

STUDY PROTOCOL

The Evaluation of The Effect of Routine Treatments Administrated in Pedodontics Clinics on Dental Anxiety in Children and Salivary Cortisol Levels

Study Identification

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Brief Title: Dental Anxiety in Children and Salivary Cortisol Levels

Official Title: The Evaluation of The Effect of Routine Treatments Administrated in Pedodontics Clinics on Dental Anxiety in Children and Salivary Cortisol Levels

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Study Population

The study was carried out following the approval by the local ethics committee (Malatya Clinical Studies Ethics Committee, 2017/76), and informed consent was signed by the parents. Power analysis was performed prior to the study in order to calculate the sample size. In the power analysis, for an $\alpha = 0.05$ and $1 - \beta$ (power) = 0.80, it was calculated that at least 12 patients is required per group. Therefore, the study was planned with 135 children with 15 children in each group. For that purpose 9 groups were formed as 6 restorative and 3 protective applications. The restorative treatment groups included procedures with- and without-local anesthesia (LA). Procedures with LA included the groups as root canal treatment, pulpotomy, two-surface restoration and one-surface restoration. Procedures without LA included the groups as two-surface restoration and one-surface restoration. The protective application groups included the groups as fluoride application (by disposable arch tray or by cotton roll) and fissure sealant.

Inclusion Criteria

A total of 135 children (69 females 51.1%, 66 males 49.9%), aged 7-8 years (7.37 ± 0.48 years), were admitted to Inonu University Faculty of Dentistry Department of Pediatric Dentistry. They were

apparently healthy and had no previous experience of dental treatment except oral diagnosis that took place 1-2 months ago. Children, who required at least one dental treatment in the upper right molar region, were included. As lower molar teeth region could differ in terms of infiltrative anesthesia block, we chose upper right molar teeth for sake of standardization.

Detailed intraoral and extraoral examination of the patients was performed by a single dentist (BA). The dentist carried out the procedures with the same colored uniform (wearing a blue uniform) in both sessions. The diagnosis and treatments were carried out by the same dentist. The personal, medical and dental history of the patients were obtained from their parents and recorded in the patients' files.

Frankl's Behaviours Rating Scale (FBRS) is a method that is frequently used in studies based on the rating of behaviours. Children's attitudes during the dental examination were evaluated using FBRS. Behaviours of the child are examined in four groups in FBRS: definitely negative (Frankl-1), negative (Frankl-2), positive (Frankl-3), and definitely positive (Frankl-4) ¹.

In terms of the standardization of the groups, only the children who were compatible with Frankl-3 or 4 classes were included in the study. Children with Frankl-1 and -2 classes had negative compliance to treatment and therefore they were not included in the study.

The patients were grouped according to treatment needs. The patients were divided into groups taking into consideration the requirements of having no pain, abscess, fistula and no need for dental treatment requiring urgent intervention. Patients, who did not meet the inclusion criteria for the study, who did not want to participate voluntarily, who ate and drank something 1 hour before the appointment, who used medication in the last 7 days, who used medication that may affect the salivary flow in the last 60 days or who left the dental treatment incomplete, were not included in the study.

Procedures Applied to Patients

Each patient who participated in the study was informed about the treatment to be applied to him/her and the measurements to be performed by using the tell-show-apply behavior method. Furthermore, the child informed the dentist about any discomforting stimuli by "raising his/her left hand up" and the dentist stopped when he/she received this warning.

In the groups treated with local anesthesia, banana or strawberry flavored topical anesthetic gel (Vision Dental Pat Gel, WP Dental, Germany) that children might like was applied first. Then, the local anesthetic solution [Ultracain D-S ampoule (40 mg articain + 0.012 mg epinephrine) Aventis Pharma, Istanbul, Turkey] was injected by the traditional method with the help of a 2 cc set inject plastic dental injector (Tibset Sterile Medical Equipment Industry Istanbul, Turkey). Only conventional root canal treatment and extirpation were planned for the children included in the root canal treatment group in the measurement session. In the groups to be treated with pulpotomy, it was noted that at least one of the approximal surfaces of the teeth had decay and iron sulfate (ViscoStat®, UltraDent, South Jordan, USA) was used as pulpotomy material. A Tofflemire matrix retainer and 0.05 mm thick matrix band (Hahnenkratt, Königsbach-Stein, Germany) were used in groups with a two-surface cavity. 2% NaF (Polimo® IMICRYL, Konya, Turkey) was preferred in groups who received fluoride application.

An aerator and micromotor were used as cavity preparation in the restorative treatment groups. Only the micromotor was used for polishing purposes in the protective treatment groups.

Study Design

The Facial Image Scale (FIS) comprises a row of five faces ranging from very happy to very unhappy and the children were asked to point at which face they felt most like at that moment ². FIS was assessed at three stages: at the moment they sat in the dental chair, 15 minutes after the start of the treatment, and 15 minutes after the end of the treatment. In the scoring of this scale, which consists of faces that express five different moods, the unhappiest face gets the score of 5 and the happiest face gets the score of 1. From the moment the patient sat in the dental chair, the probe of the bed-side monitor was attached to the patient's left index finger, and his/her heart rate and SpO₂ were monitored during the treatment period and the data were recorded. After the treatment of the patients was completed in that appointment, the CFSS-DS was filled in by the patients under the supervision of their parents. This scale consists of 15 questions about the different steps of dental treatment, such as injection, examination, dentist's use of rotary instruments, and the answers are scored from 1 (not

afraid at all) to 5 (very much afraid). Scoring shows a low level of anxiety between 15-31, a medium level of anxiety between 32-38, and a high level of anxiety at 39 and over.

In the mornings, 3 salivary samples were taken from the patients by their parents in the home environment, i.e. one day before the treatment, on the day of treatment and one day after the treatment. The non-stimulated total saliva was collected from the patients. The parents were warned about the fact that all of the three salivary samples should be taken at the 30th minute after awakening, between 07:00 and 07:30 am. Eating, drinking, brushing the teeth and using dental care products were not allowed. It was stated that they could store them in the cooler part of the refrigerator at +4 °C until the day of delivery to the dentist. For saliva collection, three labelled polypropylene tubes were given to the parents inside a sterile collection container. During the treatment period in the clinic, salivary samples were taken between 09.00 and 11.00 am. Saliva samples were taken in 3 stages, i.e. at the beginning of the treatment, at the 15th minute of the treatment, and 15 minutes after the end of the treatment. Sampling at 15th minute of the treatment process was standardized to correspond to the cavity with an aerator (at the enamel level) in restorative treatment groups and to the stage of polishing procedure with a micro motor in protective treatment groups. These measures were taken to prevent the saliva from contaminating the cavity. In the groups treated with local anesthesia, care was taken not to include blood in the samples. If there was a visible plaque in the protective treatment groups, it was removed with a sponge, and the sample was taken after the polishing procedure.

Six samples were taken from each of 135 patients, a total of 810 samples were obtained, and samples were kept at -70 °C until the day of analysis. The frozen samples were thawed at room temperature on the day of analysis and centrifuged at 3000 rpm for 5 minutes. Cortisol concentrations were measured by the ELISA (Enzyme-Linked Immunosorbent Assay) method in a microplate optical reader (Biotek, Synergy HT, USA) and quantified with its special software (Gen 5, Biotek, Synergy HT, USA) as reported by Ozgocer et al.^{3,4}.

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