http://dx.doi.org/10.35630/2199-885X/2020/10/4.33

EFFICACY OF A PLANT-BASED DENTAL GEL FOR CHRONIC SIMPLE MARGINAL GINGIVITIS: A CLINICAL TRIAL

Received 19 September2020;
Received in revised form 15 October 2020;
Accepted 22 October 2020

Adel Isaeva, Sergey Averyanov, Ilgiz Iskhakov, Oksana Gulyaeva✉, Olga Gileva, Timur Kiniabaev

Department of Prosthetic Dentistry and Maxillofacial Surgery, Institute of Continuing Professional Education, Bashkir State Medical University, Ufa, Republic of Bashkortostan, Russia

✉ *oksgulyaeva@yandex.ru*

ABSTRACT — High prevalence of inflammatory periodontal diseases in young people along with unfavourable outcomes and long-term consequences cause great damage to health, thereby determining the importance and urgency of this problem in modern dentistry. Herein, we introduced a gel based on sanguiritrin, medicinal extracts of calendula and yarrow, and evaluated its effectiveness in the treatment of chronic simple marginal gingivitis in the clinical study involving 45 patients aged 18 to 23 years (26 females and 19 males). In the treatment group (23 patients), after professional oral hygiene and correction of hygiene skills, the dental gel based on sanguiritrin, medicinal extracts of calendula and yarrow was applied as part of complex therapy, while in the control group (22 patients) the *Cholisal* gel was used. The data obtained from hygienic and periodontal indices following the treatment (OHI-S — 0.39±0.03; PBI — 1.12±0.06; PMA — 16.4±1.31%) showed clinical anti-inflammatory efficacy of the introduced dental gel in the treatment of gingivitis, while positive indices dynamics of the dental status (OHI-S — 0.64±0.03; PBI — 0.42±0.03; PMA — 9.92±1.42%) evaluated in 3rd, 6th and 12th months after the therapy indicated of the stability of obtained results.

KEYWORDS — gingivitis, herbal medicine, professional oral hygiene, personal oral hygiene, dental gel, biofilm, sanguiritrin, yarrow, calendula.

INTRODUCTION

Inflammatory periodontal diseases represent multifactorial infectious pathology caused by the body's immune reaction in response to exposure to the oral biofilm [9, 10, 12]. High prevalence of inflammatory periodontal diseases in young people [1, 3, 7], low level of oral hygiene despite a wide selection of constantly improving hygiene products [8] along with the instability of treatment results [5], adverse outcomes and long-term consequences affecting the health determine significance and urgency of this problem in the modern dentistry and healthcare system [4, 6, 11, 12].

Nowadays there is a promising technique of development and usage of medicinal products made from plant materials [1, 3], which are highly effective, easy to use, well tolerated [2, 7]. Herbal medicines have anti-inflammatory, antimicrobial, analgesic, hemostatic and reparative effects, as well as increase the defence properties of the body [1, 2, 3].

The application of herbal medicine is of considerable interest in dental practice [1, 13] namely use of herbal preparations such as yarrow and calendula in the treatment of gingivitis. In this regard, it is also promising to search for new dosage forms and drugs that could increase the effectiveness of treatment, which determined the goal and objectives of the present study.

The aim of the research was to study the efficacy of application of dental gel based on sanguiritrin, medicinal extracts of calendula and yarrow in the treatment of chronic simple marginal gingivitis.

MATERIALS AND METHODS

The group of young people with diagnosed chronic simple marginal gingivitis and dental crowding consisted of 45 people (26 females and 19 males) aged 18 to 23 years. Patients were randomized into two groups.

In the group 1 (treatment group) that included 23 patients with chronic simple marginal gingivitis K05.10, treatment was carried out according to the clinical guidelines (treatment protocols). After oral cavity sanitation, the dental gel of original composition developed by us (patent for invention No. RUS 2621297 dated 04.05.2016 "Dental gel with plant extract for the treatment of periodontal inflammation and oral mucosa") was applied on gums for 20 minutes twice a day for 10 days.

The dental gel contains sanguirithrin and oil extract of calendula flowers and yarrow herb in a 1:1 ratio. Hydroxyethyl cellulose, glycerin, Cremophor RH-40, sodium saccharinate, mint oil and purified water are used as an ointment base. The components are used in the following proportions (wt. %): sanguirithrin — 0.5; hydroxyethyl cellulose — 2.0; glycerin — 3.0; oil

extract from Calendula officinalis flowers and Achillea millefolium herb — 5.0; cremophor — 1.0; sodium saccharinate — 0.5; Peppermint Oil — 0.1; purified water — up to 100.0.

In the group 2 (control group) that included 22 patients, a standard local antibacterial treatment based on 0.06% solution of chlorhexidine bigluconate and dental gel *Cholisal* was applied after oral cavity sanitation. After hygienic cleaning of teeth 2 times a day, patients were recommended to make oral baths with 0.12% chlorhexidine solution for 3–4 minutes within 14 days and then apply the dental gel *Cholisal* to the gingival margin for 15 minutes twice a day for 10 days.

The diagnosis of periodontal diseases was formulated according to ICD-10: K05.1 chronic gingivitis (K05.10 simple marginal), K07.3 anomalies of tooth position (crowding without tooth extraction) and was substantiated by the data of clinical and instrumental studies.

We have developed an algorithm for treatment of patients with chronic simple marginal gingivitis and dental crowding. The complex therapy included the following stages:

1. Assessment and control of oral hygiene by using plaque indicator with subsequent identification with a mirror at the dentist's office and using chewable tablets at home.
2. Motivation and practicing of rational personal oral hygiene including tooth brushing twice a day with therapeutic and prophylactic toothpaste and medium toothbrush, using mouth rinses with extracts of medicinal plants within 10–14 days, flosses, dental irrigator and special dental brushes in cases with crowding. Cleaning of tongue was performed for 1 minute twice a day with a tongue scraper.
3. Professional oral hygiene, antiseptic and antimicrobial treatment of the oral cavity, prevention of biofilm formation on teeth, elimination of hard dental deposits and polishing of teeth surfaces.
4. Oral cavity sanitation (treatment of carious and non-carious defects, restoration of contact points, elimination of traumatic factors).
5. Application of the dental gel based on sanguiritrin, medicinal extracts of calendula and yarrow of the original composition on gingiva for 20 minutes twice a day within 10–14 days in the test group. In the comparison group, dental gel *Cholisal* was applied.
6. Consultation with an orthodontist aimed to eliminate existing anomalies of occlusion and dentition, if necessary, treatment and dynamic observation.
7. Consultation with a dental surgeon aimed to eliminate anomalies in the attachment of maxillary labial, mandibular labial and lingual frenum.
8. In the presence of concomitant somatic pathology, consultation, treatment and follow-up with appropriate somatic specialists.
9. Abandoning bad habits.
10. General therapy aimed for strengthening health condition including multivitamins, macro- and microelements (course of treatment is 1 month).
11. Dispensary observation in the following 3 months after complex individual treatment included examination, control and correction of hygiene once per month, and then — once every 6 months.

For objective clinical effectiveness assessment of proposed methods in the treatment of chronic catarrhal gingivitis, we analysed clinical and index dynamics of periodontal status in patients from the main and comparison groups after 7 days, 1, 3, 6 and 12 months. Statistical processing of the data was performed using standard software packages for applied statistical analysis: Microsoft Excel (Microsoft Corporation) and Statistica 6.0 (StatSoft Inc.).

RESULTS AND DISCUSSION

During primary examination, the initial values of OHI-S hygiene index in patients of both groups with chronic simple marginal gingivitis and dental crowding did not differ significantly and were 1.96±0.07 and 1.94±0.05 ($p \geq 0.05$) in the main and comparison group, respectively, which indicated of satisfactory level of oral hygiene. When patients were examined 7 days after the beginning of therapy, OHI-S index in the main group was 0.39±0.03, and in the comparison group — 0.4±0.03 ($p \geq 0.05$), which corresponded to a good level of personal hygiene. In our opinion, the obtained results demonstrate the effectiveness of professional oral hygiene procedure such as high-quality professional teeth cleaning, adequacy of selected personal oral hygiene products, patient motivation and hygiene training. In order to optimize personal oral hygiene, additional conversations and trainings on usage of hygiene products were conducted in both groups of patients. During the follow-up examination after 1 month, the values of OHI-S hygiene index were 0.41±0.04 in patients of the main group and 0.43±0.02 ($p<0.05$) in the comparison group which indicated of good level of personal hygiene (OHI-S<1.2 corresponds to good oral hygiene) and absence of possible negative effect of this indicator on the overall result of treatment. At the same time, no statistically significant difference was found between the values of

both groups (p≥0.05) (Table. 1). During the patient examination 3 months after the treatment, values of the hygiene index were 0.61±0.02 in the main group and 0.59±0.03 (p<0.05) in the comparison group, which points to consistently good level of personal hygiene (OHI-S<1.2 corresponds to good oral hygiene) (Table 1). Control examination 6 months after the therapy revealed a general tendency towards increase of OHI-S values. Accordingly, in the main group, the index was 0.42±0.03, and in the comparison group — 0.41±0.03 (p<0.05), which confirms the need for regular professional oral hygiene since there are hard-to-reach areas of tooth surface that remain not properly cleaned even when a patient uses additional hygiene products (flosses, interdental brushes, irrigators, etc.). When patients were examined 1 year after treatment, OHI-S index was 0.64±0.03 and 0.67±0.03 respectively in the test group and comparison group (p<0.05) (Table 1) indicating a good level of personal hygiene (OHI-S<1.2 corresponds to good oral hygiene).

The average value of PBI bleeding index during the primary examination in patients with chronic simple marginal gingivitis and dental crowding was 3.29±0.05 corresponding to severe inflammation in periodontal tissues, and the initial values of this index did not differ significantly (p≥0.05) in patients of both groups (3.30±0.09 — in the treatment group and 3.26±0.03 — in the control group) (Table 2). When patients were examined 7 days after the beginning of therapy, a decrease in the bleeding rate was observed with the values of PBI index 1.12±0.06 and 1.62±0.04 in the treatment and control groups, respectively (Table 2). The obtained data indicates of the clinical efficacy of treatment methods at the initial stages of complex therapy. During the follow-up examination after 1 month, PBI index in patients of the treatment group was 0.76±0.04, while in the control group - 1.22±0.06 (p<0.05) (Table 2). The observed positive dynamics of PBI index in the treatment group provides the evidence for pronounced primary therapeutic effect of the dental gel in the treatment of chronic simple marginal gingivitis. During patient examination 3 months after the treatment, the values of bleeding index in the treatment group of patients with chronic simple marginal gingivitis were 0.55±0.06, while in the control group — 1.14±0.05 (p <0.05). When patients were examined 6 months after the therapy, the values of PBI index were 0.50±0.04 in patients of the treatment group and 1.17±0.06 in patients of the control group (p<0.05) (Table 2) that could be characterized as a stable dynamics of bleeding index. At the same time, there was an insignificant tendency towards decrease of PBI index within the range of statistical error (p≥0.05). During the control examination 1 year after the *primary* course of treatment of chronic simple marginal gingivitis, bleeding index in patients of the main group was 0.42±0.03, while in the comparison group — 1.14±0.05 (p≥0.05) (Table 2). A decrease in the numerical values of PBI index can be attributed to optimization of personal oral hygiene and decrease in the severity of inflammatory processes in periodontal tissues due to the therapy, including the restoration of normal functional state of microvasculature in periodontium.

The identified significant decrease in PBI index in patients of both groups provides an indirect confirmation of the fact that effective conservative therapy conducted at this stage could achieve normalization of the periodontal tissue status, stable remission of chronic simple marginal gingivitis and prevent its transition into periodontitis. It should be noted that patient compliance with recommendations for personal oral hygiene is of great importance along with repeated plaque identification, motivational conversation with the patient and additional training of personal oral hygiene methods in accordance with the characteristics of occlusion. The obtained data show stable dynamics of decrease in PBI bleeding index (p≥0.05). The numerical values of the bleeding index in patients of the treatment group were significantly lower than those in the control group having the same initial data, which indicates of a greater efficacy of the complex treatment with the dental gel of the original composition.

During initial examination of the patients with chronic simple marginal gingivitis, PMA index was 31.8±2.2%, and 31.4±2.1% (p≥0.05) in the treatment and the control groups, respectively (Table 3). The values of the index in both groups were approximately the same before the beginning of treatment (p≥0.05) and indicated of pronounced inflammation in periodontal tissues. When patients were examined 7 days after the beginning of therapy, PMA index was 16.4±1.31% in patients of the treatment group and 14.2±1.21% in patients of the control group (p<0.05) (Table 3). Thus, there was a decreased inflammation in the periodontal tissues in both groups, but the PMA index values remained at a relatively high level. Upon the follow-up examination after 1 month, the PMA values in patients of the treatment group reached 12.2±1.27% and in the control group — 14.8±1.26% (p<0.05) (Table 3). During the patient examination 3 months after the conducted therapy, PMA index in the treatment group was 11.3±1.29%, while in patients of the control group — 15.4±1.42% (p<0.05).

When patients were examined 6 months after the treatment, the numerical values of PMA index were 9.7±1.02% (p<0.05) in patients of the treatment group and 14.6±1.2% (p<0.05) — in patients of the

Table 1. *Dynamics of the Green Vermilion hygiene index (OHI-S) in patients of the treatment and control groups (M±m)*

	Treatment Group	Control Group
Before therapy	1,96±0,07	1,94±0,05
7 days	0,39±0,03	0,4±0,03
1 month	0,41±0,04	0,43±0,02
3 months	0,61±0,02	0,59±0,03
6 months	0,42±0,03	0,41±0,03
12 months	0,64±0,03	0,67±0,03

Table 2. *Dynamics of the bleeding index (PBI) in patients of the main and comparison groups (M±m)*

	Treatment Group	Control Group
Before therapy	3,30±0,09	3,26±0,03
7 days	1,12±0,06	1,62±0,04
1 month	0,76±0,04	1,22±0,06
3 months	0,55±0,06	1,14±0,05
6 months	0,50±0,04	1,17±0,06
12 months	0,42±0,03	1,14±0,05

Table 3. *Dynamics of the papillary–marginal–alveolar index (PMA) in patients of the treatment and control groups (M±m), %*

	Treatment Group	Control Group
Before therapy	3,30±0,09	31,4±2,1
7 days	16,4 ± 1,31	14,2 ± 1,21
1 month	12,2 ± 1,27	14,8 ± 1,26
3 months	11,3 ± 1,29	15,4 ± 1,42
6 months	9,7 ± 1,02	14,6 ± 1,2
12 months	9,92 ± 1,42	13,28 ± 0,92

control group (Table 3), which indicates inflammatory progression and the need for repeated course of therapeutic and prophylactic measures.

During the dynamic examination of patients from both groups 12 months after treatment, it was found that the PMA values practically did not change ($p \geq 0.05$). Likewise, the values of PMA index were 9.92±1.42% and 13.28±0.92% ($p \geq 0.05$) in the treatment and control groups, respectively (Table 3). The obtained data demonstrate stability of results achieved by the dental gel application in treatment of patients with chronic simple catarrhal gingivitis and dental crowding.

The tendency towards decrease in the PMA index and its stabilization can be associated with the fact that regular appropriate personal oral hygiene together with courses of supportive therapy do not cause any cardinal disturbances in the periodontal tissues. At the same time, more pronounced and stable decrease in the PMA index values in patients of the treatment group ($p<0.05$) can be attributed to the greater efficiency of the dental gel based on original composition used in patients of this group as compared to the dental gel *Cholisal* applied in the control group.

CONCLUSION

Thus, we conclude that the introduced dental gel exhibited significant clinical efficacy due to its anti-inflammatory, antimicrobial, regenerating and hemostatic effects, good fixation and uniform distribution on the gingiva surface and a convenient and hygienic application. None of the patients showed signs of intolerance, side effects or allergic reactions to the components of the dental gel.

The obtained results of the clinical efficacy of our dental gel provide the evidence to recommend it as a part of the complex therapy of chronic simple marginal gingivitis.

REFERENCES

1. **Averjanov S.V., Pupykina K.A., Pupykina E.V., Garaeva K.L., Isaeva A.I.** Development and study of the fitocomplex action for treatment of inflammatory periodontal diseases // Stomatologiya. 2016. № 6–2. P. 25. (In Russ., English abstract).
2. **Averyanov S.V., Khairzamanova K.A., Kudashkina N.V., Hasanova S.R., Tuygunov M.M.** Efficiency of clinical application of phytofilm in treating patients with traumatic lesions of oral mucosa International //Journal of Pharmaceutical Research | October-December 2018 | Vol 10 | Issue 4. – P. 611–615.
3. **Averyanov S.V., Garaeva K.L., Gulyaeva O.A., Pupykina E.V.** The effectiveness of treatment of inflammatory periodontal diseases in children with the use of the phytocomplex in the form of a dental gel // Pediatric dentistry and dental profilaxis. – 2018. – No 3. 75-83. DOI: 10.25636/PMP.3.2018.3.14
4. **Axelsson, P., Nyström, B. and Lindhe, J.** (2004), The long-term effect of a plaque control program on tooth mortality, caries and periodontal disease in adults. Journal of Clinical Periodontology, 31: 749–757. doi:10.1111/j.1600-051X.2004.00563.x
5. **Bulkina N.V., Morgunova V.M., Osipova Yu.L., Pronina N.S., Polosukhina E.N., Guseva O.Yu., Kropotina A.Yu., Konnov V.V.** Cytokine profile of periodontal pocket contents in estimating theseverity and efficiency of treatment offered to patients with refractory periodontitis // Archiv EuroMedica 2019. Vol. 9 – No 2. – 133–136 https://doi.org/10.35630/2199-885X/2019/9/2/17

6. **Chapple, ILC, Van der Weijden, F, Doerfer, C, Herrera, D, Shapira, L, Polak, D, Madianos, P, Louropoulou, A, Machtei, E, Donos, N, Greenwell, H, Van Winkelhoff, AJ, Eren Kuru, B, Arweiler, N, Teughels, W, Aimetti, M, Molina, A, Montero, E, Graziani, F.** Primary prevention of periodontitis: managing gingivitis. J Clin Periodontol 2015; 42 (Suppl. 16): S71–S76. doi: 10.1111/jcpe.12366.

7. **Dmitrieva L.A., Nemeriuk D.A., Gerasimova E.V., Glybina N.A.** Possibility of combined system enzyme therapy and antioxidants in treatment of periodontal and oral mucosa diseases // Stomatologiya. 2015. No 2. P. 69–72. (In Russ., English abstract). https: doi: 10.17116/stomat201594269-72

8. **Fattal R.K., Risovannaya O.N., Melekhov S.V., Popkov V.L., Domenyuk D.A.** Comparative evaluation of the major groups of manual toothbrushes efficiency and their effect on the oral cavity hygienic status // Archiv EuroMedica. 2019. Vol. 9. No 1. P. 155–161. https://doi.org/10.35630/2199-885X/2019/9/1/155

9. **Gulyaeva O.A., Averyanov S.V.** Prevention of gingivitis in patients with dentoalveolar anomalies on the background of orthodontic treatment with fixed appliances // Stomatologiya. 2017. No 6–2. P. 45–46. (In Russ., English abstract).

10. **Gulyaeva O.A., Averianov S.V., Yakupov B.A.** The impact of the biofilm removal protocol on effectiveness of maintenance therapy in patients with dental implants // Clin oral impl res. 2018;29(suppl. 17) S324 https://doi.org/10.1111/clr.209_13358

11. **Ostrovskaya L.Yu., Beybulatova D., Zakharova N.B., Katkhanova L., Lysov A., Heigetyan A., Domenyuk D.A.** Gingival fluid as a potential object for diagnostics process // Archiv EuroMedica. 2020. Vol. 10. No 2. P. 104–106. DOI: 10.35630/2199-885X/2020/10/2.27

12. **Socransky, S., Haffajee, A., Cugini, M., Smith, C. and Kent, R.L., Jr.** (1998), Microbial complexes in subgingival plaque. Journal of Clinical Periodontology, 25: 134–144. doi:10.1111/j.1600-051X.1998.tb02419.x

13. **Zubareva A.V., Averianov S.V., Kudashkina N.V., Khasanova S.R., Iskhakov I.R.** Development and evaluation of the efficiency of ointment for cheilitis treatment in patients with dental and jaw anomalies // PRENSA MÉDICA ARGENTINA. 2019. –No 9. (In Russ). indd 652–659.