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RESEARCH PROPOSAL: QUANTITATIVE AND QUALITATIVE EVALUATION OF THE ART IN INFANTS

PROTOCOLO DE PESQUISA: AVALIAÇÃO QUANTITATIVA E QUALITATIVA DO TRA EM BEBÊS

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ABSTRACT

The accomplishment of the Atraumatic Restorative Treatment (ART) approach during the early childhood may represent a remarkably less traumatic and less expensive therapeutic choice. The purpose of this study is to investigate the mothers' perceptions about the ART technique in the oral health/disease process of their children diagnosed with Early Childhood Caries (ECC), and to evaluate the clinical performance of the atraumatic restorations placed in these children at six-, twelve- and twenty-four-month intervals.
Uniterms: Atraumatic Restorative Treatment; Early childhood caries; Severe childhood caries.

RESUMO

O emprego do Tratamento Restaurador Atraumático (TRA) durante a primeira infância pode representar uma escolha terapêutica menos traumática e menos dispendiosa. Esta pesquisa propõe investigar a percepção das mães sobre o TRA no processo saúde/doença bucal de seus filhos portadores de Cárie Precoce da infância (ECC), e avaliar o comportamento clínico destas restaurações, após períodos de seis, doze e vinte e quatro meses.
Unitermos: Tratamento Restaurador Atraumático; Cárie precoce da infância; Cárie severa da infância.

INTRODUCTION

In children of tender age, caries disease manifests in an aggressive form, leading to complete destruction of tooth crowns in a short period of time, with possibility to evolve to so severe conditions that interfere negatively with the normal growth and development of the affected infants[22].

The pattern of caries lesions in babies has distinctive characteristics. The lesions develop rapidly, frequently soon after tooth irruption, involving tooth surfaces that are usually at low risk of caries onset, such as the buccal surfaces of the maxillary incisors and the buccal and palatal surfaces of the maxillary and mandibular molars. If the condition of exposure to a high cariogenic challenge is maintained and no preventive/interceptive measures are implemented, the demineralization process advances through the enamel into the dentin, and the crowns of almost all teeth are rapidly involved and completely destroyed, thus leaving root remnants only[4,10,18].

Regarding the epidemiology of the early childhood caries (ECC), Milnes[13] (1996) observed that while ECC prevalence ranges between 1% to 12% in first-world countries, in developing countries and in deprived populations of first-world countries, this prevalence increases to 70%.

The findings of a 7-year evaluation of a dental program for babies[7], implemented at the Baby Clinic of the Faculty of Dentistry of the Federal University of Rio Grande do Sul (FO/UFRGS), revealed that the most prevalent reason that led the mothers to seek for assistance to their children at the Baby Clinic was caries disease (51%), followed by interest in preventive programs (30%), traumatism (12%), dental anomalies (5%) and oral diseases (2%). This survey also identified that 61.5% of the children assisted at the Baby Clinic had caries activity on beginning of the dental treatment.

Weisntein[23] (1998) emphasized that the social factors act either direct or indirectly as causative agents of many diseases, including the early childhood caries, and that the healing treatment of caries disease in children of tender age should be carried out on the basis of the atraumatic restorative treatment (ART) approach, in an attempt to

minimize the fear and anxiety that dental care usually imposes to parents and children alike.

The ART benefits socially excluded populations with limited access to conventional dental assistance. The proposed technique does not require the use of sophisticated materials or electric dental equipments (only hand instruments are necessary for cavity access and caries removal)[9]. Another relevant factor that should be accounted for indication of the ART approach for infants is the high cost of the conventional restorative treatment in children diagnosed with early childhood caries. According to Weisntein[23] (1998), the ECC treatment costs covered by the public dental care system (in American dollars) would range between U$700 to U$1.000 per child. Additional U$1.000 would be needed in cases in which general anesthesia is required.

The findings of a comparative study between the costs of the atraumatic restorative treatment and the costs of conventional amalgam and composite resin restorations, in South Africa, estimated that ART restorations are 50% less expensive than conventional restorations placed in bur-prepared cavities. From this point of view, the authors suggested that, whenever possible, the ART approach should be preferred[12].

The outcomes of an educative-preventive-healing dental program based on the principles of the atraumatic restorative treatment[1] revealed that the program had 98% of acceptance among the treated children mainly due to the minimally invasive nature of the ART technique, which employs hand instruments only, and because, in most cases, the procedures are painless thus eliminating the need of local anesthetics. Another relevant observation of the above-mentioned study was that the ART restorations yielded the adequacy of the children's oral conditions. The treatment did not interfere with the oral microbiota on a quantitative basis, but was able to shift the balance of the ecosystem with selection of microorganisms towards a less cariogenic microbiota.

Considering that dental care of infants is usually carried out with the mother present in the dental office, in direct contact with the child, it is proposed to investigate which are the mothers' perceptions about the ART technique with respect to the oral health/disease process of their children diagnosed with early childhood caries.

The specific objectives of this study are: 1. To identify and describe the background knowledge of the patients' mothers of oral health and caries disease etiology and management/treatment; 2. To investigate and to understand the mothers' feelings before, during and after the completion of the ART-based dental care of their children; 3. To collect data and evaluate the clinical performance of the ART restorations placed in the children at 6-, 12- and 24-month intervals.

PATIENTS AND METHODS

Study Design

The qualitative part of this study will consist of structured interviews with the participating mothers. They will provide direct descriptions of their experience regarding the atraumatic treatment carried out in their children.

The quantitative part of this study, which is relative to the placement and follow-up of the ART restorations, will consist of a randomized, double-blinded clinical assay[20].

This study will be conducted at the Clinic of the Discipline of Pediatric Dentistry at the Faculty of Dentistry of the Federal University of Rio Grande do Sul (FO/UFRS), the Baby Clinic.

Selection of the participants

The infants participating in this study (and their respective mothers) will be selected from a representative group of children seeking for dental treatment at a University Extension Course offered at the Baby Clinic of the Faculty of Dentistry of the Federal University of Rio Grande do Sul.

Sample Size

A total of 50 children ranging in age from 18 to 42 months will be enrolled in this study. This sample size was determined on the basis of a comprehensive review of the literature referring to the accomplishment of the ART approach in children, and is consistent with the number of subjects usually recruited in these studies[3,5,6,16,19].

Inclusion criteria

Children of both genders who meet the following criteria will be enrolled in the study:

- Children aged between 18 and 42 months;
- Children diagnosed with early childhood caries (ECC);
- Children with a minimum d-t* score = 2 (*decayed primary teeth); the decayed teeth may be either incisors, canines or molars, as long as they have only small to medium size cavities, in the beginning of the ART treatment;
- Either the parent or the legal guardian should sign an approved Informed Consent Form, authorizing the participation of the child in the trial and the accomplishment of the ART restorations.

A total of 8 mothers of children aged 18, 24, 30 and 36 months (2 mothers per age group, respectively) who present the following characteristics will be selected by intentional non-probabilistic, strategic sampling[15].

- Having attended the introductory lecture to the Baby Clinic Program;
- Having children with early childhood caries;
- Presenting the updated baby's Vaccination and Health Card;
- Being compliant with dental care appointments scheduled for their children;
- Being enrolled in the Oral Health Promotion Program of the Baby Clinic, at FO/UFRGS;
- Being available for taking part in the trial;
- Consenting voluntarily to be enrolled in the study and accepting to take part in the structured interviews carried out by the investigators (the researchers should obtain the participants' permission to audio record these interviews, which will facilitate further data collection);

• Signing the approved Informed Consent Form.

Although the selection of the mothers will be made on an intentional basis, their confidentiality will be maintained throughout the study.

Exclusion Criteria

Children/mothers will be excluded from the study if any of the following conditions are observed:

• Children with primary teeth with deep caries and clinical evidence of pulp involvement, such as the presence of fistula, edema, spontaneous or persistent pain and dental mobility not compatible with the physiological root resorption stage.

• Mothers who are not enrolled in the Oral Health Promotion Program of the Baby Clinic at FO/UFRGS or those who are enrolled in the Program but are not compliant with the dental care appointments of their children;

Clinical examination

Intraoral clinical examination will be performed using dental mirror and explorer after professional prophylaxis.

The parameters used to describe the ECC activity will be in accordance with the criteria of the Health Policy Bureau of the Ministry of Health and Welfare of Okayama, Japan, which consist of 5 classifications related to ECC severity degree, as depicted below[21].

C0= Non-cavited white spot lesions only; C1= Cavity in enamel; C2= Cavity in dentin; C3= Cavity with pulp exposure; C4= Root remnants only

The total number of erupted teeth will be added to these records.

Group Assignment

The selected group of 50 children will be randomly assigned to two groups of 25 children each. A random allotment will be made in a table of random numbers, for the placement of the ART restorations using two glass ionomer restorative materials.

The children will undergo the following treatments:

• GROUP A: Removal of the infected carious dentin according to the ART technique + restoration with VITRO-MOLAR Glass Ionomer Cement (DFL) + protection of the restored tooth surfaces with Alpha Bond adhesive system.

• GROUP B: Removal of the infected carious dentin according to the ART technique + restoration with KETAC-MOLAR EASY MIX Glass Ionomer Cement (3M) + protection of the restored tooth surfaces with Alpha Bond adhesive system.

Clinical evaluation of the restorations

The clinical evaluation of the ART restorations will be carried out according to the criteria proposed by Phantumvanit, et al.[17] (1996) and further updated by Lo and Holmgren[11] (2001). Intraoral clinical examination will be performed under relative isolation and artificial illumination with use of dental mirror and periodontal probe (HULFRIEY, CP10SE, Chicago, IL, USA) for assessment of the possible imperfections and/or alterations of the ART restorations.

Qualification and calibration

The clinical examinations will be performed by two dentists who attend the University Extension Course at the Baby Clinic of the FO/UFRS.

In a first stage, the examiners will be submitted to a qualifying training, in order to observe the clinical variables relative to the dental examination, in accordance with the definition of the parameters preconized by Tsubosuchi, et al.[21] (1994). Each child will be examined by the two dentists and 20% of the children will be reexamined by both examiners seven days later. This approach will be carried out to provide optimal intra- and inter-examiner accuracy on clinical examination.

In a second stage, the ART restorations will be clinically evaluated by both professionals. The same calibration procedure will be done, that is, 20% of the restorations will be reexamined seven days after the first evaluation.

These qualifying and calibrating procedures will be carried out throughout the study. The examiners will be trained and calibrated to obtain an intra- and inter-examiner agreement of 90%, using Kappa statistics.

Anamnesis

The investigator will fill in the Clinical Form of the University Extension Course (offered at the Baby Clinic, FO/UFRS) with the information collected from the mothers chosen for the audio-recorded interviews, and will conduct the first interview with the purpose of investigating the mothers' expectations about the restorative treatment to be performed in their children. The mothers will voluntarily answer to questions referring to the health and daily routine of the children.

Audio-recorded Interview

Before the beginning of the clinical procedures (together with the anamnesis), during the restorative procedures and after completion of the ART treatment (seven to fourteen days), the researcher will schedule an audio-recorded semi-structured interview with the mothers, as proposed by Olabuénaga[15] (1999). This interview will have open questions that aim to investigate the mothers' beliefs, attitudes and behaviors concerning their perceptions and evaluation of the treatment rendered to their children, summarized as follows: 1. The reason that led the mothers to seek for assistance at the Baby Clinic (FO/UFRGS); 2. The concept of caries disease; 3. The importance of primary teeth care; 4. Their perception of the atraumatic restorative treatment (before, during and after the treatment); 5. Final report; 6. Evaluation of the interview.

Treatment Protocol

All children participating in this study will be enrolled in the Oral Health Promotion Program of the Baby Clinic, at FO/UFRGS. The mothers will receive individual-targeted information and instructions with respect to breast-feeding; diet counseling for optimal development of the babies; problems involved in early introduction of sucrose; etiology, signals and symptoms of caries and periodontal diseases;

the most common deleterious habits in infancy, and traumatism. The dentists will emphasize the instructions on how to perform effective oral hygiene for maintenance of the children's optimal oral health status.

The ART technique should be performed according to the following sequence:

1. Toothbrushing for plaque removal;
2. Relative isolation of the operative field with cotton rolls;
3. Cleaning of the surface of the tooth to be restored with moist cotton pellets;
4. If necessary, widening of the cavity entrance and margins with a sharp hand instrument (i.e., enamel hatchets and small excavators);
5. Removal of the infected carious dentin using hand instruments (i.e., spoon excavators) with circular and horizontal movements at the dentinoenamel junction. Carious dentin should be removed using clinical criteria, such as softness, but should be limited to an extension that does not cause pulp exposure or painful sensitivity to the child[8];
6. Cleaning of the cavity with moist cotton pellets followed by drying of the cavity with cotton pellets;
7. Dentin conditioning with 10% polyacrilic acid for 10 seconds (the conditioner should be applied onto the surfaces with a microbrush disposable applicator). Removal of excess conditioner with moist cotton pellets (the cavity must be cleaned at least twice) and drying of the cavity with cotton pellets;
8. Mixing of the glass ionomer cement (powder and liquid components), according to the manufacturer's instructions on a glass slab or a mixing pad;
9. Insertion of the glass ionomer cement into the cavity as follows:

• GROUP A - Insertion of VITRO-MOLAR glass ionomer cement (DFL) into the cavity using an insertion spatula. A Centrix injector should be used when there is more than one restoration per hemiarch;

• GROUP B - Insertion of KEATC-MOLAR EASY MIX glass ionomer cement (3M) into the cavity using an insertion spatula. A Centrix injector should be used when there is more than one restoration per hemiarch;

10. After the glass ionomer cement loses its surface gloss, the soft material should be firmly pressured into the cavity for 30 seconds ("press-finger" technique);
11. Occlusal
12. Application of Alfa Bond adhesive system (DFL) onto all surfaces of the restored teeth to protect the glass ionomer restorations from water sorption or desiccation;
13. Removal of the relative isolation;
14. The patient's mother should be instructed not to offer hard foods at least during the first hour after the restorations are placed.

Follow-up and continuity of the study

After the restorative phase is completed, the children should return every three months for oral hygiene control. The children will be followed up for at least two years, in order to carry out longitudinal middle- and long-term evaluations of the atraumatic restorative treatment.

Analysis and interpretation

Data collected from the audio-recorded interviews will be interpreted according to the content analysis[14], by means of a research methodology used to describe the content of all classes of documents and texts. This analysis, considering the systematic descriptions, helps to re-interpret messages and to reach an understanding of their meanings in a level that goes beyond the common reading. The analysis will be carried out on the basis of the methodology proposed by Bardin[2] (1977), which comprises three basic stages: pre-analysis, exploration of the material and treatment of the results (inference and interpretation). A double-entry table will be used, in which all the answers formulated for the structured interviews will be displayed.

The evaluations of the ART restorations will be expressed in initial and final success averages. The time necessary for placement of the atraumatic restorations will be recorded. The differences between the materials and the types of restorations (in the event they are detected) will be analyzed using the Chi-square test and the analysis of variance (ANOVA), at a 0.05% significance level.

Ethical Considerations

This research proposal will be submitted to the Ethics in Research Committee of the Faculty of Dentistry of the Federal University of Rio Grande do Sul, and is in compliance with the Resolution CNS 196/96 from October 10th, 1996 issued by the Brazilian National Commission of Ethics in Research (CONEP).

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