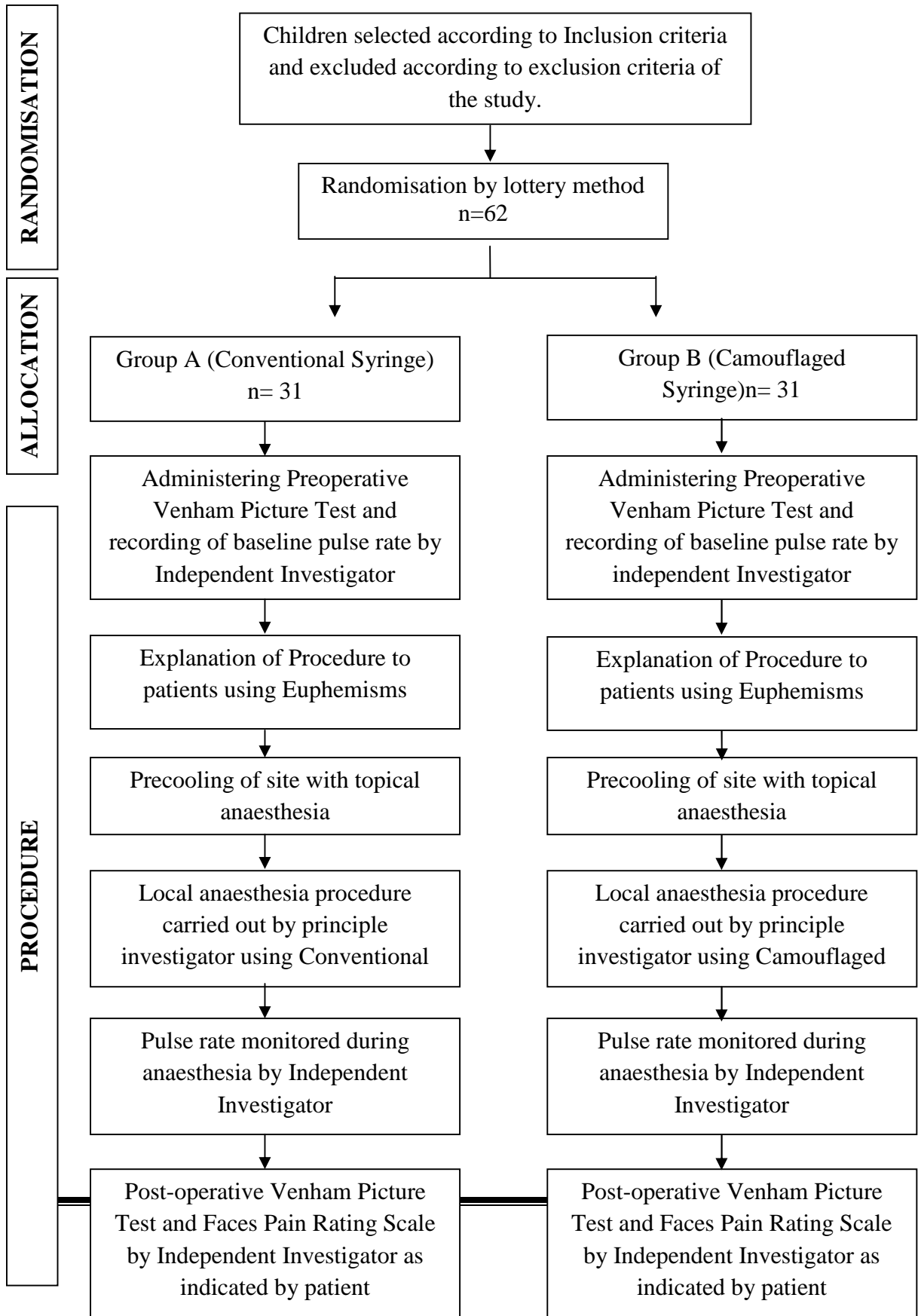
H) Procedure of recording post-operative Pain Perception through self-report Faces Pain Rating Scale:

Self-report pain perception was recorded for both Group A and Group B with Faces Pain Rating Scale. The scale was shown to the patients and they were made to point the intensity of pain experienced, lowest being 0 and highest being 10. (Figure No. 11)



Figure No. 11: Photograph showing post-operative faces pain rating scale being recorded

Flow chart of the Methodology



STATISTICAL TEST:

The results were tabulated and entered on the excel sheet. Then the results were subjected to the following statistical tests using IBM SPSS software (version 20.0 Chicago IL, USA):

Parametric tests for pulse rate scores:

- Independent t test for intergroup analysis
- Dependent t test for intragroup analysis

Non Parametric tests for VenhamPicture Test Scores, Faces Pain Rating Scale

Scores and other factors:

- Chi Square Test
- Mann Whitney U Test
- Wilcoxon Matched Pairs Test
- Correlation analysis with Karl Pearson for intragroup analysis

RESULT

TABLES, GRAPHS AND OBSERVATIONS

Tables showing master chart of the anxiety scores using self-reported anxiety scale (Venham Picture Scale) and physiological anxiety score (pulse oximeter) during and after injection have been included in the annexures. The tables also show pain perception post-injection using Faces Pain Rating Scale. (Annexure Ia, Ib)

Table 1: Table showing distribution of percentages of males and females in two groups (control and experiment) using Chi-square test.

Sex	Experiment group	%	Control group	%	Total	%
Male	16	51.61	19	61.29	35	56.45
Female	15	48.39	12	38.71	27	43.55
Total	31	100.00	31	100.00	62	100.00
Chi-square=0.5901 p = 0.4422						

Table 1 shows a comparison of percentages of males and females in two groups (control and experiment). In the experimental group, out of 31 participants, 15 (48.39%) were male and 16 (51.61%) were females. In the control group, out of 31 participants, 19 (61.29%) were males and 12 (38.71%) were females. The intergroup comparison was done among the two groups using Chi square test to assess the mean percentage of males and females in the two groups. The Chi square test was found to be 0.59 ($p=0.44$) which was not statistically significant. This shows that both the groups have common mean gender ratios which will maintain standardization of selection criteria in our study.

Table 2: Table shows comparison of two groups (control and experiment) according to mean age groups of the participants.

Age groups	Experiment group	%	Control group	%	Total	%
6-7yrs	8	25.81	8	25.81	16	25.81
8-9yrs	13	41.94	10	32.26	23	37.10
10-11yrs	10	32.26	13	41.94	23	37.10
Total	31	100.00	31	100.00	62	100.00
Mean age	8.55		8.77		8.66	
SD age	1.31		1.50		1.40	
Chi-square=0.7833 P = 0.6762						

Table 2 shows comparison of two groups (control and experiment) according to mean age groups of the participants. The control group has 25.81% of the participants in age group between 6-7 years, 32.26% between age groups of 8-9 years and 41.94% between age groups of 10-11 years. The experimental group has 25.81% of the participants in age group between 6-7 years, 41.94% between age groups of 8-9 years, 32.26% between age groups of 10-11 years. The mean ages in experimental and control group is 8.55 and 8.77 respectively. Intergroup comparison was done by Chi square test which was 0.7833 (p=0.6762). This shows that both groups have statistically insignificant age difference, and hence standardization has been maintained in this aspect.

Table 3: Table no 3 shows comparison of two groups (control and experimental) with respect to Frankl's behaviour rating before treatment.

Behaviour	Experimental group	%	Control group	%	Total	%
Definitely Positive	7	22.58	5	16.13	12	19.35
Positive	21	67.74	16	51.61	37	59.68
Definitely negative	0	0.00	2	6.45	2	3.23
Negative	3	9.68	8	25.81	11	17.74
Total	31	100.0	31	100.0	62	100.0
Chi-square=5.2824 P = 0.1523						

Table 3 shows intergroup comparison between the two groups with respect to pre-procedure Frankel's Rating Scale. In the control group, 16.13% were definitely positive, 51.61% were positive, 6.45% were definitely negative and 25.81% were negative. In experimental group, 22.58% of the participants were definitely positive, 67.74% were positive and 9.86% were negative as per the Frankel's Behaviour Rating Scale. The intergroup comparison using Chi square test yielded a result of 5.2824 ($p=0.1523$). As the score is not statistically significant, there was proper standardization achieved in both the groups as far as behavior of patients was concerned.

Table 4: Normality of pulse rate and Venham scores at before and after time points in two groups (control and experiment) by Kolmogorov Smirnov test

Variables	Time points	Experiment group		Control group	
		Z-value	p-value	Z-value	p-value
Pulse rate	Before	0.3860	0.9980	0.5320	0.9400
	During	0.9720	0.3020	0.4090	0.9960
	Difference	0.5340	0.9380	0.6820	0.7410
Venhams	Before	1.5360	0.0180	1.3530	0.0500*
	After	0.9390	0.3410	0.7980	0.5470
	Difference	1.2220	0.1010	1.5240	0.0190*

* $p < 0.05$

The before and during pulse rate follow a normal distribution in two groups (control and experiment), therefore, the parametric tests like independent t test and dependent t test were applied. But, the before and after Venham and pain perception scores are not following a normal distribution in two groups (experiment and control), therefore, the non-parametric tests like Mann-Whitney U test and Wilcoxon matched pairs test were applied.

Table 5: Table showing comparison of two groups (control and experiment) with respect to before and during treatment pulse rates by independent t test

Time points	Experiment group		Control group		t-value	p-value
	Mean	Std.Dev.	Mean	Std.Dev.		
Before treatment	101.06	16.52	97.97	19.46	0.6754	0.5020
During treatment	106.06	17.29	105.55	17.61	0.1165	0.9077
Difference	-5.00	13.35	-7.58	17.53	0.6520	0.5169

Graph 1: Graph showing comparison of two groups (control and experiment) with respect to before and during treatment pulse rates by independent t test

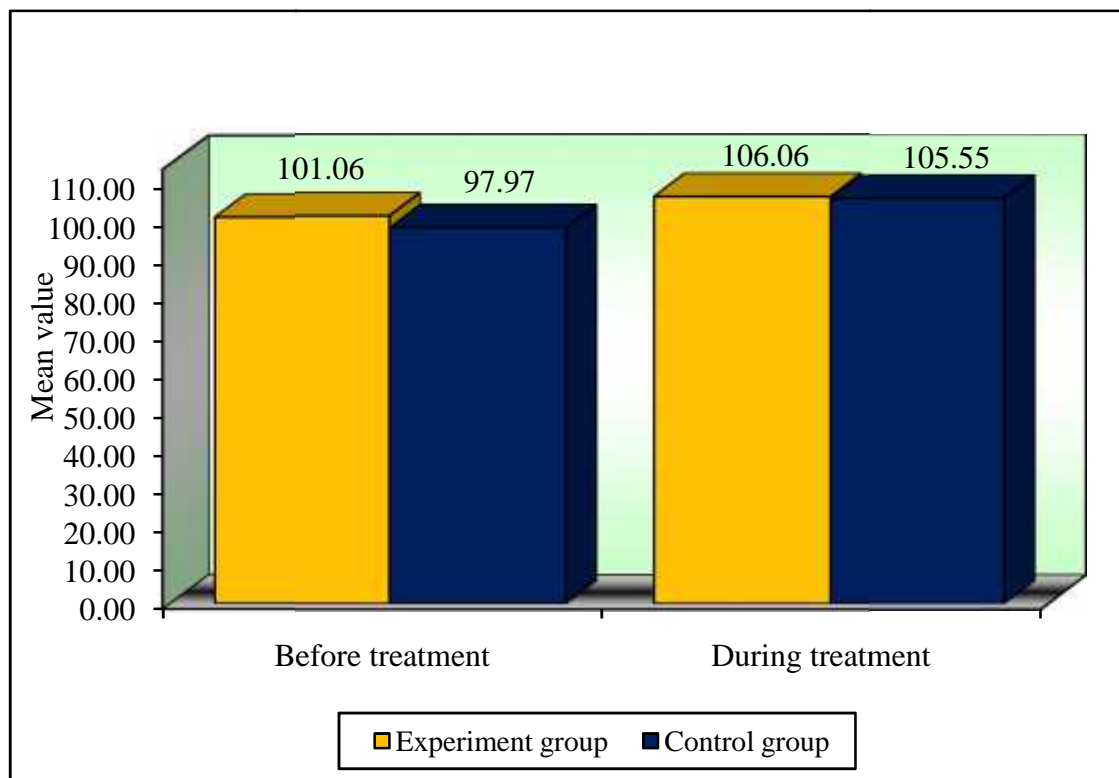


Table 5 and **Graph 1** show comparative pulse rates before and after treatment as indicated by independent t-test. The mean pulse rate before the treatment was found to be 101.06 (SD = 16.52) in experimental group and 97.97 (SD= 19.46) in the control group. The difference in both the groups was seen to statistically irrelevant.(p=0.5020) The mean pulse rates during the procedure was seen to be 106.06 (SD= 17.29) in experimental group and 105.55 (SD= 0.1165) in control group. The difference in the pulse rates before and during local anesthesia was seen to be statistically insignificant. (p=0.5169)

Table 6: Comparison of before and during treatment times with respect to pulse rates in two groups (control and experiment) by dependent t test

Groups	Time points	Mean	Std.Dv.	Mean Diff.	SD Diff.	% of change	t-value	p-value
Experimental	Before treatment	101.06	16.52					
	During treatment	106.06	17.29	-5.00	13.35	-4.95	-2.0847	0.0457*
Control	Before treatment	97.97	19.46					
	During treatment	105.55	17.61	-7.58	17.53	-7.74	-2.4079	0.0224*

*p<0.05

Graph 2: Comparison of before and during treatment times with respect to pulse rates in two groups (control and experiment) by dependent t test

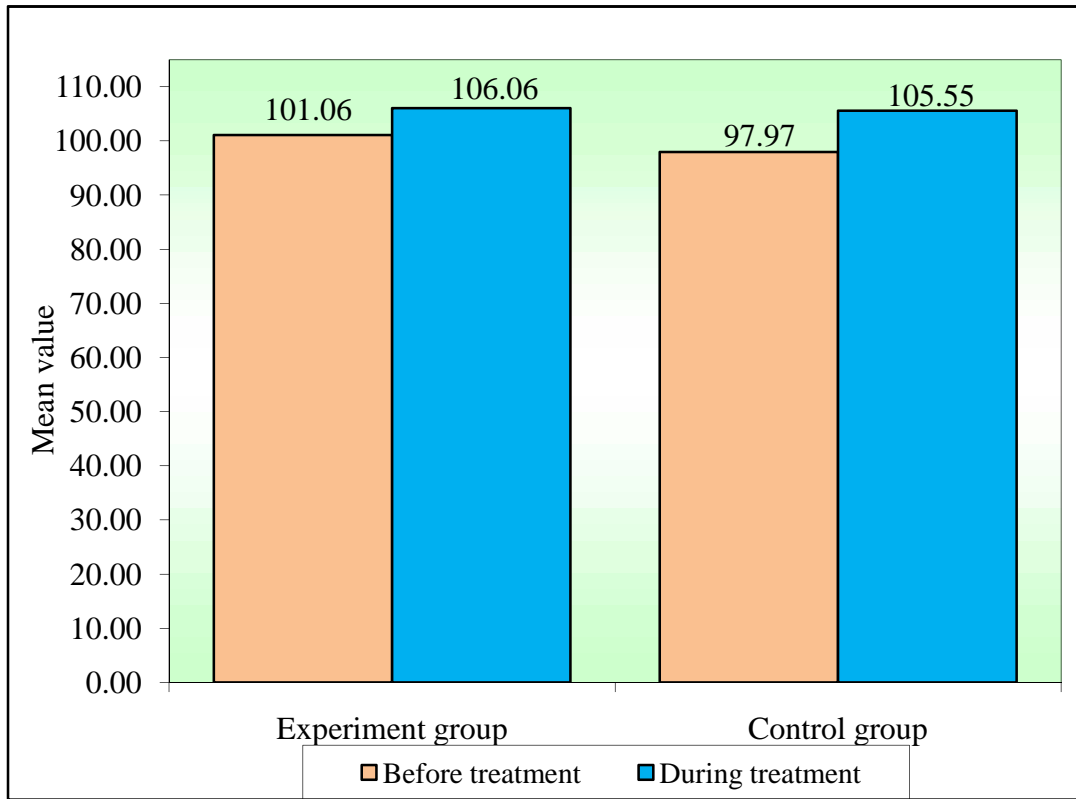


Table 6 and **Graph 2** show the difference in pulse rates before and during local anesthesia as calculated using dependent t-test. The difference was found to be statistically significant in both experimental ($p=0.0457$) and control group ($p=0.0224$) ($p<0.05$) Inter group comparison shows no significant difference in the two groups.

Table 7: Table showing comparison of two groups (control and experiment) with respect to before and after treatment Venham scores by Man-Whitney U test

Time points	Experiment group			Control group			U-value	Z-value	p-value
	Mean	SD	Mean rank	Mean	SD	Mean rank			
Before treatment	1.26	2.11	28.81	1.65	1.94	34.19	397.00	-1.1756	0.2398
After treatment	2.35	2.36	28.77	3.19	2.74	34.23	396.00	-1.1896	0.2342
Difference	-1.10	3.13	32.74	-1.55	2.25	30.26	442.00	-0.5420	0.5878

Graph 3: Graph showing comparison of two groups (control and experiment) with respect to before and after treatment Venham scores by Man-Whitney U test.

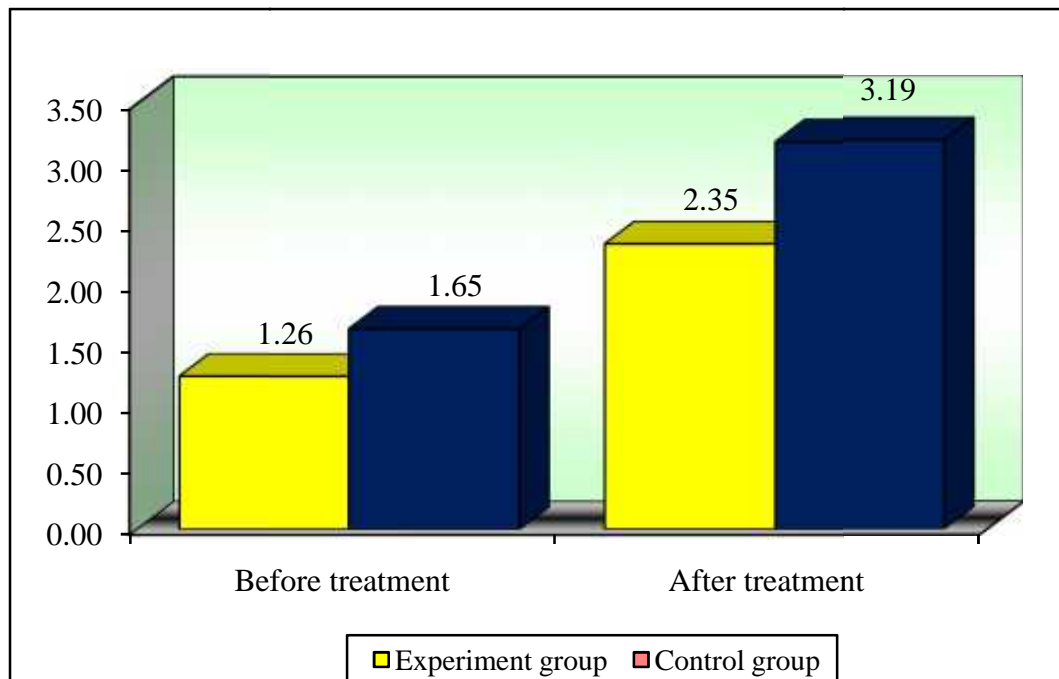


Table no 7 and **Graph 3** show before and after comparison between experimental and control groups using Venham Picture Test by Mann Whitney test. The mean Venham score before the treatment started was 1.26 for experimental group and 1.65 for control group. The mean Venham score of post treatment anxiety for experimental group is 2.35 and for control group is 3.19. The difference in pre-treatment and post-treatment anxiety was found to be statistically insignificant.($p=0.5878$)

Table 8: Comparison of before and after treatment times with respect to Venham scores in two groups (control and experiment) by Wilcoxon matched pairs test

Groups	Time points	Mean	Std.Dv.	Mean Diff.	SD Diff.	% of change	Z-value	p-value
Experimental	Before treatment	1.26	2.11					
	After treatment	2.35	2.36	-1.10	3.13	-87.18	2.5946	0.0095*
Control	Before treatment	1.65	1.94					
	After treatment	3.19	2.74	-1.55	2.25	-94.12	3.4320	0.0006*

* $p<0.05$

Graph 4: Comparison of before and after treatment times with respect to Venham scores in two groups (control and experiment) by Wilcoxon matched pairs test

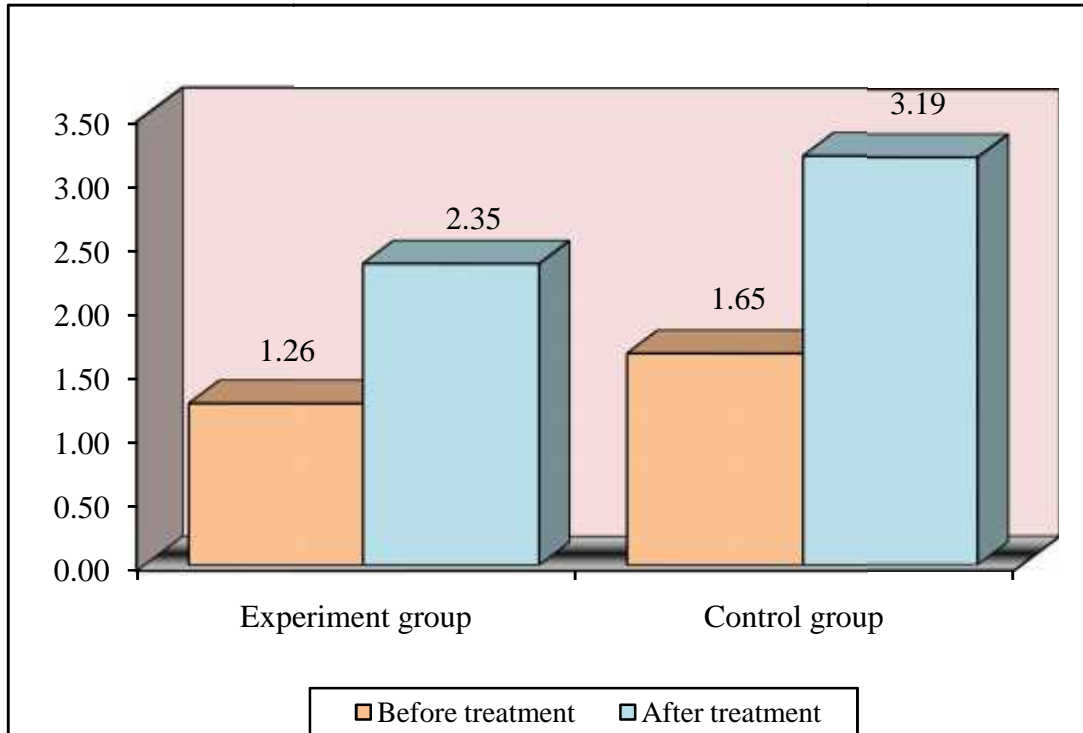


Table 8 and **Graph 4** show a comparative intra-group comparison of post-operative anxiety as measure by Venham Picture test in the two groups. There is statistically significant change seen in the pre- anxiety and post anxiety score in both experimental as well as control group using Wilcoxon matched pairs test ; $p=0.0095^*$ and $p=0.0006^*$ respectively. The inter group comparison shows that the difference in pre and post anxiety is comparatively greater in control group as compared to experimental group, but this difference is not statistically significant.

Table 9: Comparison of two groups (control and experiment) with respect to pain perception scores by Man-Whitney U test

Groups	Mean	SD	Mean rank	U-value	Z-value	p-value
Experiment group	5.03	3.86	32.89			
Control group	4.58	4.26	30.11	437.50	-0.6054	0.5449

Graph 5: Comparison of two groups (control and experiment) with respect to pain perception scores by Man-Whitney U test

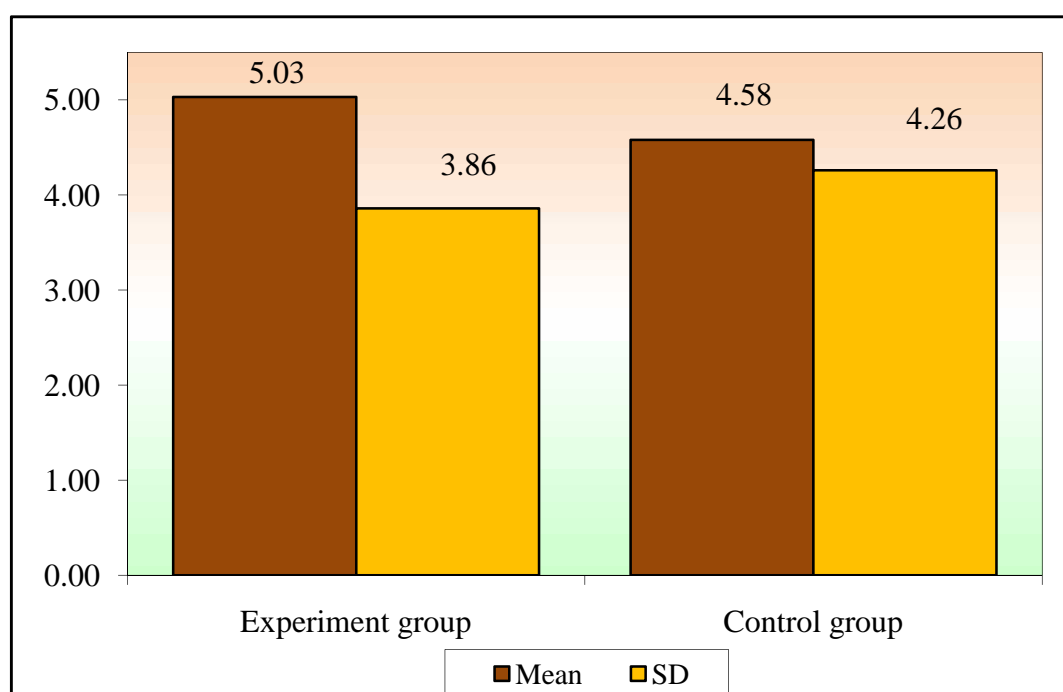


Table 9 and **Graph 5** show comparison of post-injection the pain perception in control and experiment groups as rated by self-report Faces Pain Rating Scale. The mean post-injection pain perception in experimental group was 5.03 (SD=3.86) and 4.58 (SD=4.26) Intergroup comparison using Man-Whitney U test shows no statistically significant difference in post-injection pain perception in two groups.

Table 10: Correlation between pain perception with pulse rate at before and during treatment time points in two groups (control and experiment) by Spearman's rank correlation coefficient

Group	Treatment	n	Correlation between pain perception with		
			Spearman R	t-value	p-level
Experimental group	Pulse rate before	31	0.1101	0.5964	0.5555
	Pulse rate during	31	0.2833	1.5909	0.1225
	Difference	31	-0.2035	-1.1195	0.2721
Control group	Pulse rate before	31	-0.2162	-1.1926	0.2427
	Pulse rate during	31	0.3405	1.9500	0.0609
	Difference	31	-0.4993	-3.1037	0.0042*

*p<0.05

Table 10 shows that the correlation between the Pain perception and pulse rate before and during the injection procedure. It is seen that there is statistically significant correlation between the difference in level of pain perception and pulse rate in the control group, but insignificant correlation in experimental group.

Table 11: Correlation between pain perception with Venham scores at before and after treatment time points in two groups (control and experiment) by Spearman's rank correlation coefficient

Group	Treatment	n	Correlation between pain perception with		
			Spearman R	t-value	p-level
Experimental group	Venham before	31	0.1822	0.9978	0.3266
	Venham after	31	0.4788	2.9371	0.0064*
	Difference	31	-0.3953	-2.3177	0.0277*
Control group	Venham before	31	0.2869	1.6126	0.1177
	Venham after	31	0.5451	3.5017	0.0015*
	Difference	31	-0.2854	-1.6034	0.1197

*p<0.05

Table 11 shows the correlation between pain perception and anxiety levels measured by Venham picture test before and after treatment procedure by Spearman's Rank Correlation coefficient. It is seen that there exists a statistically significant correlation between anxiety and pain perception post- injection of local anesthesia in both experimental (p= 0.0064) and control group(p=0.0015).

SYNTHESIS OF RESULTS

Homogeneity of the sample:

The results of studies conducted under behavioral sciences sector have a drawback as to numerous confounding factors and resultant biases. In our study we have tried to reduce any such heterogeneity. Analysis of the percentages of males and females in the group was analysed by Chi Square Test. In Group A (Control Group) 15 were females and 12 were males and in Group B (Experimental group) 16 were males and 15 were females. The difference in gender ratio in both groups was found to be statistically insignificant. ($p=0.4422$)

With respect to age, the experimental group has 25.81% of the participants in age group between 6-7 years, 41.94% between age groups of 8-9 years, 32.26% between age groups of 10-11 years. The control group has 25.81% of the participants in age group between 6-7 years, 32.26% between age groups of 8-9 years and 41.94% between age groups of 10-11 years. The mean ages in experimental and control group is 8.55 and 8.77 respectively. Intergroup comparison was done by Chi square test which was 0.7833 ($p=0.6762$). This shows that both groups have statistically insignificant age difference, and hence standardization has been maintained in this aspect. The pre appointment behavior was analysed by Frankl's behavior rating scale. Intergroup comparison in the Frankl's Behavior Rating Scale was seen to be statistically insignificant ($p=0.1523$)

Anxiety by Pulse rate:

The Pulse rate was seen to follow a normal distribution, and hence parametric tests like independent and dependent t-test were used. The comparative difference in

before and after pulse rate in Group A and B was analysed by independent t test which were statistically insignificant ($p=0.5169$).

Intragroup differences in before and after pulse rates in each groups were statistically significant; $p=0.0224$ and $p=0.0457$ respectively for Group A and B. Although intergroup comparison was not statistically significant showing that there was similar mean increase in anxiety measured by pulse rate during local anesthesia delivery in both experimental and control groups.

Anxiety by Venham Picture Test:

Since the distribution of Venham Picture Test scores did not follow normal distribution, Non Parametric test (Man Whitney U test) was used. It was seen that no statistically significant difference was seen in before and after Venham test scores when Group A and B scores were compared. This shows that the comparative difference in anxiety before and after the anesthesia procedure with and without intervention remained same. When intergroup analysis was done by Wilcoxon Matched Pairs analysis, there was statistically significant change seen in individual groups ; $p=0.0006$ and $p=0.0095$ in control and experimentgroup respectively. Although the intergroup difference is not significant, it is seen that pre and post anxiety score difference was slightly more in control as compared to experimental group suggesting that intervention was useful in reduction of anxiety to some extent.

Pain perception:

The post injection pain perception was scored using self-report faces pain rating scale. The mean pain perception in Group A was 4.58 and in Group B was 5.03.

The difference in the pain perception in two groups was not statistically significant.
($p=0.5449$)

Correlation of pain perception and anxiety:

The correlation between pain perception and anxiety was checked using Spearman's rank correlation coefficient. In both groups, it was seen that there was a significant correlation between pain perception and post injection anxiety score.
($p=0.0064$; $p=0.0015$) This finding shows that pain during injection is a significant factor in increasing anxiety.

Correlation of pain perception and pulse rate:

This correlation too has been tested by Spearman's rank correlation coefficient. The findings of this are interesting indeed. It has been shown that the correlation between the pulse rate and pain perception is not significant in experimental group. Despite this, there is a statistically significant correlation between before and after pulse rate and pain perception in control group.
($p=0.0042$) This signifies that increase in pulse rate in control group is correlated to the pain perception of this group.

DISCUSSION

The present study attempted to answer whether the camouflaging of the syringe needle would indeed lead to reduction in child's anxiety and post-operative pain perception. It is a common knowledge and experience of all dental practitioners that patients are anxious and fearful of dental injection. Local anaesthetics have been used to block the specific receptors causing pain via the penetration into the cell membrane, blocking the receptor sites.⁴⁸ In spite of their usefulness to manage pain and anxiety, a study conducted by Milgrom, Mancl, King and Weinstein showed that children ranked fear of injection second, the first being fear of strangers touching them.⁴⁸ The basis of this fear is the visual stimulus which triggers it.³⁴

The physiology of fear due to threatening visual stimulus starts the moment the child enters the dental clinic. The eye sends an electrical stimulus to the brain which initiates an autonomic response which is conveyed to the amygdala and then to the hypothalamus, in turn activating the sympathetic stimulus and increasing the heart rate.⁴⁹ This makes it a logical clinical practice to hide threatening objects from the patient. The reduction of anxiety due to absence of an obvious threatening stimulus may result in decreased pain perception too. A recommended practice is the use of cotton rolls to hide the needle from the view. Drawback of such intervention is that the cotton roll may fall off revealing the needle to the child or may harm the child in an endeavour to deliver anaesthesia.³³ Hence, this age old technique needs a practical alternative. In our study we utilised a toy alligator camouflaged sleeve to hide the needle from the view of the child before local anaesthesia injection. This was also convenient for the operator as not much effort goes in hiding the injection apparatus from sight.

Pain, pain perception and pain reaction:

Pain has a long history in human evolution. The mechanism of action of pain were stated by different philosophers as a result of arrows being shot (Homer), passion of the soul (Aristotle) and an “Emotional experience” (Plato). In the 19th century, the recent concepts of pain came into being. Freud suggested that the physical symptoms of pain resulted from thought processes.¹

Pain is a localised sensation that occurs as a result of actual or potential noxious stimulation. It has surpassed physiological boundaries, and is now considered as an experience rather than just a sensation.¹ It consists of a spectrum of cognitive, emotional and motivational factors. It is perceived by sensory neurons and processed in the central nervous system. The main processes that constitute the pain are classified by Field’s as Transduction, Transmission, Modulation and Perception.⁴⁹ Pain perception occurs as a result of complex interactions in the higher centers of brain. Attentional modulation of pain is said to take place in the superior post parietal cortex and emotional modulation in the preaqueuductal grey mater.²³ Melzack suggested that the multidimensional experience of pain was produced by special “neurosignature” patterns of nerve impulses generated by network of neurons in the nervous system.⁵⁰

Having said that, it has been claimed the pain experience may not be related to the amount of tissue injury experienced.²³ One of the contributing factors is the attention paid to the stimulus at the time of noxious injury. Pain is said to intensify if more attention is paid to the injury.⁵¹ On the other hand, this has mainly been studied using stimuli which are less intense in nature.²³ In case of an injection, the stimulus is

more intense, which may cause more distress and hence the corresponding increase in anxiety.²⁸

Mechanism of pain

The sensation of pain begins at the primary afferent neuron located at the site of the noxious stimulus. This wave of stimulus is further carried to the second order neuron located in the trigeminal spinal tract. The crossover takes place in the spinal cord and passes through neospinothalamic tract. The stimulus is relayed in thalamus, where it can be modulated to some extent. The reticular inhibitory region can also modulate or inhibit a painful stimulus. Pain stimulus becomes a pain experience in the cortex. The cortex can modulate the pain according to previous memory. Only those signals carried higher will lead to pain perception.⁴⁹ It is the pain perception that we intended to alter. The concept of pain has many faces and each important in its own aspect. The two faces of pain are pain perception which is physio-anatomic and pain reaction which is psycho-physiologic.¹

Development of anxiety

The negative behavioural responses in children undergoing dental procedures is mainly the product of pain and anxiety.⁴³ In the present study, there was a statistically significant increase in anxiety as measured by pulse rate and Venham's Picture Test after the injection of local anesthesia. Many authors have mentioned the spectrum of factors causing anxiety. To isolate the cause of heightened post-operative anxiety, we have tried to identify the factors which may influence this and discussed each in relation to our study.

1. Age :

Anxiety related to dental treatment is age related, which means that different age groups possess a varying magnitude of anxiety.⁵² The same can be said regarding pain perception. Pain perception decreases with increase in age.⁵³ This may be due to sensitization of the patient over time to painful stimuli. In this study, a population between the ages of 6-11 years was selected. This age group proved to be most suitable as recording of anxiety and pain perception in children was an important aspect of the study.

Children below the age of 6 years may have difficulty in understanding abstract concepts according to Piagetian principles.⁵⁴ Self-reporting of anxiety levels and pain perception maybe difficult for them and ultimately be unreliable for research purposes. In the light of this, development of cognition seems to be an important factor, explaining why the children between age group 6-11 years were chosen to participate.³⁴ Children in this age group are competent to understand the concepts of pain and anxiety making the self-reporting scales more reliable. In our study, statistical homogeneity was achieved in the two groups with respect to age factor.

2. Gender:

Both the conventional as well as the camouflaged syringe groups were homogenous in relation to the gender ratio (M : F) of the study population included in this study. Hence, we can eliminate any bias related to this factor.

The widely believed fact is that female population has a higher anxiety and thus pain perception as compared to male population. The differences mentioned are:

1. Primary afferent fibre excitability
2. Degree of sensitization in secondary neurons
3. Efficiency of endogenous pain modulatory pathways⁴⁹

We believe that the difference in expression of anxiety may also be an attributable factor in this aspect. Despite this assumption, the results did not show any statistically or clinically relevant difference in the pre- and post- anxiety levels neither the pain perception which would suggest that gender of the population played a role in development of anxiety, nor was there any significant difference in pain perception in females as compared to males of both groups.

3. Needle Size:

In dentistry, for local anaesthesia 27-30 guage needles are recommended.⁵⁴ It is a common belief that the tissue injury is proportional to the pain perceived.²⁵ Another school of thought also exists in which they believe that the degree of pain and suffering that a patient experiences, is not related to the tissue injury. It is related to the attention paid at that particular time.²³ In our study we standardized the needle size. We used 27 guage needle for conventional syringe and 27^{1/2} Guage needle for the camouflaged syringe utilizing a metal syringe. In both the groups the needle was of approximately of same guage to reduce bias.

4. Operator factors and communication:

Operator plays a major role in the dental experience of the child. The operator can provide firm verbal assurance to the child with the use of euphemisms.⁵⁵ In our study single trained operator conducted the procedure in all the children. Use of tell- show- do and voice control was used in addition to providing information of the procedure to

child prior to injection in case required. The words to describe the procedure were devoid of any threatening words. Substitution of words with appropriate euphemisms was carried out in all subjects before the procedure. The children were told their tooth would be put to sleep with the help of magic water. The words and the protocol used were kept same in children of both Groups to eliminate bias. The uniform of the investigator and the principle operator did not vary from patient to patient. All the patients were treated in the same clinical setting.

5. Preoperative Frankl's behaviour scale:

The preoperative behaviour rating was assessed as it may influence the pain related behaviour of the child. The preoperative behaviour was analysed by Frankl's Behaviour rating scale. When the Frankl's behaviour was analysed for both groups, the maximum number of children were either definitely positive or positive. Statistically speaking, the sample was found to be homogenous. Hence, no bias was encountered wherein Preoperative behaviour of patients was concerned.

6. Appointment :

The most likely mechanism of development of anxiety is the direct conditioning as proposed by Rachman.⁵⁶ In this, stress has been laid on negative dental experiences of a child in dental clinic which may contribute to the development of phobias in future. Anxiety is related to former pain memory of the injection. This may result in a higher pain perception. The perception of pain during injection is heightened during second appointment.³⁶ In our study, the patients had no previous experience of dental injection and hence may have similar anxiety scores irrespective of the injection technique used.

7. Site of administration:

In this study, only teeth in the maxilla requiring anaesthesia procedure were chosen for the allocation. The type of bone in the maxilla is porous as compared to mandibular bone.⁵⁷ We did not want variation in findings due to site variability hence chose only maxillary arch infiltration anaesthesia procedures.

Distraction

Cognition plays a key role in the development and maintenance of anxiety. It has been seen that any stimuli which maybe of unpredictable nature, uncontrollable by the patient, dangerous or disgusting to sight may trigger and maintain anxiety in children.⁵⁸ To achieve success in the paediatric dental practice, it is necessary to step into the shoes of the dental patient and view through their eyes. Since it has been established that the visual stimulus of the injection apparatus is the root cause of anxiety and pain reaction in children, use of distractors is the most logical option to help a child in coping with this stimulus.³⁴

Distractors are stimuli that may gain some control over the pain related behaviour of children.³² The mechanism of action of distraction is modulating pain perception by diverting attention. By using camouflage sleeve, we hoped to convert a potentially threatening stimulus into a non-threatening stimulus, thereby creating a response of a lower threshold.

CAMOUFLAGED SLEEVE

The Intervention used in this is the alligator sleeve. The Camouflaged sleeve is shaped like a toy alligator. It has soft edges and is child-friendly. Influence of colour on mental state of children has been shown in various studies. Bright colours are said

to positively affect the mental state of child and reduce anxiety.⁵⁹ The sleeve is available in two bright colours - green and pink. In our study we gave the child a choice of colour of sleeve to be used during the procedure.

Control of head of the child before injection is often difficult to achieve. We observed in our study that the camouflaged sleeve did not evoke aberrant head movement in the patient. This makes us wonder if the real applicability of this is in patients with definitely negative behaviour. Further research can be done on this aspect.

Proposed Mechanism of Action

It is mentioned by Illana elli and Peter Svenson that the contribution of anxiety is not only to lower the threshold of pain, but also perceive unthreatening stimuli to be threatening.⁴⁹ The sequence behind association of anxiety and pain seems logical. An anxious patient who may expect pain in the course of treatment will be aroused sympathetically. In a study conducted by Myers and coworkers it was seen that the highest mean pulse occurred during pre-injection period.⁶⁰ This will increase the muscle tension and may cause additional pain. In our study, the factor of “expectation of pain” was eliminated by camouflaging the injection apparatus. In spite of this logical sequence, in our study no statistically significant difference was observed between both the groups. In accordance to our findings, there were few authors who did not support the practice of hiding the injection apparatus as they believed that there is no difference in anxiety or pain perception either way.³³

PRIMARY OUTCOME ASSESSMENT**a) Comparative post-operative pain assessment using Faces Pain Rating****Scale:**

In our study, post-operative pain is analysed using the self-report Faces Pain Rating Scale. This is a simple and understandable scale which may be used for children above the age of 3 years and has been proved to be reliable.⁶ The difference in the pain perception between the control and experimental groups were statistically insignificant. It was seen in our study that the overall pain perception using conventional and camouflaged syringes remained almost same in both the groups. Few other studies utilizing distraction too showed no difference in pain perception post injection.⁴¹ The results contradicted findings of few others.³⁴ We perceived from our results that it is the other factors like tissue injury during penetration or the rate of deposition of local anaesthesia which may play a role in the pain perception during local anaesthesia procedure.

Surprisingly, when the correlation between the pulse rate assessing anxiety and pain perception measured by Faces Pain Rating Scale was analysed, the correlation of anxiety and pain perception was significant in the conventional syringe group whereas it was not statistically significant in camouflaged syringe group. This indicated that it is possible that the anxiety levels and pain perception is interrelated and more in control group. Nevertheless, in case of correlation between pain perception and anxiety measured by Venham Picture Test it was found that the relation was statistically significant in both groups.

b) Comparative assessment of anxiety levels in children using Venham Picture Test

The measurement tools for assessment of anxiety can be categorised as assessment of physiological response, subjective assessment of behavioural response by the dentist, self-report questionnaires completed by guardian or parent and self-report questionnaires completed by the child patient.¹⁸ In the course of dental treatment of a child patient, assessment of dental anxiety is an important step. The reason can be attributed to its inherent usefulness in managing this anxiety. According to literature, the best available assessment scales are the self-report anxiety scales for children.⁶¹ In our study to study the pre injection and post injection anxiety levels self-report Venham Anxiety Rating Scale was used.

Various anxiety measurement scales have been developed to assess anxiety, but Venham Picture Test is probably the best because the cognitive and linguistic requirements for this scale are limited. It presents as a useful anxiety measuring tool in children in clinical context.⁶ This tool comprises of a picture selection task wherein the picture corresponding to the child's current mental state can be chosen from eight pairs of pictures. The anxious pictures are scored one point and the overall score ranging from 0-8 is allotted.⁸ The higher the score, more is the anxiety level in the child. In our study we hypothesised that since the camouflaged sleeve hid the injection apparatus, the post-operative anxiety would be significantly less. The findings were statistically deviated from this hypothesis, but clinically relevant. The difference between comparative post-operative anxiety levels using the conventional and the camouflaged syringe measured by Venham's Picture Test were not found to be statistically significant. Despite this, the increase in anxiety is slightly more in

control group as compared to experimental group. It was observed in both groups that the anxiety levels increased significantly post-injection. This shows that local anaesthesia injection is indeed an anxiety provoking stimulus which corresponds to the literature available.⁹ We believe that it is the pain of the local anaesthesia delivery that gets converted to resultant post-operative anxiety. Clinically, we observed that children were more comfortable with camouflaged sleeve than conventional injection, and a better head control was achieved in the former group.

Our study was in accordance to the findings in other studies which stated that there was no statistically significant comparative difference in anxiety measured by pulse oximeter seen using conventional and camouflaged sleeve.^{29,34} In the one of the studies, contradictory to our results the authors stated a statistically significant decrease in post-operative anxiety levels in children measured by operator based assessment scales. We can argue that the scale used for measurement was not the same as our study which may have been a reason for this difference.²⁹ An objective FLACC scale was used as opposed to our study where Venham Picture Test was used, since FLACC scale was ineffective for use in the age group included in our study.

In another study, a camouflaged sleeve made of cold cure acrylic resin was used.³⁰ Similar to our study they found high parental acceptance of the use of camouflaged sleeve. In this study only the post-operative anxiety was measured. They found low Venham Picture Test score in camouflaged sleeve group.

SECONDARY OUTCOME ASSESSMENT**a) Physiological parameters:**

Physiologic parameters are objective assessment tools of pain and anxiety. Pain and anxiety activate the compensatory mechanisms which lead to tachycardia, vasoconstriction and thus increased pulse rate.⁷We used a finger pulse oximeter to analyse the pulse rate in the patient. This instrument allows setting of parameters for physiologic functions apart from pulse oximetry, above or below which an alarm is triggered. In our study, no statistically significant variation was found in the difference in pre-operative and intra-operative pulse rate in the two groups. This suggests that the preoperative and post-operative pain and anxiety were comparable in the two groups.

Nevertheless, it was found in our study that the pulse rate increased during the delivery of anaesthesia in both groups. This can be a result of pain due to injury to the tissue. An interesting finding was that the pulse rate was correlated to post-operative pain perception, a statistically significant correlation was found in the control group but not the experimental group. Review of literature showed that studies existed which corroborated with these findings.³⁴ An alternative to the use of pulse oximeter may be the use of novel biofeedback machine which may give better results.

Possible Explanation:

The results of our study indicate that the use of distraction using camouflaged sleeve may not help in alleviating pain during injection technique. The technique of injection in itself may help in relieving the pain during dental anaesthesia procedure.

Pain due to dental injection is a type of acute pain which is mediated by peripheral pain receptors. The factors associated maybe the tissue puncture during injection which may cause short, intense pain and the activation of nociceptors during deposition of local anesthesia solution which may cause distention of tissue resulting in a prolonged, intense pain.⁶² Since the activation of nociceptors and release of chemical mediators like bradykinin will remain same in both experimental, and control group, this may be the contributing factor to the resultant pain perception. Modulation of pain refers to mechanisms by which transmission of noxious stimuli to the brain is reduced. It is possible that the pain pathway for both conventional and camouflaged syringe remain same irrespective of the intervention. Hence inhibition of pain may not effectively take place.⁴⁹

The nature of pain may also be able to play a role in the perception using distracting agents. Chronic pain may be relieved better as compared to acute pain. Also important is the fact that most studies for modulation of pain have either been done on animals or consist of a heat stimulus application on humans which is not comparable to an injection.²³

Perception is the final step in pain pathway. When nociceptive impulse reaches the sensory cortex, perception occurs. The effective dimension of pain is responsible for emotions of unpleasantness associated with the pain related behaviour.¹⁸ MRI studies have demonstrated the involvement of thalamus and multiple cortical areas. The alligator sleeve is made according to the syringe apparatus and still gives a perception of syringe. The older group of children may be able to associate this with injection and may not be enough to modulate pain.

Advantages of the technique

1. The technique is definitely helpful in head control of the patient. We are of opinion that despite the statistical findings, camouflaged sleeve is a good alternative to conventional syringe apparatus.
2. Clinically significant observations like fascination of the parent and patient were seen in our study. None of the parents of the children undergoing local anaesthesia procedure with camouflaged sleeve rejected the use of apparatus or expressed concern.
3. Efforts have been made to modify the appearance of the injection apparatus in various innovative ways. The camouflaged sleeve is a child friendly, potentially cost effective way in which anxiety can be reduced in children.

Disadvantages of the technique

1. The toy looks like an alligator which in itself may be a source of anxiety for few children
2. Older children may be able to guess looking at the overall appearance of the apparatus as to the use in procedure.
3. It is slightly technique sensitive owing to the bulkiness of the sleeve.

What are the alternatives?

In general, various distraction techniques have been used as a part of non-pharmacological behavioural management in children, but the researchers have not come to any successful conclusion as to the efficient distracting agent.⁶³ Modification or replacement of the injection apparatus may be a useful alternative. Active research is going on to replace the conventional injection with non-conventional, innovative modalities. The alternatives to camouflaged syringe are the following modalities.

1. Insulin syringes:

Insulin Syringes can be a good alternative and have been studied with positive results with respect to post-operative pain.³² The advantages of this technique is that the thin and small needle will give a comparatively less threatening appearance to the injection apparatus. The penetration into the mucosa is stable and has been proved to be less painful by few researchers.³² Disadvantages of this technique being that it may not be of much use other than infiltration due to the short length of the needle, and not many studies have been conducted, proving its usefulness in dentistry.

2. Trans electronic nerve stimulation:

This works by Gate control mechanism and Endogenous opioid system. This was introduced in 1967 by Shealy. This is a type of electronic dental anaesthesia works on activation of alternate A beta fibres which causes pain relief. It is also said to stimulate endogenous opioid peptides in the pituitary and hypothalamus.⁶⁴

This has commonly been used in controlling chronic pain. This technique is said to have potential to replace the local anaesthesia. Cho et al tested the efficacy of TENS in dentistry during restorative procedures and found it promising. Nevertheless, it is shown in the study conducted by Wilson et al that the efficacy is not comparable to local anaesthesia injection.

3. Jet Injectors:

These were developed in 1866 for intra muscular and subdermal delivery of drugs with needleless injectors.⁶⁵ The mechanical energy causes pressure and pushes a column of liquid beneath the superficial layer. The advantages of this technique are that it is fast and easy to use and uptake is immediate using this technique. In spite of this, it is not used in paediatric dentistry because of the noise and pressure produced

and a possibility of hematoma formation. Till date, efficacy in dentistry is reported to be limited using this technique.

4. Iontophoresis:

It uses the positive charged lignocaine and adrenaline to push it deeper into the tissues without the use of a needle. It can be used for treating hypersensitive dentine, oral ulcers or for topical anaesthesia. A study was conducted by Tharian et al to check the effectiveness of this treatment during extraction of deciduous teeth. However, this may irritate the mucosa.⁶³

5. Computer controlled local anaesthesia delivery:

These technologically advanced delivery techniques use the computer control for steady delivery of anaesthesia. The steady delivery will cause less pain in the children. Ample literature is available regarding the computer controlled delivery of anaesthesia. This discovery too, has contrasts in the outcome. Whereas in some studies it has been shown to reduce the pain perception using computer controlled delivery, others agree that there is no relevant reduction in pain perception using these syringes.⁶³

6. Telescopic dental needles:

In a study conducted by Habib agahi et al, telescopic needles were used for local anaesthesia procedure. The results of this study showed lower pain and anxiety levels in children belonging to the group being treated using telescopic needles.⁶⁶

Local anaesthesia procedure, in spite of the developments in dentistry remains an anxiety provoking stimulus. The best way of long term management of anxiety in child patient is guiding the child to cope with his fears. Coping of anxiety provoking stimulus is different in different children and is broadly divided into strategies that are adaptive and those that are maladaptive. Adaptive strategies must be encouraged for

developing of a pleasant dental experience. The vicious cycle of avoiding dental treatment due to pain and developing anxiety will break if a fool proof painless anaesthesia can be developed.

CONCLUSION

Untreated dental caries can cause reduced oral health related quality of life in children which may continue throughout their lives. Impending anxiety due to fear of injections may lead to more patients disregarding their oral problems. These can be seen to be the major hindrances to a pediatric dentist whose responsibility is not only to treat the child patient, but also make him a responsible adult.

Distraction techniques serve a potentially beneficial alternative to pharmacological behavior management techniques, which help a child in coping with dental fear and anxiety. To eliminate the concepts of a “painful” or “traumatic dental appointment”, camouflaged sleeve can be used as an alternative to conventional syringe. These products need to be studied and modified over time.

In our study, we concluded that although there was no statistically significant reduction in anxiety using camouflaged syringe, the child was more comfortable with the camouflaged sleeve as compared to conventional sleeve. Although, we would like to add that there is no difference in pain perception using either the conventional or the camouflaged syringe. Our study proves that local anesthesia is definitely an anxiety inducing stimulus in children and alternatives like camouflaged sleeve can be utilized for a smooth dental visit of the child.

SUMMARY

The present study was a concurrent parallel arm randomized control trial. It was conducted on children between the ages of 6-11 years, with the aim of evaluating the anxiety and perception using conventional and camouflaged techniques of local anesthesia delivery. Sixty two children with treatment need in the maxillary arch requiring local anesthesia procedure and fulfilling inclusion and exclusion criteria was selected. (n=62) The children were randomly allocated to either conventional syringe group (Group A, n=31) or camouflaged syringe group (Group B, n=31). After taking proper consent and assent, preoperative Venham Picture Test score and baseline anxiety were recorded. The children were then subjected local anesthesia procedure using either camouflaged syringe or conventional syringe. Pulse rate during the procedure was noted. The post-operative Venham Picture Test score was noted. Post-operative pain perception was analysed using Faces Pain Rating Scale.

The collected data was statistically analysed. The Pulse rate was seen to follow a normal distribution, and hence parametric tests like independent and dependent t-test were used. The comparative difference in before and after pulse rate in Group A and B was analysed by independent t test which were statistically insignificant ($p=0.5169$). When intergroup analysis was done by Wilcoxon Matched Pairs analysis to assess Venham Picture test, there was statistically significant change seen in individual groups ; $p=0.0095$ and $p=0.0006$ in control and experimental group respectively. The mean pain perception in Group A was 4.58 and in Group B was 5.03. The difference in the pain perception in two groups was not statistically significant. ($p=0.5449$) In both groups, it was seen that there was a significant

correlation between pain perception and post injection anxiety score. ($p=0.0064$; $p=0.0015$).

It was concluded that anxiety increases during local anesthetic procedure. But there was no significant difference between preoperative and postoperative anxiety levels with and without camouflaged sleeve. There was no statistically significant difference in pain perception during the delivery of anesthesia, using conventional and camouflaged syringes. In spite of this, the head control was better attained in the camouflaged syringe group as compared to conventional syringe group.

BIBLIOGRAPHY

1. Okeson JP. Bell's orofacial pains: the clinical management of orofacial pain. Chicago, Ill, USA: Quintessence Publishing Company; 2005.p 261.
2. Folayan MO, Ufomata D, Adekoya-Sofowora CA, Otuyemi OD, Idehen E. The effect of psychological management on dental anxiety in children. *J Clin Pediatr Dent* 2003;27:365-70
3. Lang PJ, Bradley MM, Cuthbert BN. Emotion, motivation, and anxiety: Brain mechanisms and psychophysiology. *Biological psychiatry*. 1998;44:1248-63.
4. Rajaa SN, Carrb DB, Cohenc M, Finnerupd NB, Florf H, Gibsong S, Keefeh FJ, Mogili JS, Ringkampj M, Slukak KA, Songl XJ. The revised International Association for the Study of Pain definition of pain: concepts, challenges, and compromises. *development*. 2020;7:19.
5. Stedman TL, Dirckx JH. Stedman's concise medical dictionary for the health professions: Illustrated. Lippincott Williams & Wilkins; 2001.p 73
6. Buchanan H, Niven N. Validation of a Facial Image Scale to assess child dental anxiety. *Int J Paediatr Dent*. 2002;12:47-52.
7. Bloom LJ, Trautt GM. Finger pulse volume as a measure of anxiety: Further evaluation. *Psychophysiology*. 1977;14:541-4.
8. Venham LL, Gaulin-Kremer E. A self-report measure of situational anxiety for young children. *Pediatr Dent*. 1979;1:91-6.
9. Klingberg G, Raadal M, Arnrup K. Dental fear and behavior management problems. *Pediatr Dent*. 2009;2:32.

10. Venham LL, Goldstein M, Gaulin-Kremer E, Peteros K, Cohan J, Fairbanks J. Effectiveness of a distraction technique in managing young dental patients. *Pediatr Dent*. 1981;3:7
11. Koller D, Goldman RD. Distraction techniques for children undergoing procedures: a critical review of pediatric research. *J PediatrNurs*. 2012;27:652-81.
12. Cianetti S, Lombardo G, Lupatelli E, Pagano S, Abraha I, Montedori A, Caruso S, Gatto R, De Giorgio S, Salvato R, Paglia L. Dental fear/anxiety among children and adolescents. A systematic review. *Eur J Paediatr Dent*. 2017;18:121-30.
13. Prado IM, Carcavalli L, Abreu LG, Serra-Negra JM, Paiva SM, Martins CC. Use of distraction techniques for the management of anxiety and fear in paediatric dental practice: A systematic review of randomized controlled trials. *Int J Paediatr Dent*. 2019;29:650-68.
14. Sciascia AD, Jacobs CA, Morris BJ, Kibler WB. The degree of tissue injury in the shoulder does not correlate with pain perception. *J Shoulder Elb Surg*. 2017;26:151-2.
15. McCaul KD, Malott JM. Distraction and coping with pain. *Psychol Bull*. 1984;95:516.
16. Brill W. Behavior of pediatric dental patients throughout the course of restorative dental treatment in a private pediatric dental practice. *J ClinPediatr Dent*. 2002;26:55-60.
17. Taani DQ, El-Qaderi SS, Abu Alhaija ES. Dental anxiety in children and its relationship to dental caries and gingival condition. *Int J Dent Hyg*. 2005;3(2):83-7.

18. Campbell C, editor. Dental fear and anxiety in pediatric patients: Practical strategies to help children cope. Springer; 2017.p 89-91
19. Maunuksela EL, Olkkola KT, Korpela R. Measurement of pain in children with self-reporting and behavioral assessment. *ClinPharmacolTher.* 1987;42:137-41.
20. Khatri A, Kalra N. A comparison of two pain scales in the assessment of dental pain in East delhi children. *ISRN dentistry.* 2012. doi:10.5402/2012/247351
21. Klorman R, Michael R, Hilpert PL, Sveen OB. A further assessment of predictors of the child's behavior in dental treatment. *J Dent Res.* 1979;58:2338-43.
22. Krishnappa S, Srinath S, Vishwanath SK, Bhardwaj P, Singh R. Evaluation of facial image scale and Venham picture test used to assess dental anxiety in children. *J Indian Assoc of Public Health Dent.* 2013;11:31.
23. Loggia ML, Schweinhardt P, Villemure C, Bushnell MC. Effects of Psychological State on Pain Perception in the Dental Environment. *J Can Dent Assoc.* 2008;74.
24. Hansen GR, Streltzer J. The psychology of pain. *Emerg Med Clin.* 2005;23:339-48.
25. Gill HS, Prausnitz MR. Does needle size matter?. *J Diabetes Sci Technol.* 2007;1:725-9.
26. Milgrom P, Coldwell SE, Getz T, Weinstein P, Ramsay DS. Four dimensions of fear of dental injections. *J Am Dent Assoc.* 1997;128:756-62.
27. Asokan A, Kambalimath HV, Patil RU, Maran S, Bharath KP. A survey of the dentist attire and gender preferences in dentally anxious children. *J Indian SocPedodPrev Dent.* 2016;34:30.

28. Babaji P, Chauhan PP, Rathod V, Mhatre S, Paul U, Guram G. Evaluation of child preference for dentist attire and usage of camouflage syringe in reduction of anxiety. *Eur J Dent.* 2017;11:531.
29. Melwani AM, Srinivasan I, Setty JV, Pamnani SS, Lalitya D. A clinical comparative study between conventional and camouflaged syringes to evaluate behavior and anxiety in 6–11-year-old children during local anesthesia administration—a novel approach. *J Dent Anest Pain Med.* 2018;18:35-40.
30. Ujaoney S, Mamtani M, Thakre T, Tote J, Hazarey V, Hazarey P, Kulkarni H. Efficacy trial of Camouflage Syringe to reduce dental fear and anxiety. *Eur J Paediatr Dent.* 2013;14:273-8.
31. Monika K, et al. Comparative Evaluation of Dental Anxiety and Fear in Children by using Camouflaged Syringe and Conventional Syringe. *J Dental Sci.* 2019;4(1): 1-4
32. Bondarde P, Mujawar S, Bhandari SC. A Clinical Comparative Study of Camouflaged Insulin Syringe With Conventional Syringe For Dental Extractions In Children. *J Appl Sci.* 2016;2:37-39
33. Maragakis G, Musselman R, Ho C. Reaction of 5 and 6 year olds to dental injection after viewing the needle: pilot study. *J Clin Pediatr Dent.* 2007;31:28-31
34. Vallakatla V, Vallakatla S, Dutta S, Sengupta P, Penukonda R. Conventional and Camouflage Syringe during Maxillary Dental Procedures: Relevance to Anxiety and Pain Levels in Children. *Biomed Pharmacol.* 2020;13:253-8.
35. Monteiro J, Tanday A, Ashley PF, Parekh S, Alamri H. Interventions for increasing acceptance of local anaesthetic in children and adolescents having dental treatment. *Cochrane Database of Systematic Reviews.* 2020.

36. Hegde KM, Srinivasan I, DR MK, Melwani A, Radhakrishna S. Effect of vibration during local anesthesia administration on pain, anxiety, and behavior of pediatric patients aged 6–11 years: A crossover split-mouth study. *J Dent Anesth Pain Med.* 2019;19:143-9.
37. Kamath PS. A novel distraction technique for pain management during local anesthesia administration in pediatric patients. *J ClinPediatr Dent.* 2013;38:45-7.
38. Nuvvula S, Alahari S, Kamatham R, Challa RR. Effect of audiovisual distraction with 3D video glasses on dental anxiety of children experiencing administration of local analgesia: a randomised clinical trial. *Eur Arch Paediatr Dent.* 2015;16:43-50.
39. Ramírez-Carrasco A, Butrón-TéllezGirón C, Sanchez-Armass O, Pierdant-Pérez M. Effectiveness of hypnosis in combination with conventional techniques of behavior management in anxiety/pain reduction during dental anesthetic infiltration. *Pain Res Manag.* 2017;17-18.
40. Al-Khotani A, Bello LA, Christidis N. Effects of audiovisual distraction on children's behaviour during dental treatment: a randomized controlled clinical trial. *ActaOdontol Scand.* 2016;3:34-36.
41. Mittal M, Kumar A, Srivastava D, Sharma P, Sharma S. Pain perception: computerized versus traditional local anesthesia in pediatric patients. *J ClinPediatr Dent.* 2015 Sep;39:470-4.
42. Langthasa M, Yeluri R, Jain AA, Munshi AK. Comparison of the pain perception in children using comfort control syringe and a conventional injection technique during pediatric dental procedures. *J Indian SocPedodPrev Dent.* 2012;30:323.

43. Smolarek PD, da Silva LS, Martins PR, Hartman KD, Bortoluzzi MC, Chibinski AC. Evaluation of pain, disruptive behaviour and anxiety in children aging 5-8 years old undergoing different modalities of local anaesthetic injection for dental treatment: a randomised clinical trial. *Acta Odontol Scand.* 2020;28:1-9.
44. Haber TM, Foster CB, inventors; Habley Medical Technology Corp, assignee. Safety syringe having a combination needle cannula and articulating hub for retracting said cannula into a medication carpule. United States patent US 4,931,040. 1990.
45. Xiang W, inventor. Puncture Depth Controlling and Needle Hiding Device and Usage Method Thereof. United States patent application US 16/003,101. 2018 Oct 11.
46. Pham T, inventor. Camouflaged syringe arrangement. United States patent application US 09/749,145. 2002.
47. Krejcie RV, Morgan DW. Determining sample size for research activities. *EduPsychol Meas.* 1970;30:607-10.
48. Malamed SF, Quinn CL. Handbook of local anesthesia. Mosby Elsevier Health Science; 1990.p 34-36
49. Silverman S, Eversole LR, Truelove EL. Essentials of oral medicine. PMPH-USA; 2002.p78-89
50. Melzack R, Katz J. The gate control theory: Reaching for the brain. *Pain: psychological perspectives.* 2004:13-34
51. Levine JD, Gordon NC, Bornstein JC, Fields HL. Role of pain in placebo analgesia. *Proceedings of the National Academy of Sciences.* 1979;76:3528-31.

52. Oliveira MM, Colares V. The relationship between dental anxiety and dental pain in children aged 18 to 59 months: a study in Recife, Pernambuco State, Brazil. *Cadernos de Saúde Pública*. 2009;25:743-50.
53. Mumford JM. Toothache and orofacial pain. Churchill Livingstone; 1976.p 112-14
54. Ram D, Peretz B. Administering local anaesthesia to paediatric dental patients—current status and prospects for the future. *Int J Paediatr Dent*. 2002 Mar;12:80-9.
55. Shapiro M, Melmed RN, Sgan-Cohen HD, Eli I, Parush S. Behavioural and physiological effect of dental environment sensory adaptation on children's dental anxiety. *Eur J Oral Sci*. 2007;115:479-83.
56. Ollendick TH, King NJ. Origins of childhood fears: An evaluation of Rachman's theory of fear acquisition. *Behav Res Ther*. 1991;29:117-23.
57. Kumar GS. Orban's oral histology and embryology. Elsevier India; 2015.p 78
58. Armfield JM. Towards a better understanding of dental anxiety and fear: cognitions vs. experiences. *Eur J Oral Sci*. 2010;118:259-64.
59. Umamaheshwari N, Asokan S, Kumaran TS. Child friendly colors in a pediatric dental practice. *J Indian Soc Pedod Prev Dent*. 2013;31:225.
60. Ripa LW. Children's reaction to the dental experience. *Management of Dental Behavior in Children*. Littleton, Mass: PSG Publishing Co. 1979:1-4.
61. Franck LS, Greenberg CS, Stevens B. Pain assessment in infants and children. *Pediatr Clin North Am*. 2000;47:487-512.
62. Isaac Zilinsky MD, Bar-Meir E, David Mendes MD, Eyal Winkler MD, Orenstein A. Ten commandments for minimal pain during administration of local anesthetics. *J Drugs Dermatol*. 2005;4:67-68.

63. Goettems ML, Zborowski EJ, dos Santos Costa F, Costa VP, Torriani DD. Nonpharmacologic intervention on the prevention of pain and anxiety during pediatric dental care: A systematic review. *AcadPediatr.* 2017;17:110-9.
64. Shealy CN. Transcutaneous electrical nerve stimulation: the treatment of choice for pain and depression. *J Altern Complement Med.* 2003;9:619-23.
65. Clark W, Hollenbeck K, inventors. Disposable needleless injector. United States patent US 3,853,125. 1974.
66. Habib-Agahi R, Gandjalikhan-Nassab SA, Hashemipour MA, Saidi A, Eskandarizadeh A. Comparing pain and pain-related behavior in children with invented telescopic dental needles. *J Oral Health Oral Epidemiol.* 2017;6:33-9.
67. deArmendi AJ, Govindaraj R. Pulse Oximetry. In *Data Interpretation in Anesthesia* 2017;p. 43-46

ANNEXURE I a - MASTER CHART**Table showing the anxiety and pain perception score of the control group A (Conventional syringe) participants.**



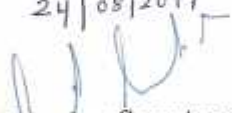
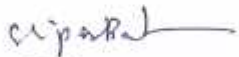
CONVENTIONAL GROUP								
Sl. No.	AGE	FRANKL'S BEHAVIOUR RATING	GENDER	PULSE RATE BEFORE	PULSE RATE DURING	VENHAM BEFORE	VENHAM AFTER	VISUAL ANALOGUE
1	9	Negative	Female	91	112	1	5	10
2	6	Definitely negative	Female	141	147	4	4	10
3	11	Negative	Female	111	112	5	6	0
4	7	Negative	Male	105	115	5	5	10
5	9	Positive	Male	85	90	0	0	2
6	9	Negative	Female	106	105	0	2	8
7	10	Definitely positive	Female	106	76	1	1	0
8	10	Positive	Female	136	122	0	0	0
9	9	Definitely positive	Male	72	97	8	8	10
10	7	Negative	Male	74	117	1	7	8
11	10	Definitely positive	Male	97	103	0	0	2
12	10	Positive	Male	88	87	3	4	4
13	9	Positive	Male	84	127	1	9	10
14	10	Positive	Male	87	76	0	0	0
15	7	Positive	Female	117	120	2	3	0
16	10	Positive	Male	67	96	2	7	8
17	9	Negative	Female	127	131	0	3	8
18	7	Positive	Male	97	107	1	2	2
19	8	Positive	Male	104	90	1	0	0
20	9	Positive	Male	93	108	2	4	0
21	10	Positive	Male	107	123	4	4	4
22	8	Positive	Female	101	104	3	3	10
23	10	Positive	Female	86	85	0	1	0
24	8	Negative	Male	79	77	0	0	10
25	10	Positive	Male	90	114	2	6	10
26	10	Definitely positive	Male	99	107	0	0	0
27	10	Definitely positive	Male	96	92	1	1	4
28	11	Positive	Female	109	95	0	0	0
29	6	Negative	Female	71	89	3	4	0
30	6	Definitely negative	Male	137	130	0	3	4
31	7	Positive	Male	74	118	1	7	8

ANNEXURE I b- MASTER CHART

Table showing the anxiety and pain perception score of the experimental group B (Camouflaged syringe) participants.

CAMOUFLAGED GROUP								
Sl. No.	AGE	FRANKL'S BEHAVIOUR RATING	GENDER	PULSE RATE BEFORE	PULSE RATE DURING	VENHAM BEFORE	VENHAM AFTER	VISUAL ANALOGUE
1	7	Positive	Male	99	94	0	1	0
2	9	Definitely Positive	Female	105	109	0	0	0
3	8	Positive	Female	101	83	5	4	10
4	10	Positive	Male	135	145	1	3	4
5	7	Positive	Female	104	125	0	3	6
6	11	Definitely Positive	Male	89	93	0	1	4
7	10	Positive	Female	87	119	0	1	10
8	10	Positive	Male	65	98	1	5	6
9	8	Definitely Positive	Female	74	82	2	2	4
10	9	Definitely Positive	Male	75	78	2	2	4
11	8	Positive	Female	93	99	2	1	4
12	10	Positive	Male	79	89	0	0	0
13	7	Positive	Male	92	105	4	3	2
14	8	negative	Female	110	126	10	0	10
15	8	Positive	Female	113	122	0	0	2
16	8	Definitely Positive	Male	98	88	4	3	0
17	9	Positive	Female	130	138	1	4	10
18	10	Positive	Male	103	93	0	0	4
19	7	Positive	Male	105	107	0	0	0
20	10	Positive	Female	106	116	0	0	0
21	7	Positive	Male	119	107	0	10	10
22	7	Positive	Male	124	103	2	4	0
23	9	negative	Male	89	106	0	0	10
24	8	Definitely Positive	Female	94	97	0	6	8
25	10	negative	Male	95	92	1	4	6
26	8	Positive	Female	117	104	0	0	2
27	10	Positive	Female	107	105	1	3	10
28	6	Positive	male	85	100	0	0	4
29	7	Definitely Positive	Male	105	109	0	4	6
30	10	Positive	Female	121	147	2	5	10
31	9	Positive	Female	114	109	1	4	10

ANNEXURE II**ETHICAL CLEARANCE CERTIFICATE**

 <p>KLE UNIVERSITY BIRMINGHAM</p>	<p>Research and Ethics Committee KLE V K INSTITUTE OF DENTAL SCIENCES KLE University</p> <p>Accredited 'A' Grade by NAAC Placed in Category 'A' by MHRD (Govt) Nehru Nagar, Belagavi - 590 010, Karnataka State</p> <p>☎: 0831-2470362 Web: http://www.kledental-bgm.edu.in FAX: 0831-2470640 E-mail: principal@kledental-bgm.edu.in</p>	
		SI. No. : 1253
CERTIFICATE		
<i>This is to Certify that the synopsis titled</i>		
<i>Comparative evaluation of anxiety levels and pain perception</i>		
<i>during local anaesthesia administration using conventional and</i>		
<i>camouflaged syringes in 6-year old children Submitted by</i>		
<i>An in vivo study</i>		
<i>Dr. RIDDHI S. JOSHI P. G. Student /</i>		
<i>Staff, Guided by Dr. NIRAJ S. GOKHALE from Department of</i>		
<i>Pedodontics & Preventive Dentistry has been critically evaluated by</i>		
<i>committee members and granted ethical clearance to conduct the above</i>		
<i>mentioned study</i>		
Date : 24/05/2019		
 Member Secretary Research and Ethical Committee KLEVK Institute of Dental Sciences Belagavi		 Chairman Research and Ethical Committee KLEVK Institute of Dental Sciences Belagavi

ANNEXURE III a

CONSENT FORM (ENGLISH)

KLE Academy of Higher Education and Research

KLE VK Institute of Dental Sciences

Department of Pediatric and Preventive Dentistry

Belagavi.

Title: “Comparative Evaluation Of Anxiety Levels And Pain Perception During Local Anaesthesia Administration Using Conventional And Camouflaged Syringes In 6–11 Year-Old Children: An In Vivo Study.

Date :

1. I, Kumar/Kumari, have received all the information about my son/daughters....., years treatment and participation in the study, performed under the guidance of Dr. Niraj S. Gokhale and by Dr. Riddhi S. Joshi
2. I agree to give detailed information of my son/daughter like name/age/sex and health information.
3. I give permission for oral examination or to treat my child/ward.
4. **PATIENT INFORMATION MESSAGE:**
I give permission to get my ward treated using injection and camouflaged syringe and I will come for regular dental checkup as and when the doctor’s ask.
5. I do not expect any kind of gift or reward for participating in the study.
6. In the case of an adverse effect I have been told to inform the concerned doctor and they have assured that they will take care of the adverse effect.
7. I have been informed that I can withdraw myself from the study at any given time.
8. I have been informed that all the study related matter about me will be kept confidential.
9. I have been informed that there will be no harm in participating in the study.
10. I have been informed that all the cavities present in the oral cavity will be treated and will be restored.
11. I have been informed about all these and I give my consent after reading/understanding the above in the language which is best understood by me.

(Relation to the patient)

(Signature)

ANNEXURE III b - CONSENT FORM (KANNADA)**ಸಮ್ಮತಿ ಪತ್ರ**

ಜಠ್ಮಕೃತ ದಂತ ಚಿರತ್ನಾ ವಿಭಾಗ
ಕೆಎಲ್ಇ ಏಕ ದಂತ ಮಹಾವಿದ್ಯಾಲಯ, ಬೆಳಗಾವಿ.

Title: "Comparative evaluation of anxiety levels and pain perception during local anaesthesia administration using conventional and camouflaged syringes in 6–11 year-old children: An in vivo study."

ನಾನು ಶ್ರೀ/ಶ್ರೀಮತಿ _____ ಎಲ್ಲಾ ಮಾಹಿತಿಯನ್ನು ಪಡೆದುಕೊಂಡಿದ್ದೇನೆ ಮತ್ತು ನನ್ನ ಮಗ/ಮಗಳು _____ ವಯಸ್ಸು _____ ಈ ಸಂಶೋಧನೆಯಲ್ಲಿ ಭಾಗವಹಿಸಲು ಅನುಮತಿಯನ್ನು ಸಹಿ ಸಹಕರಿಸುತ್ತೇನೆ.

1. ನನ್ನ ಮಗ/ಮಗಳ ಬಗ್ಗೆ ಎಲ್ಲಾ ಮಾಹಿತಿ- ಹೆಸರು, ವಯಸ್ಸು, ಆರೋಗ್ಯದ ಬಗ್ಗೆ ಮಾಹಿತಿ ಕೊಡಲು ಒಪ್ಪುತ್ತೇನೆ.

2. ನನ್ನ ಮಗ/ಮಗಳ ಜಾಯಿಯ ಅವಾಸವೆ ಪಾಠು ಚಿರತ್ನ ಮೂಡಲು ಸಹಕರಿಸುತ್ತೇನೆ.

3. ರೋಗಿಯ ಚಿರತ್ನೆಯ ಬಗ್ಗೆ ತಿಳುವಳಿಕೆ:

ನನ್ನ ಮಗ/ಮಗಲೆ ಹಲ್ವನ್ನು ಇಂಜೆಕ್ಷನ್ ಮೂಲಕ ಲರಿವೆಆರೆ(ಸುಂದ) ಮೂಡಲಾಗುವುದು ಹಾಗು ಲವೆಷ್ಟುಕೆಲೆ ಇರುವೆ ಚಿರತ್ನಿ ಸೂಡಲಾಗುವುದು.

4. ನಾನು ತಲ್ಲರು ಕೊಟ್ಟಿರುವೆ ಸೂಡವೆಗಲೆನ್ನು ಒಲೂಡುತ್ತೇನೆ.

5. ಈ ಸಂಶೋಧನೆಯನ್ನು ಪ್ರಕಟಿಸಲು ಅನುಮತಿಯನ್ನು ಕೊಡುತ್ತೇನೆ.

6. ನನ್ನ ಮಗ/ಮಗಲು ಭಗವೆಹಿಸಿಲ್ವೆಲ್ಲೆ ಪ್ರತಿಯೆಲೆಗೆ ಂನೂ ಕೆಲುವೆಬಿಲ್ಲ.

7. ಂನುಬೆರು ಕೂಲಂದಲೆಯೆಬಿಲ್ಲ ತಲ್ಲರು ಂಲ್ಲಾ ಜಿಂಜಿಲ್ಲಲಿಯೆನ್ನು ತೆಗೆದುಕೂಳ್ಳಲೆಲ್ಲ.

8. ಯೆಂಫೆಲೆ ಕಾರಣಲೆಗಲೆ ನನ್ನ ಮಗ/ಮಗಲು ಭಗವೆಹಿಸಿಲ್ವೆಲ್ಲೆ ಹಿಂತೆಗೆದುಕೂಳ್ಳೆಜುಡುಡು.

9. ಎಲ್ಲಾ ಮಾಹಿತಿಯನ್ನು ಗುಪ್ತವಾಗಿಡಲಾಗುವುದು.

10. ಈ ಸಂಶೋಧನೆಯಲ್ಲಿಭಾಗವಹಿಸುವೆಬರಿಂದ ಯಾವ ಪಾಲು/ಅಪಾಯ ಇಲ್ಲ.

11. ಬೆಲೆ ಚಿರತ್ನಿ ಬಗ್ಗೆ ಮೂಹಿತಿ ಕೂಡಲಾಗುವುದು.

ನಾನು ಮೂಲೆ ತಿಳಿಸಿದ ಎಲ್ಲಾ ವಿಷಯವನ್ನು ಕೂಡಿದ್ದೇನೆ ಮತ್ತು ಅಧಿಕಮೂಡಿಕೊಂಡು ಸಹಿ ಮಾಡಿದ್ದೇನೆ.

ದಂತ ವೈದ್ಯಕರ ಹೆಸರು: ಡಾ: ರಿಧಿ ಚೂಲಿ
ವಿಜಾಸ: ಜಠ್ಮಕೃತ ದಂತ ಚಿರತ್ನಾ ವಿಭಾಗ
ಕೆಎಲ್ಇ ಏಕ ದಂತ ಮಹಾವಿದ್ಯಾಲಯ
ಬೆಳಗಾವಿ-10

ಮೂಗಲೆಡಲೆಕರರು: ಡಾ: ನಲಜ ಸ. ಗೂಣಲೆ
ವಿಜಾಸ: ಜಠ್ಮಕೃತ ದಂತ ಚಿರತ್ನಾ ವಿಭಾಗ
ಕೆಎಲ್ಇ ಏಕ ದಂತ ಮಹಾವಿದ್ಯಾಲಯ
ಬೆಳಗಾವಿ-10

ಪಾಲಕರ ಹೆಸರು:

ಪಾಲಕರ ಸಹಿ:

ಪಾತ್ರಿ ಹೆಸರು:

ಪಾತ್ರಿ ಸಹಿ:

ದಿನಾಂಕ:

ಊರು:

ANNEXURE IIIc

छोड्या म्

. . . . इन्स्टिट्यूट ऑफ डेंटल सायन्सेस बे
सम्मती पत्र

- मी श्री/श्रीमती _____, हे मान्य करत आहे की मला माझ्या मुलाचा / मुलीचा (नाव _____, वय _____ वर्ष) उपचारांबद्दल माहिती दिली आहे आणि मी Dr. रिद्धी जोशी व Dr.नीरज गोखले हयांचा अभ्यासाला पूर्ण सम्मती देत आहे
- मी माझा मुलाची/ मुलीची वय्यक्तिक माहिती जसे की, नाव, वय, लिंग, पत्ता, मागील व सध्याची दंत उपचाराची माहिती व अन्य तपशील देण्यास सहमत आहे.
- मी दंतचिकित्सक हयांना त्यांच्या अभ्यासासाठी पुर्ण सहकार्य देईन.
- दंतचिकित्सक हयांचा अभ्यास चालू असताना, मी त्यांनी दिलेल्या सर्व सुचनांचे पालन करीन.
- मी दंतचिकित्सक हयांनी सांगितलेल्या वेळेला व तारखेला त्यांच्या अभ्यासासाठी हजर राहीन
- _____ :-अभ्यासात _____ केमोफ्ला _____ वापरून
सुत्र _____
- दंतचिकित्सक हयांच्या अभ्यासा दरम्यान त्यांनी प्राप्त केलेली माझी सर्व माहिती व अभ्यासाचे परिणाम माझी ओळख न उघडता कुठल्याही प्रकाशनात सादर करायला माझी परवानगी आहे.
- मी दंतचिकित्सक हयांच्या अभ्यासात माझे सहकार्य दिल्या बद्दल कोणत्याही परताव्याचा दावा करणार नाही, त्यांचा अभ्यास कोणत्याही एजन्सि मार्फत प्रायोजित केला असेल तरीही मी परताव्याचा दावा करणार नाही. मी माझ्या स्वतः च्या इच्छेने हया अभ्यासात सहभागी होत आहे.
- मी कोणत्याही कारणास्तव अभ्यासात भाग घेऊ शकत नसून, तर मी हया अभ्यासातून बाहेर पडू शकतो/शकते.
- मी पुर्ण शुद्धीत व माझ्या मनाच्या उपस्थितीत, सर्व प्रक्रिया व त्यांचे क्वचित होऊ शकणारे दुष्परिणाम समजून, माझ्या मातृभाषेत हया अभ्यासात सहभागी होण्यास सम्मती देतो/देते.

दंतवैद्य :
रुग्णाचा :
पत्ता :

स्वाक्षरी :
स्वाक्षरी :

ANNEXURE IV

ASSENT FORM

DEPT.OF PEDIATRICS AND PREVENTIVE DENTISTRY

KAHER'S K.L.E. V.K. INSTITUTE OF DENTAL SCIENCES.

BELAGAVI.

My name is Dr. Riddhi S. Joshi. I am a Pedodontist. I am doing a study to learn about the germs in your teeth and how to destroy them. I will be applying a magic water on your teeth . The entire procedure will not cause any harm to you.

You can ask questions at any time that you might have about this study. Also, if you decide at any time not to finish, you may stop whenever you want. Signing this paper means that you have read this or had it read to you and that you want to be in the study. If you don't want to be in the study, don't sign the paper. Your parent(s) know that I am asking you to do these things. Remember, being in the study is up to you, and no one will be angry if you don't sign this paper or even if you change your mind later.

Signature of participant _____ Date _____

Signature of investigator _____ Date _____

ANNEXURE V

CASE-HISTORY

DEPARTMENT OF PEDIATRICS AND PREVENTIVE DENTISTRY

PATIENT INFORMATION:

Name:

Sex:

Age:

Parent/Guardian:

Address:

Contact Number:

HISTORY:

Chief Complaint:

History Of Present Illness:

Relevant Medical History:

Previous Dental History:

NATAL HISTORY:

POST NATAL HISTORY:

GENERAL EXAMINATION:

INTRA-ORAL EXAMINATION

Soft Tissue Examination:

Hard Tissue Examination:

Tooth no:

No of Teeth:

Decayed Teeth:

Filled Teeth:

Missing Teeth:

Root Stumps:

Mobility:

PROVISIONAL DIAGNOSIS:

INVESTIGATION: Intra-oral periapical radiograph

FINAL DIAGNOSIS:

TREATMENT PLANNING:

ANNEXURE VI**Table Showing Baseline Pulse Rate In Different Age Groups**⁶⁷

AGE GROUP	PULSE RANGE (Beats/Min)	AVERAGE PULSE (Beats/Min)
Infant (Birth- 1 Yrs)	120-160	140
Toddler (1-3 Yrs)	90-140	115
Preschool Child (3-6 Yrs)	80-110	95
School Age Child (6-12 Yrs)	75-105	90
Adolescent (12-18yrs)	60-100	80
Adult (After 18 Yrs)	60-100	80
Adult (After 60th Year)	67-80	74
Well Trained Athletes	40-60	50

ANNEXURE VII

BIostatISTICS CERTIFICATE



KLE V.K. Institute of Dental Sciences

(A Constituent unit of KLE Academy of Higher Education & Research Deemed-to-be-University u/s 3 of the UGC Act, 1956)

Nehru Nagar, Belagavi-590 010 INDIA

Re-Accredited 'A' grade by NAAC (2nd Cycle) & Placed in Category 'A' by MHRD (GoI)




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FAX: 0831-2470640

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E-mail: principal@kledental-bgm.edu.in



BIostatISTICS CLEARANCE CERTIFICATE

This is to certify that the Biostatistics aspect of the Dissertation / Research work of **Dr. Riddhi S. Joshi**, Postgraduate Student under the guidance of **Dr. Niraj S. Gokhale**, Reader, Department of Pediatric and Preventive Dentistry Entitled "*Comparative Evaluation of Anxiety Levels and Pain Perception During Local Anaesthesia Administration Using Conventional and Camouflaged Syringes in 6-11 Year-Old Children: An In Vivo Study*" has been done under my guidance and considered satisfactory.

Place : Belagavi
Date : 26.8.2020


Name & Signature of Biostatistician
(Dr. S.B. Javali)

ANNEXURE VIII**PLAGIARISM CERTIFICATE**

Scientific Correspondence and Review Committee	
KLE VK Institute of Dental Sciences	
A Constituent Unit of KLE Academy of Higher Education and Research (Deemed-to-be-University u/s 3 of the UGC Act, 1956)	
Nehru Nagar, Belagavi - 590 010, Karnataka State	
Accredited 'A' Grade by NAAC (2nd Cycle)	Placed in Category 'A' by MHRD (GoI)
☎: 0831-2470362 FAX: 0831-2470640	Web: http://www.kledental-bgm.edu.in E-mail: principal@kledental-bgm.edu.in
Date : 28/08/2020	Serial No. : 027
PLAGIARISM CHECK REPORT	
Name of the Applicant : Dr. Reddhi. S. Joshi	
UG / PG / Ph.D / Staff : Post graduate	
Batch & Year : 2018 - 2021	
Department : Pedodontics	
The soft copy of Research Work / Manuscript by Dr. Reddhi. S. Joshi..... entitled "Comparative evaluation of anxiety levels & Pain perception during local anaesthesia administration using conventional & camouflaged" Syringes in 6-11 yrs old children: An pilot study, under the guidance of Dr. Neelaj. S. Gokhale..... has been submitted for Anti-Plagiarism check to the Scientific Correspondence & Review Committee of KLE VK Institute of Dental Sciences using "Turn-it-in" software.	
The scan has been carried out and the scanned output reveals a Similarity Index of6.....%, which is within / not within the acceptable limits of 10% as per the UGC guidelines.	
 Member Secretary Scientific Correspondence and Review Committee KLEVK Institute of Dental Sciences KAHER-Belagavi	 Chairman Scientific Correspondence and Review Committee KLEVK Institute of Dental Sciences KAHER - Belagavi

