VOLUME - 10, ISSUE - 12, DECEMBER - 2021 • PRINT ISSN No. 2277 - 8160 • DOI : 10.36106/gjra

Original Research Paper

Dental Science

COMPARATIVE EVALUATION OF PAIN, ANXIETY AND COMFORT IN PATIENTS UNDERGOING LOCAL ANESTHESIA USING VIBRAJECT AND CAMOUFLAGE SYRINGE SYSTEMS IN AHMEDABAD CITY, GUJARAT: AN IN VIVO STUDY

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ABSTRACT

BACKGROUND: Dental injections are associated with anxious thoughts and fears in children and can be one of the most difficult aspects of treating a child dental patient. Thus, the knowledge and skills in using newer alternatives in pain control and management helps in administering local anesthesia by increasing the comfort level of patients and resolve the clichéd paradigm of "Pain and Dentistry are inseparable".**AIM:** To compare and evaluate pain, anxiety and comfort in paediatric patients undergoing local anesthesia using Vibraject syringe system and Camouflage syringe with Conventional Cartridge based syringe. **METHODS:** Study design: A double-blinded, randomized controlled trial of efficacy of the Camouflage syringe and Vibraject syringe system over Conventional Cartridge based syringe in children seeking dental treatment under local anaesthesia. **RESULTS:** On evaluating the pain perception and anxiety using subjective evaluation (Wong Baker's scale and Venham's rating scale), Group II (Vibraject) was found to be the most effective as compared to Group I (Camouflage) and Group III (Conventional) in both i) 5-8 years ii) 9-12 years. But when physiologic parameters like blood pressure, pulse rate were measured, Group II (Vibraject) showed increase in anxiety of patients while Group I (Camouflage) showed decrease in anxiety and pain perception in 9-12 years age group. **CONCLUSION:** The study emphasizes on need of masking techniques for LA administration either by using vibratory devices, camouflaging, application of topical anesthetics and effective distraction methods to reduce pain and anxiety in paediatric patients.

KEYWORDS : Pain, Anxiety, Local anesthesia, Children.

INTRODUCTION:

One of the most important events that shape the relationship between a dentist and a child dental patient is the successful administration of local anesthesia for an operative procedure. Paradoxically, administration of local anaesthetic drugs itself produces pain and anxiety that may cause subsequent unfavorable behaviour in children. So one of the most important and challenging aspects of behavior management in children during dental treatment is pain control.[1]

Colares et al. in a cross-sectional study found a prevalence of dental fear and anxiety of 14.4% .The strongest fears are associated with injections.[2] Moreover, the effects of children's dental fears may persist into adolescence and lead to avoidance of care-seeking with subsequent long term detrimental consequences. This can be of significant impediment to dental care and can negatively influence the patient's global health.[3,4]

In literature, various innovations have been added to traditional methods of drug delivery system like WAND, jet injectors, intraosseous system, vibrotactile devices, camouflage syringes and denti-patch.[5-12] Recently, a vibrating dental local anesthesia attachment (Vibraject, LLC, California) has been introduced. Vibration of soft tissue has been employed for relief of pain in other areas of the body, but very few attempts to use vibration to relieve the pain of oral injections has been observed.[13-15] Moreover, one of the most common cause of dental fear is generally attributed to 'the needle hence a novel, simple camouflage sleeve (Angelus™) was used to conceal the needle from the child's sight, thus reducing dental fear and anxiety.[16-17] We conducted a randomized control trial with to evaluate the efficacy of Camouflage syringe and Vibraject syringe system over Conventional syringe. Thus, the knowledge and skills in using newer alternatives in pain control and management can be helpful in administering local anesthesia comfortably in children and resolve the clichéd paradigm of "Pain and Dentistry are inseparable".[5]

AIM:

To compare and evaluate pain, anxiety and comfort in paediatric patients undergoing local anesthesia using Vibraject syringe system and Camouflage syringe with Conventional Cartridge based syringe.

MATERIALS AND METHODS:

Study design: The concurrent, parallel, double-blinded randomized control trial was conducted at the Department of Paediatric And Preventive Dentistry, Ahmedabad Dental College and Hospital, Ahmedabad, India. The data collection phase spanned from June 2018 to the end December 2018. Protocol approval was obtained from the Ethical Committee of Ahmedabad Dental College. Results are described as outlined in the CONsolidated Standards of Reporting Trials (CONSORT) guidelines.

SAMPLE: Informed consent of parents and patients were obtained for the subjects participating in the study. Simple randomized, parallel-group studies with sample size of 120 children with 40 in each group, between age group of 5-12 years were taken.

INCLUSION CRITERIA: Dental treatment requiring local anaesthesia administration; Subjects with age range of 5-12 years; Subjects belong to American Society of Anaesthesiologists I category; Subjects with no previous dental experience.

EXCLUSION CRITERIA: Mentally challenged children; Patients having significant behavioral management problem; Patients with underlying medical history and developmental anomalies; Patients with a known history of allergy to local anesthetic agents.

Procedure and discusion: The study had three groups. Each group was further subdivided in two sub-groups: i) 5-8 years old ii) 9-12 years old. Each group had 40 patients with 20 in each sub-group.

GROUP I –Local anesthesia administration with cartridge based syringe system concealed with Camouflage sleeve (Camouflage)

GROUP II – Local anesthesia administration with cartridge based syringe system attached with Vibraject device (Vibraject)

GROUP III – Local anesthesia administration with cartridge based syringe system (Conventional).

The Modified Wong Baker's Rating Scale, Venham rating scale and local anesthesia procedure were explained to the child before starting the procedure. Strict adherence to basic injection techniques were followed. Pre-procedural evaluation of intraoral, extraoral and child's airway was done. Childs anxiety level was assessed by the observer using Frankl's behaviour rating. The technique was described to the patient as per the child's level of understanding using euphemisms followed by local anaesthesia administration. After application of topical anaesthesia, 2% lignocaine hydrochloride with 1:80,000 adrenaline was used. After 5-7 minutes of topical application, the syringe was loaded with the local anaesthetic solution away from patient's sight. Allocation of Group I/II/III was done using Fishbowl method. Then this entire assembly was used to approach the area of block anaesthesia. The needle was then inserted into the mucosa, aspiration results checked and the injection procedure carried out normally. The field block was given and each patient was evaluated using the scales for pain, comfort and anxiety. Immediately after the injection the child (or a parent in case of a very young child) was requested to fill out the Wong Baker's rating Scale and Venham's rating scale questionnaire; while the objective assessment was done using Venham's clinical rating scale by the observer. Pulse rate, blood pressure was recorded using digital sphygmomanometer before and after the injection.

RESULTS:

Results of the study were tabulated and evaluated using Chi-Square Test and unpaired t-test Statistical Package for the Social Sciences (SPSS version 20.0) for Windows. Confidential interval for mean was considered to be 95% and p value <0.05 considered significant.

A total of 120 subjects (44 females, 76 males) aged 5-12 years were included.

Two age - wise subgroups were created.

1) 5-8 years (n=57)
2) 9-12 years (n=63)

CONCLUSION:

In Group I, Reduction in pain perception and anxiety were observed significantly in 9-12 years age. This could be because they are more easily distracted and the toy-like appearance of the camouflaged syringe takes away the fearprovoking stimuli of a conventional syringe It provoked anxiety in 5-8 years of age due to unacceptability of sight of sleeve.

In addition, due to its large size, it is not currently known whether the Angelus™ sleeve is acceptable to dental practitioners. The sleeve is presently only compatible with the metal aspirating dental syringe which uses local anesthesia cartridges and disposable needles. Hence, it can be concluded that a simple and novel innovation to camouflage conventional syringes can result in improved outcomes related to dental fear and anxiety in 9-12 years age group. Camouflage sleeve with an attractive shape and structure might prove more beneficial in younger children.

In Group II, Vibraject provides reduction in anxiety and pain perception in comparison to the conventional injection technique and Camouflage syringe in clinical dental procedures in children of 5-12 years of age. While the role of physiological parameters in pain perception was inconclusive, Vibraject may be a promising alternative method of delivering local anesthesia in children.

In Group III, Pain perception, anxiety and discomfort were higher in this group compared to other two groups in 5-8 and 9-12 years age group.

Thus, the study emphasizes on need of masking techniques for LA administration either by using vibratory devices, camouflaging, application of topical anesthetics and effective distraction methods to reduce pain and anxiety in child patients. Such simple effective and concrete measures would bring a paradigm shift in old saying "Dentistry and pain are inseparable."

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