RESEARCH PROTOCOL

1. PROJECT NAME:

Clinical Evaluation and Comparison of Pain Acceptance of Different Types of Injection Systems in Palatal Anesthesia Applied to Children

2. JUSTIFICATION OF THE PROJECT:

Dental anxiety and fear are very common in the pediatric population. In order to cope with this feeling, the dentist must have knowledge about the degree of anxiety in children, its etiology and the child's psychology.[1] One of the most widely known and important factors in the development of dental anxiety or fear is “painful dental treatments”. The child’s encounter with a painful procedure just once or even the feeling that they will feel pain is enough to cause anxiety and fear. A friendly relationship with the dentist helps patients cope with specific stimuli known to cause anxiety and fear, such as anesthesia, the sound and sight of the aerator.[2] Local anesthesia is the blocking of pain sensation by applying a drug topically or by injection to a part of the body without affecting the level of consciousness. Preventing pain sensation during dental procedures can increase the relationship between the patient and the dentist, develop trust, alleviate fear and anxiety, and enable the patient to have a positive attitude towards dental procedures.[3]

Traditional local anesthesia application methods can cause increased dental anxiety in children. Therefore, new needle-free and painless local anesthesia techniques are being developed in parallel with technological developments. With the development of needle-free injection systems, the patient's needle phobia and the resulting dental anxiety are prevented. Jet injection systems, computer-controlled local anesthesia injection systems, electronic dental anesthesia, vibration systems, laser analgesia, virtual reality anesthesia and iontophoresis are needle-free injection methods. The Comfort-in jet injection system is a device that injects the anesthetic solution with pressure in a short time.[4]

There are many studies on various anesthetic agents used during operations, different anesthesia, and different analgesic, anti-inflammatory and immunosuppressive agents used after the operation, in order to ensure that patients tolerate this surgical procedure more easily, feel less pain, and go through this period more easily and without problems, both during and after the operation.

The aim of this study is to compare the injection pain experienced during palatal local infiltration anesthesia in patients undergoing maxillary tooth extraction with the Comfort-in jet system, which is a needle-free injection method. In addition, to compare the acceptability of anesthesia provided by the Comfort-in jet injection system in children, to determine their preferences, and to evaluate the effect of anxiety level on the severity of pain felt.

***2.1*. Local Anesthesia**

Local anesthesia is an analgesia method performed by injecting an anesthetic substance, usually near the sensitive nerve fibers, to temporarily prevent the transmission of pain impulses to the brain, without causing the patient to lose consciousness.5 Since the transmission of impulses to the brain is blocked, the patient cannot interpret it as pain.5 Local anesthesia can be examined in 3 groups:

1. Topical (Superficial) Anesthesia
2. Infiltration Anesthesia
3. Regional Anesthesia

2.1.1. Infiltration Anesthesia

This type of anesthesia, which is one of the most commonly used methods for obtaining local anesthesia in dentistry, is based on the principle of blocking the nerve endings in the operation area.[6]

2.1.2. Innervation of the Upper Jaw and Teeth

N. maxillaris is one of the three main branches of N. trigeminus. It passes through the cavernous sinus, pierces the anterior wall of the sinus, enters the foramen rotundum and exits into the pterygopalatine fossa. It divides into various branches within this fossa.[8]

2.1.2.1. Nervus Palatinus

It is composed of two branches, one thick in front (n. palatinus majus) and the other thin and posterior (n. palatinus minores), which branch off from the maxillary nerve and extend downward from the pterygopalatine ganglion.[10] The palatinus majus is a branch that originates from the palatine foramen and extends from the roof of the oral cavity to the incisors to innervate the mucosa, hard palate and adjacent gingiva.[11] Palatal infiltration anesthesia is used to provide local anesthesia. In this technique, the anesthetic substance is deposited between the periosteum and the bone. Since the periosteum is tightly fixed to the bone, the injection is very painful in this area.[6] The palatinus minores originates from the palatine foramen and distributes to the soft palate and tonsil, providing innervation to this area.[9]

2.1.2.2. Rami Alveolares Superiores Posteriores (RASP)

It branches off from the maxillary nerve in the pterygopalatine fossa in 2 or 3 branches.[10] It gives off just before entering the sulcus infraorbitalis. It innervates the maxillary sinus, all of the upper molars except the mesiobuccal root of the first molar, the adjacent upper jaw gum, and the cheek[11] In addition to tuber (regional) anesthesia, local infiltration anesthesia is applied to these teeth because the cortical layer of the upper jaw is thin and porous.[7]

2.1.2.3. Rami Alveolares Superiores Medius

It separates from the infraorbital nerve within the infraorbital sulcus. It descends down the lateral wall of the maxillary sinus and innervates the mesiobuccal root of the first molar tooth of the maxilla, the premolars, the adjacent gingiva, and the cheek.[11] Vestibular infiltration anesthesia is used as anesthesia technique.[7]

2.1.2.4. Rami Alveolares Superiores Anteriores

It separates from the infraorbital nerve in the middle of the infraorbital canal. It descends from the anterior wall of the maxillary sinus and extends to the canine and incisor teeth of the upper jaw. Some of its fibers enter the nasal cavity and are distributed in the anterior mucosa of the meatus nasi inferior.[9] Vestibular

infiltration anesthesia is applied for anesthesia of the incisor and canine teeth.[7]

2.2 Pain Acceptance and Clinical Success Evaluation Criteria

2.2.1 Wong Baker Pain Rating Scale

The Wong-Baker Pain Rating Scale pain scale was developed by Donna Wong and Connie Baker. It can be used from the age of 3. It consists of 6 face shapes that express the pain condition. In a study, it was concluded that the Wong-Baker pain scale was more understandable than the VAS scale in children aged 3-14.[12]

2.2.2 FLACC Scale

The FLACC scale was first introduced in 1997. This scale scores behavioral characteristics consisting of 5 categories. It reminds us of scoring with initials; F: Face, L: Legs, A: Activity, C: Cry, C: Consolability. Each category is scored between 0 and 2. The highest value is 10. Total score; 0: Calm and comfortable, 1-3: Mild discomfort, 4-6: Moderate pain, 7-10: Can be evaluated as severe discomfort or pain or both.[13]

2.2.3 Complications of Anesthesia

Complications related to the tissue may be observed after anesthesia. These complications are listed below:

1- Hematoma
2- Pain
3- Needle breakage
4- Infection
5- Emphysema
6- Inadequate anesthesia
7- Palatal mucosa necrosis

Complications that may be observed after two different anesthesia systems are applied will be recorded.

3. PURPOSE OF THE PROJECT:

3.1. Main Purpose of the Project:

Palatal injection, which is routinely used in the extraction of primary molars, causes pain and fear due to the tight connection between the palatal mucosa and bone, and causes difficulty in tolerating by pediatric patients. The purpose of our study is to evaluate Comfort-In™ Needle-Free Injection in terms of pain perception in children in palatal infiltration anesthesia applied to the upper jaw, which is difficult to tolerate by patients.

4. MATERIALS AND METHODS OF THE RESEARCH:

The required number of participants was obtained after power analysis based on the data of a previously conducted study on the subject [alpha(α)=0.05 beta(β)=0.05 and power=0.95]. Considering that 60 people

should be included in the study and the possibility of loss, the sample size was determined as 90.[14]

The groups will be formed according to the split mouth method in the same patient with symmetrical primary molar teeth. In all groups, “Ultrave D-S Forte 80 mg + 0.03638 mg/ 2 mL (Articaine hydrochloride Epinephrine bitartrate)” will be used as a local anesthetic. In the study group, teeth will be extracted using Comfort-In™ Needle-Free Injection with a single point palatal injection. In the control group, teeth will be extracted using a single point standard injection. Parents of patients who are considered to participate in the study will have their consent forms filled out and a previously prepared informed consent form will be obtained. Children who have planned extraction treatment for maxillary primary molars, have symmetrical teeth, do not have any systemic disease, and whose parents can give consent will be included in the study. Necessary anesthesia will be applied before the extraction procedure and the tooth will be extracted. In patients who are anesthetized with Comfort-In™ Needle-Free Injection during the procedure, if they feel serious pain, the procedure will not be continued and the patient will be excluded from the study. After the anesthesia procedure, the patient will be able to mark the pain level using the Wong Baker Pain Rating Scale. The FLACC test will be evaluated with the video taken during the anesthesia procedure. The obtained data will be evaluated with descriptive and explanatory statistics using the SPSS package program. Anova test and Post Hoc Tukey test will be used for comparison between groups, and an independent two-group t test will be used to evaluate the pain level between male and female patients within groups.

In the volunteer group to which the drug is applied with the “Comfort-in Needle Injection”, if the anesthesia procedure is insufficient and/or does not occur, the patient will be given the traditional injection method as a rescue treatment and the patient will be excluded from the study, but the treatment will continue.

A guarantee will be given that the personal data collected will be collected and processed in accordance with the Personal Data Protection Law No. 6698, will not be used or shared for any purpose other than the purpose of collection/processing, that the data will be destroyed when the volunteer withdraws his/her consent, the research ends or the processing of personal data ends, and that the collected personal data will not be shared.

4.1. Location of the Research:

Children aged 4-11 years who do not have any systemic disease and who apply to the Department of Pedodontics of Necmettin Erbakan University Faculty of Dentistry are planned to be included in our study.

4.2. Time of the Research:

It is planned to be held between 01.02.2024 - 01.08.2024.

4.3. Research Universe, Sample, Research Group:

Children between the ages of 4 and 11 who apply to the Department of Pedodontics, Faculty of Dentistry, Necmettin Erbakan University, and who do not have any systemic diseases will be included in our study. The groups will be formed according to the split mouth method, with symmetrical primary molar teeth in the same patient. Teeth in the study group will be extracted with Comfort-In™ Needle-Free Injection. Standard injection will be applied for teeth extraction in the control group.

Inclusion criteria for the study;

Patients;

-Between the ages of 4-11

-Bilateral maxillary primary molars with an indication for extraction

-Have not taken any analgesics up to 12 hours before treatment

-Have not used antibiotics in the last month

-Teeth with no more than 1/2 of the root physiologically resorbed

-Systematically healthy children

-Those who agree to participate in the study

-Must show a score of 3-4 or 1-2 according to the Frankle Behavior Scale

-Frankle 1: Patients who refuse treatment, cry, are excessively anxious or show signs of severe negative behavior

-Frankle 2: Patients who are non-compliant, unwilling to treat, show vague signs of negative behavior, are sullen but do not express anxiety

-Frankle 3: Patients who accept treatment, are compliant, shy, establish a relationship with the physician but approach it in a measured manner

-Frankle 4: Patients who cooperate with the physician, are curious about treatment, smile and are happy with the environment Frankle(1962)

Teeth;

- Bilateral maxillary primary molars with extraction indication

4.4. Type of Research:

Prospective, experimental, randomized clinical trial

4.5. Manpower Required for Research:

Assistant Professor Halenur ALTAN (Project manager, creation of research design, clinical evaluation, data analysis and study writing)

Dt. Busra ALMAS (Assistant researcher, routine patient follow-up, application of extraction treatment, data analysis and study writing)

4.6. Data Collection Tools of the Research:

4.6.1. General Method

This study will be conducted by including children between the ages of 4-11 who apply to the Department of Pedodontics, Faculty of Dentistry, Necmettin Erbakan University, and who do not have any systemic diseases. The required number of participants was obtained after power analysis based on the data of a previously conducted study on the subject [alpha(α)=0.05, beta(β)=0.05 and power=0.95]. Considering that 60 people should be included in the study and the possibility of loss, the sample size was determined as 90.[14]

Patients who apply to the Department of Pedodontics, Faculty of Dentistry, Necmettin Erbakan University, meet the inclusion criteria and will be offered to participate in the study if they give their consent to the informed consent form.

The study and control groups will be determined randomly in order to eliminate variables that may cause differences in patients over time. Randomization will be done through the website ‘’randomizer.org’’. Before starting the study, patients and their parents will be informed about the treatment procedure to be applied.

Systemic and dental history will be taken from the patients before starting the extraction procedure. After clinical examination with inspection, palpation and percussion, periodontal and radiographic examination will be performed. Patients who meet the inclusion criteria will be informed about the study and their written informed consent will be obtained. Since gender is one of the factors that can affect postoperative pain, female and male patients will be distributed equally. Postoperative pain will be assessed using the Wong Baker Pain Rating Scale, where the patient can mark the pain level after the anesthesia procedure. The FLACC test will be evaluated with the video taken during the anesthesia procedure. Later, statistical evaluations and comparisons between groups will be made.

4.6.1. Components of a Study-Specific Clinical Assessment:

Sociodemographic form: This is a sociodemographic information form prepared by the researchers that includes information such as age, gender, contact information, and medical condition of the patients.

Tooth-material information form: This is a form prepared by the researchers that records which teeth were included in the study and the file system used on the teeth.

FLACC Scale: This is the form where the pain status is recorded using the FLACC scale at the end of the procedure for the teeth included in the study prepared by the researchers. This scale will be evaluated by looking at the video recording taken during palatal anesthesia of the upper primary molar teeth that need to be extracted. The tooth will be extracted after anesthesia.

Wong Baker Pain Rating Scale: This is a form that records the pain status of the teeth included in the study, prepared by the researchers, using the Wong Baker Pain Scale at the end of the procedure. This scale will be used immediately after the palatal anesthesia of the upper primary molars that need to be extracted. The tooth will be extracted after anesthesia.

Dental Anxiety and Fear Index (IDAF-4C): The four components covered by the measure include

emotional, behavioral, physiological, and cognitive modules, and a basic fear module.15 This index will be administered to the patient before anesthesia. After anesthesia, the tooth will be extracted.

4.7. 4.7. Evaluation of Data:

The data obtained as a result of our study will be evaluated with the help of SPSS package program. Postoperative pain will be evaluated using Wong Baker Pain Rating Scale, where the patient can mark the pain status after the anesthesia procedure. FLACC test will be evaluated with the video taken during the anesthesia procedure. The obtained data will be evaluated with descriptive and explanatory statistics with the help of SPSS package program. Anova test and Post Hoc Tukey test will be used for comparison between groups, and independent two-group t test will be used to evaluate the pain status between male and female patients within the groups.

RESOURCES:

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