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CLINICAL AND LABORATORY EVALUATION OF A NOVEL DENTAL GEL FOR TREATMENT OF CHRONIC CATARRHAL GINGIVITIS

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ABSTRACT — This article presents the study of a dental gel developed by us, containing, as an active ingredient, sanguitritrin and oil extract from calendula flowers and yarrow grass. As a result of our studies of the dental gel on 1,844 children and adolescents, we revealed that it has anti-inflammatory and wound-healing activities and produces anti-inflammatory, reparative, hemostatic and trophic effects. The results of the study make it possible to use the dental gel in clinical practice for treatment of inflammatory periodontal diseases in children. We substantiated the prospects of using the phytocomplex in the form of a dental gel and proved it as effective and safe. Besides, its dosage form is convenient for use in dental practice and even provides advantages over known domestic analogues.

KEYWORDS — plant-based (phyto) dental gel, periodontal diseases, anti-inflammatory effect.

INTRODUCTION

An analysis of the results of epidemiological studies conducted in various countries and regions indicates a high prevalence of inflammatory periodontal diseases in people of all age groups, including children and adolescents (4, 7, 8, 11).

The high prevalence of inflammatory diseases is due to inadequate diagnosis, the course of inflammatory periodontal diseases is particularly resistant to treatment, which determines the importance and urgency of this problem in modern dentistry (5, 6). The initial manifestations of inflammatory periodontal diseases occur in children with temporary bite, with age, the prevalence increases and their severity worsens, while undiagnosed catarrhal gingivitis without appropriate local and general therapy can turn into a more severe form - periodontitis (9, 10).

In modern dentistry, many options for therapeutic effects are considered using well-known methods and means, while the use of alternative methods is also relevant, including various natural components — herbal remedies that reduce the possibility of imbal-

ance in the normal flora (1, 2, 3, 12). This served as the basis for the development of our composition in the form of a dental gel based on the phytocomplex and evaluation of its effectiveness in the treatment of chronic catarrhal gingivitis.

The aim of the study

was to evaluate the effectiveness of the treatment of chronic catarrhal gingivitis using a phytocomplex in the form of a dental gel.

MATERIALS AND METHODS

A comprehensive dental examination was carried out in 1,844 children and adolescents, including 625 children at the age of 6: 610 adolescents at the age of 12 and 609 adolescents at the age of 15. The next step was the development of the technology and composition of a dental gel based on a phytocomplex containing an oil extract from calendula flowers and yarrow herb and sanguitritrin in a 1: 1 ratio. (Pupykina K.A., I shmakova Z.P., Shikova Yu.V., Averyanov S.V. (2016) Dental Gel with plant extract for treatment of inflammatory diseases of periodontium and oral mucosa. Patent RF, 2621297, May 4, 2016). Then, the effectiveness of the treatment of chronic catarrhal gingivitis was evaluated.

Statistical processing of the obtained data was performed using the STATISTICA software package for Windows 10.0. and Microsoft Excel. Methods of parametric and nonparametric statistics were used. The arithmetic mean (M), the arithmetic mean error (m), the reliability criterion (τ), and the standard deviation were calculated.

RESULTS

An epidemiological examination of 1844 patients — children aged 6 years and adolescents 12, 15 years old — revealed a high prevalence of chronic catarrhal gingivitis (K05.1 according to ICD-10) in 1344 children, which amounted to $72.88 \pm 1.21\%$ of cases. An intact periodontium was found in 27.12% (500) of the examined 6-year-old children and adolescents aged 12, 15 years.

Depending on age, inflammatory periodontal diseases were noted in $53.44 \pm 2.85\%$ (334) cases in 6-year-old children, in $80.28 \pm 3.45\%$ (490) — in

12-year-old adolescents and in $85.38 \pm 3.68\%$ (520) in 15-year-olds.

The intensity of lesions of the periodontal tissues in the examined children according to the indicators of the complex periodontal index KPI (Leus P.A., 1988) also had a tendency to a gradual increase in the indicator depending on age. Thus, in 6-year-old children it was 1.21 ± 0.02 , in 12-year-old adolescents — 1.56 ± 0.03 points, and in 15-year-old adolescents it reached 1.74 ± 0.01 points.

When assessing the PMA index in children aged 6 years, a mild degree of inflammation in the periodontal tissues was revealed in $43.24 \pm 2.71\%$ of cases, and in $10.2 \pm 1.66\%$ of cases — an average degree of inflammation. In adolescents aged 12 and 15 years, a mild degree of inflammation according to the PMA index was diagnosed in $65.26 \pm 2.15\%$ and $66.0 \pm 2.08\%$, respectively, the average degree was diagnosed in $15.02 \pm 1.64\%$ and $19.38 \pm 1.73\%$ of adolescents, respectively.

Thus, when assessing the dental status and condition of periodontal tissues, among the main dental diseases in the examined children, chronic catarrhal gingivitis (K05.1, according to ICD-10) prevailed — in $63.3 \pm 1.33\%$ of cases.

DEVELOPMENT OF A DENTAL GEL CONTAINING PHYTOCOMPLEX

The proposed method of application of the dental gel used for the treatment of chronic catarrhal gingivitis, showed that the dental gel was reliably fixed on the area of chronic catarrhal gingivitis and had high manipulation characteristics.

The composition of the dental gel provided a drug with a high therapeutic activity and prolonged action. At the third stage, as a result of a preclinical study of the phytocomplex with a known proportion of individual components, the anti-inflammatory activity of the dental gel was established — the inflammation index was 36.14 ± 1.32 ($p < 0.05$).

In a laboratory study of the antimicrobial activity of the original dental gel, the largest value of the diameter of the zone of inhibition of the growth of microorganisms was established for a 0.5 solution of sanguirithrin (20 mm). The lowest antimicrobial activity was found in the oil extract of calendula petals (*Calendula officinalis*) and herbaceous herb (*Herba Millefolii*) (3 mm).

Analysis of the data of the study on antimicrobial activity revealed that a mixture of a solution of sanguirithrin, an oil extract of *calendula officinalis* and a herb of yarrow, and has the greatest antibacterial activity against gram-positive bacteria and fungi.

EFFECT OF THE DENTAL GEL ON THE CONDITION OF PERIODONTAL TISSUES

For the clinical assessment of the effectiveness of local treatment of chronic catarrhal gingivitis in children of 6 years old and adolescents aged 12, 15 years, an examination was carried out before and after treatment. Patients' complaints were studied and the data of objective examination, index assessment, microbiological research in dynamics were compared before and after the treatment in 14 days, 6 months, 12 months.

The scheme of complex treatment of inflammatory periodontal diseases included the phytocomplex developed by us in the form of a dental gel containing sanguirithrin and an oil extract from calendula flowers and yarrow herb as an active component. At the same time, the choice of the drug in the prognostic aspect turned out to be pathogenetically justified and promising. During the clinical stage of the study, we assessed the state of periodontal tissues in children of 6 years old and adolescents 12, 15 years old according to all criteria, which characterizes the level of inflammation in patients of the studied groups in the presence of chronic catarrhal gingivitis.

Patient K., 15 years old, complained of bleeding gums when brushing teeth. Denies somatic pathology, allergic history is not burdened. The analysis of the hygienic index revealed an unsatisfactory level of oral hygiene, the study of the CPI and PMA indices showed the presence of gingivitis, according to the PMA index — corresponds to moderate severity, the GI index corresponds to moderate gingivitis, when studying the PBI index, bleeding was noted when probing along the edge of the apex of the papilla. Diagnosis: chronic catarrhal gingivitis (K05.1) (Fig. 1, 2, 3, 4).

The assessment of the hygienic and periodontal status was carried out after 6 months in dynamics. When determining the hygiene status, a good level of oral hygiene was noted.

CONCLUSION

The results of our study substantiate the pathogenetic mechanism and indications for the use of the dental gel based on sanguinethrin and oil extract of calendula flowers and yarrow herb in the treatment of chronic catarrhal gingivitis in children and adolescents. The prospects for the use of the phytogel of the specified composition were observed as an effective and safe, with a convenient dosage form for the use in dental practice. The use of the gel provides advantages over known domestic analogues.

The obvious advantages of the dental gel of the proposed composition are its relative cheapness, ease



Fig. 1. Patient K., 15 years old. Diagnosis: chronic catarrhal gingivitis (K05.1) initial situation



Fig. 3. Patient K., 15 years old. Periodontal condition 6 months after starting treatment with the dental gel



Fig. 2. Patient K., 15 years old with applied dental gel



Fig. 4. Patient K., 15 years old. Periodontal condition 12 months after treatment with the dental gel

of use by a dentist, good handling characteristics. It is fundamentally important that all components of the phytogel are included in the list of the Russian State Pharmacopoeia.

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