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Clinical and Immunological Evaluation of FarGALS Efficacy During the Process of Adaptation in Patients with Removable Plate Prosthesis Depending on Age

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ABSTRACT

Patient adaptation to complete removable plate prosthetics (different types) is one of the acute problems for dental specialists. In addition, some factors including the negative impact of prosthetics on the condition of prosthetic bed, the function of the salivary glands, immunological reactivity, microbiological diversity of oral cavity and insufficient quality of prosthetics manufacture and design features, contribute to the problem. This study aimed to evaluate FarGALS efficacy during the process of adaptation in patients with removable plate prosthesis depending on age. Patients were divided into two control and treatment groups consisted of 3 internal groups. Control group included 19, 43, and 37 (1st-3rd, respectively) was treated with the traditional method. Treatment group included 23, 52, and 45 (1st-3rd, respectively) was treated with FarGALS. Patients of this group after meal at bedtime performed the processing of removable plate prostheses and rinsing them 3-4 times during the day by diluting FarGALS with distilled water (1:4). Antibacterial and anti-inflammatory properties of the drug FarGALS directed against the risk of pathogen attachment and appearance of inflammation in the oral cavity. Therefore, optimal conditions are created to stimulate the activity of neutrophilic leukocytes and macrophages, which leads to the destruction of pathogens of inflammatory surfaces, and intensive filling of the mucosal defects. In conclusion, FarGALS is safe and effective drug which can be used in patients with removable plate prosthesis.

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INTRODUCTION

In the current era, there is an urgent need for production of new effective drugs against pathogenic microorganisms resistant to current antibiotics and chemotherapeutic treatment [1]. In this regard, the high antimicrobial activity of a new biotechnological drug (FarGALS) against a wide spectrum of pathogenic microorganisms, suggests that it can be effective against the risk of pathogen attachment and appearance of inflammation in the oral cavity or in treatment of different diseases associated with this pathogen [1-3].

Adaptation to complete removable plate prosthetics is acute problem for dental specialists. The negative influence of prosthetics on the prosthetic bed of the oral cavity, the function of the salivary glands, immunological reactivity, microbiological diversity and insufficient quality of prosthetics contribute to the actuality of the problem. It is especially relevant to the elderly patients; at who, along with the complete loss of dental rows, the adaptive capabilities of the body, including the oral cavity, are sharply reduced and do not positively resist the negative effects associated with removable prosthesis [4-6].

Unreasonable and uncontrolled use of chemotherapy leads to the formation of strains with resistance to drugs. This can be avoided by using antiseptic drugs that have a broad antibacterial spectrum and do not induce microbial resistance [6-9]. Further application of the medicinal forms of antiseptics for topical application is undoubtedly a very promising direction, as it allows changing the nature of the effect on the humoral and cellular inflammation factors in the adaptation period while using complete removable plate prostheses [6, 7, 10].

The particular interest from the point of view of the use of new medicines forms for the use of complete removable plate prostheses lays in the influence of FarGALS on local immunity and bacteriological parameters of the oral cavity of elderly patients using complete removable plate prostheses and on the process of adaptation to them. The drug FarGALS is included in the pharmacotherapeutic group: antiseptic wound-healing agents.

MATERIAL AND METHODS

Patients were divided into two control and treatment groups. Control group consisted of 3 internal groups included 19 patients as 1st group, 43 as 2nd group, 37 as 3rd group, was treated with the traditional method. Treatment group consisted of 3 internal groups included 23 patients as 1st group, 52 as 2nd group, 45 as 3rd group, was treated with FarGALS. Patients of treatment group after meal at bedtime performed the processing of removable plate prostheses and rinsing them 3-4 times during the day by diluting FarGALS with distilled water (1: 4).

Patients of group 1 were from 40 to 59 year-old after the start of traditional therapy. Patients of 2nd group were from 60 to 74 year-old and patients of 3rd group were from 75 to 90 year-old. At the background of the treatment, immunological and microbiological studies were conducted in dynamics with admission, and data were collected on day 15, and day 30 of treatment.

Ethical approval

The review board and ethics committee approved the study protocol and informed consents were taken from all the participants.

RESULTS AND DISCUSSION

As has been shown in elderly patients with complete absence of teeth, at the seeking orthopedic care, there is a violation of local immunity in the form of deficiency of PhAN (Phagocyte Activity of Neutrophils), PhI (Phagocytose Index), lysozyme, secretory sIgA in the oral cavity, depending on the age aspect. In this connection, it is of interest to study the effectiveness of the current therapy of impaired local immunity in the process of adaptation to removable prostheses, depending on the method of treatment for these body indices. The results of the study are presented in Table 1.

Table 1. Level of content of local immunity parameters in mixed saliva in patients of the 1st group (from 40 to 59 years) with orthopedic treatment in dynamics.

Items	Indicators	Baselines	15 days after treatment	30 days after treatment
Control group	PhAN in %	52.8 ± 0.82	54.4 ± 2.8	46.6 ± 2.26 $^{*\ \#}$
	PhI	4.06 ± 0.82	4.12 ± 0.21	3.95 ± 0.17
	Lysozyme (mg/ml)	19.3 ± 0.46	28.8 ± 0.86 **	19.5 ± 0.62 $^{\#\#}$
	SIgA (µg/l)	199 ± 6.0	226 ± 8.3 *	188 ± 9.2 $^{\#}$
Treatment Group	PhAN in %	52.8 ± 0.82	60.4 ± 1.9 $^{**\ °}$	52.0 ± 1.24 $^{\#\#\ °}$
	PhI	4.06 ± 0.82	4.83 ± 0.19 $^{**\ °}$	4.28 ± 0.17 $^{\#\#}$
	Lysozyme (mg/ml)	19.3 ± 0.46	32.2 ± 0.90 $^{**\ °}$	20.4 ± 0.58 $^{\#\#}$
	SIgA (µg/l)	199 ± 6.0	302 ± 7.8 $^{**\ °°}$	205 ± 7.9 $^{\#\#}$

The reliability of differences from baseline (**: P<0.001 and *: P<0.05); Data from 15 days ($^{\#\#}$: P<0.001 and $^{\#}$: P<0.05); and control data ($^{°°}$: P<0.001 and $^{°}$: P<0.05). PhAN = Phagocyte Activity of Neutrophils; PhI = Phagocytose Index.

As can be seen from the data of Table 1, in patients of group 1 (from 40 to 59 years after the start of traditional therapy), in patients receiving treatment with removable prostheses and oral rinsing, there were insignificant positive shifts in PhAN, lysozyme and sIgA values in local immunity on the 15th day of the study and were respectively 54.9±1.1%; 22.7±0.83 mg/ml and 226 ± 8.3 µg/l. It can be seen that only the lysozyme and sIgA

values are significantly higher in comparison with the initial indices (P<0.001 and P<0.05), respectively. However, on day 30 of the study, the local immunity indices of the 1st group of patients examined were below the normative value.

A very different picture was observed in group 1 patients (from 40 to 59 years after initiation of therapy (local treatment by FarGALS) on the day 15. a significant increase was observed on the part of the phagocytic index of neutrophils: if in the given group, on admission, the PhAN was averaged 52.8±0,82%, in the process of treatment with FarGALS, this index averaged 60.4 ± 1.9% and the number of positive samples normalized, these values were significantly higher in relation to the parameters before treatment (P<0.001) and the control group (P<0.05). However, at the FN of neutrophils derived indicators have not changed significantly in the first group of patients throughout the study and the number of positive samples in 30 days was equal to 26.1%.

Application of FarGALS drug in the patients of the treatment group led to the activation performance of lysozyme and sIgA content in the saliva of patients. At the patients aged 40 to 59 years, baseline activity of lysozyme and sIgA were 19.0±0.46 mg/ml and 199±6.0 g/l, whereas after use of FarGALS preparation for rinsing the mouth lysozyme activity and sIgA increased sharply and correspondingly was 32.2±0.9 mg/ml and 302±7.5 µg/l, the differences were statistically significant compared to the initial values of the control groups (P<0.001), respectively. The normalized water permeability (NWP) indicators also normalized. After adaptation to removable dentures by 30th day, these indicators came close to the initial indicators.

At the patients from 60 years to 74, PhAN content and lysozyme before and after using traditional mouthwash increased after 15 days, respectively, was 48,5±0,78% and 51.9±1.1%; 17.3±0.53 and 22.7±0.83 mg/ml (P<0.05 and P<0.001), the differences are statistically significant (Table 2). NWP was 20.9% and 13.9% in the group. It revealed significant shifts reliable indicators from the FF and sIgA oral cavity after 15 days (P>0.05), respectively, and found significantly higher NWP (27.9% and 30.2%). in other words, after 15 days at 43/13patients local immunity of the oral cavity In the 2nd group after using the traditional mouth rinse is weakened.

Table 2. The level of local immunity in the mixed saliva of the patients of 2nd group (60 to 74 years) in orthopedic treatment in the dynamics

Items	Indicators	Baselines	15 days after treatment	30 days after treatment
Control group	PhAN in %	48.5 ± 0.78	51.9 ± 1.1*	45.2 ± 1.31$^{*\,\#\#}$
	PhI	3.68 ± 0.07	3.92 ± 0.12*	2.81 ± 0.17$^{**\,\#\#}$
	Lysozyme (mg/ml)	17.3 ± 0.53	22.7 ± 0.83**	15.6 ± 0.75$^{\#\#}$
	SIgA (µg/l)	180 ± 8.9	200 ± 5.8	167 ± 4.56$^{\#\#}$
Treatment Group	PhAN in %	48.5 ± 0.78	55.1 ± 1.2$^{**\,\circ}$	49.7 ± 1.9$^{\#}$
	PhI	3.68 ± 0.07	4.12 ± 0.13**	3.76 ± 0.09$^{\#\,\circ\circ}$
	Lysozyme (mg/ml)	17.3 ± 0.53	25.7 ± 0.88$^{**\,\circ}$	19.6 ± 0.57$^{\#\#\#\,\circ\circ}$
	SIgA (µg/l)	180 ± 8.9	238 ± 4.5$^{**\,\circ\circ}$	192 ± 5.6$^{\#\#\,\circ\circ}$

The reliability of differences from baseline (**: P<0.001 and *: P<0.05); Data from 15 days (##: P<0.001 and #: P<0.05); and control data (°: P<0.001 and °: P<0.05). PhAN = Phagocyte Activity of Neutrophils; PhI = Phagocytose Index.

As shown by the results of studies in table 2, after 30 days of continuous use of complete removable dentures, despite the fact that patients regularly rinsed the mouth and dentures with conventional rinse oral fluid, a significant decrease in the level sIgA- 12.1%, reduced lysozyme activity - 11.7%, PhAN - 15.8%, and the FF of 21.7% in saliva are reported compared with the control data.

At patients of the treatment groups by rinsing oral cavity and processing complete dentures with "FarGALS" positive local immunity changes are marked. After 15 days after the professional oral hygiene and the processing of dentures with "FarGALS" the level of local immunity (PhAN, the FF, lysozyme and sIgA) in all patients was increased. And correspondingly, the average indices for the group was 55.1±1.1%; 4.12±0.13; 25.7±0,88mg/ml and 238±4,5 mkg/l, the differences are statistically significant (P<0.001), respectively, with the baseline level. And the number of positive probes was only for the PhAN and PhI indicators 11.6%. With other words 88.4% of the surveyed subjects normalized. We also note that on the 15th day of the study, the local immunity indices (PhAN, PhI, lysozyme and sIgA) in patients within the 2-group (from 60 to 74 years) were significantly higher in comparison with the indices of patients in group 1 (P<0.05, P<0.05, P<0.001 and P<0.001), respectively. On the 30th day, these indicators decreased and were within the initial values. Indices of local immunity (PhAN, PhI, lysozyme and sIgA) in patients of senile age (from 75 to 90 years) with orthopedic treatment in dynamics are given in Table 3.

Table 3. Level of content of local immunity parameters in mixed saliva in patients of 3rd group (from 75 to 90 years) with orthopedic treatment in dynamics.

Items	Indicators	Baselines	15 days after treatment	30 days after treatment
Control group	PhAN in %	45.5 ± 0.90	47.1 ± 1.21	41.0 ± 1.85$^{*\cdot}$
	PhI	3.23 ± 0.1	3.61 ± 0.13 *	2.75 ± 0.18$^{*\,\#\#}$
	Lysozyme (mg/ml)	16.6 ± 0.53	20.3 ± 0.39 **	14.5 ± 0.78$^{*\,\#\#}$
	SIgA (µg/l)	169 ± 3.2	185 ± 8.3	156 ± 4.2$^{\#}$
Treatment Group	PhAN in %	45.5 ± 0.90	51.9 ± 1.51 $^{**\circ}$	46.1 ± 1.41$^{\#\#\,\circ}$
	PhI	3.23 ± 0.1	3.94 ± 0.12 $^{**\circ}$	3.76 ± 0.17$^{\infty}$
	Lysozyme (mg/ml)	16.6 ± 0.53	21.7 ± 0.52 $^{**\circ}$	17.5 ± 0.81$^{\#\#\,\circ}$
	SIgA (µg/l)	169 ± 3.2	196 ± 5.2 *	167 ± 4.7$^{\#\#}$

The reliability of differences from baseline (**: P<0.001 and *: P<0.05); Data from 15 days ($^{\#\#}$: P<0.001 and $^{\#}$: P<0.05); and control data ($^{\infty}$: P<0.001 and $^{\circ}$: P<0.05). PhAN = Phagocyte Activity of Neutrophils; PhI = Phagocytose Index.

As can be seen from the data given in Table 3 in patients of group 3 (from 75 to 90 years), after traditional therapy (with the processing of removable prostheses and rinsing the oral cavity) on the side of local immunity, the heterogeneous responses of PhAN, lysozyme and sIgA were observed on the 15th day of the study . It can be seen from the table that in all patients only the indices of PhI and lysozyme increased insignificantly. And accordingly, the average indices for the group were 3.23±0.1 and 16.6±0.53 mg/ml and above 3.61±0.13 and 20.3±0.39 mg / ml, the differences are statistically significant in comparison with initial indices (P<0.05 and P<0.001). The normalized water permeability (NWP) decreased by 54.8% and 32.9 to 35.4%. From the side indicators PhAN and sIgA on the 15 day study significant positive changes in comparison Baseline not detected (P>0.05), respectively. In the course of traditional treatment on the 30th day of the study, the local immunity indices significantly decreased in comparison with the baseline and control group parameters (P<0.001) and a sharp increase in NWP to (48.8, 57.3 and 46.3%), respectively were observed. Apparently, with the aging of the organism and the insufficiency of individual links of nonspecific immunity and the weakness of the controlling parts of the immune system in patients of senile age, a sharp decrease in the response of local immunity to the inflammatory process of the oral cavity occurred after removal of removable prostheses.

In patients of senile age, the main treatment groups when treating the oral cavity and rinsing complete removable dentures with FarGALS, a positive shift of changes in local immunity is noted 15 days after orthopedic treatment. The level of local immunity (PhAN, PhI, lysozyme and sIgA) in all patients significantly increased (P<0.001), respectively, compared with baseline. Moreover, the number of positive probes also decreased and amounted to an average of the group (26.6, 35.6, 24.4%). In other words, in 2/3 of the patients after the treatment, local immunity parameters were restored. After adaptation to removable dentures by 30th day, these indicators approached the initial values.

Thus, when studying the dynamics of the values (PhAN, PhI, lysozyme and sIgA) of these indices, it was shown that in patients in the treatment group, after the use of the FarGALS drug in orthopedic practice, there was a significant increase, in contrast to the comparison group, local immunity in all examined groups, which suggested a positive effect of FarGALS on local immunity. Despite extremely unfavorable conditions for the functioning of the tissues of the prosthetic bed, the use of FarGALS resulted in positive effects, that led to the preservation of the initial level of local immunity and the clinical effect after the application of prostheses. Whereas with traditional orthopedic treatment, this indicator significantly worsened after the application of prostheses, with further aggravation of this negative effect over time. It should be noted that the most pronounced differences between the patients of the observation and comparison groups were noted in the early period, that is, up to 15 days of treatment. An increase in the local immunity index indicates the activation of nonspecific immune defense of the oral cavity in patients of the treatment group. The increase in PhAN and FF indicates a response to pathogenic microorganisms, which are noted in patients with complete absence of teeth. PhAN and FF in the observed patients of the treatment group, were decreased by 30th day, which indicates the relief of inflammation.

CONCLUSION

In our opinion, antibacterial and anti-inflammatory properties of the drug FarGALS directed against the risk of pathogen attachment and appearance of inflammation in the oral cavity. As a result, optimal conditions are created to stimulate the activity of neutrophilic leukocytes and macrophages, which leads to the destruction of pathogens of inflammatory surfaces, intensive filling of the mucosal defect. The absence of an irritant effect on the mucous retains its integrity. The intact mucosa, especially the tissues of the prosthetic bed, is an important source of the epithelial layer covering erosion: the microenvironment activates a sufficient number of viable cells that activate healing, thereby guaranteeing the preservation of the oral microbiocenosis.

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Competing interests

The author declares that they have no competing interests.

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