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Clinical and Immunological Study of the Effectiveness of the Medications, Lazolex and Zovirax, during the Complex Treatment of Chronic Recurrent Herpetic Stomatitis

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Abstract

At present, our country continues intensive research to find and introduce into practice new natural medicinal preparations made from ecologically pure endemic plants of Georgia. An example of such an agent in the Iveria-Pharma company is a Georgian medication - LAZOLEX (extract of the pericarpium of an unripe walnut), which has passed the necessary preclinical tests and now is used as an antiherpetic agent. We found positive immunotropic effects of Lazolex on healthy volunteers. Therefore, we considered it necessary to study the antiviral effects of the drug and its immunomodulatory properties in a clinical setting, specifically its effect on chronic herpetic stomatitis.

First of all, it was shown that the immune system status of the patients was in an apparent correlation with the severity of the course of herpes stomatitis, i.e. the most severe immunosuppression was recorded in patients with severe stomatitis. It should be noted that this medication not only doubles the efficiency of the results of antiviral treatment but also serves as an immune restoration agent in patients with herpetic stomatitis.

As a result of a parallel study of Zovirax and Lazolex, a high clinical activity of both drugs was recorded. However, the presence of pronounced immunocorrective properties of Lazolex manifested itself in an improvement of the quality of patient treatment: active tissue regeneration and a significant decrease in the timing of exacerbation of local herpetic lesions, an increase in the duration of remission. Conducted clinical, laboratory, and immunological studies allow us to recommend Lazolex for active use in dental practice for viral diseases.

Keywords: Herpetic stomatitis, Zovirax, Lazolex, Antiviral, and immunocorrective effect.

Introduction: Diseases of the mucous membrane of the oral cavity are most often of viral origin. 38% of them appear to be herpes stomatitis [Abashidze N. 2005; Mackenizie-Dyck et al., 2015]. Despite the great variety of drugs available nowadays, the recurrence rate of herpes stomatitis is increasing. It is established that exacerbation of chronic recurrent herpetic stomatitis is associated with undesirable changes in the immune status, which is why it is often advisable to include immunomodulating medications in the treatment plan [Jouanguy E. et al., 2020; Carter, S.B. et al., 2016]. However, on the one hand, the existence of resistant forms of the disease to various antiviral drugs should be taken into account, because of the anatomical and physiological features of the oral mucosa and, on the other hand, the pathogenetic mechanism of the spread of the disease. All of the above puts on the agenda the need to develop more effective approaches for the treatment of herpes stomatitis [Boeckh M. et al., 2017; V.A. Isakov e. al.,2015].

Based on the extensive experience in the production of medicinal products made from different components of walnut in the medicine of several countries, the pharmaceutical company "Iveria Pharma" developed the medication - LAZOLEX GEL containing the extract of the pericarpium of unripe fruits of walnut. Biologically active substances of plant origin contained in the extract are characterized by a wide range of antimicrobial activities. This is confirmed by the results of experimental studies (in-vitro studies based on standard tests on strains of bacteria and fungi) against the main pathogens. They are as follows: Staphylococcus Epidermidis, Staphylococcus aureus, Streptococcus Pyogenes, Pseudomonas Aeruginosa, Salmonella typhimurium, Propionibacterium acnes, Aspergillus niger, Malassezia furfur, Candida Ablicans, Trichophyton Rubrum. The antiviral activity of the drug has been identified in the culture of herpes simplex virus type I (HSV-1), and also, in-viva studies on herpes infection models in mice [N. Alavidze et al.,2013; www.iveriaparhma.com].

Based on the above, we aimed to find out if the medication would be effective in the treatment of lesions of the oral mucosa, particularly during herpetic stomatitis, and study it in dental settings.

Materials and methods

To achieve the set goals, we examined and treated 54 patients aged 19 to 55 with Chronic Recurrent Herpetic Stomatitis. We divided the examined patients with **CRHS** into 2 groups. We enrolled 27 (50%) patients in each group. We treated the patients of both groups with the same treatment plan, with the difference that we used a 5% gel of Lazolex in the topical treatment plan of the patients of the main group, and a 5% cream of Zovirax in the control group.

For patients with mild and moderate forms of CRHS, we provided only topical treatment, and for etiotropic therapy, we prescribed a topical application of Lazolex 5% protective gel 3-4 times a day to the members of the main group. In the control group, we used Zovirax 3% cream topically 3-4 times a day. And, in the treatment plan of the patients who had a severe form of CMHS, an infectious disease doctor prescribed Zovirax tablets according to the following treatment plan: Zovirax - 200 mg 5 times a day for 5 days.

We investigated the immune status of the patients suffering from CRHS before and after the treatment. The state of immune homeostasis of the patients was evaluated dynamically: at the first visit to the clinic and on the 10th to 13th day of treatment. In patients with CRHS, we investigated: the phagocytotic activity of neutrophils, the ability of leukocytes to induce alpha- and gamma-interferon, immunoregulation index, level of lysozyme, and secretory IgA in saliva.

The statistical processing of the research results revealed significant changes in the immune status, which mainly suggests the inhibition of its function and that it depends to a significant extent on the degree of severity of the pathological processes of the disease. Special immunosuppression was revealed in patients who suffered from a severe form of chronic herpes stomatitis. The changes in immunity indicators that are compared to healthy controls are presented in the table (see **Table N1**).

Statistical analysis

Statistical analysis of the experimental data was conducted using Student's t-test [McDonald JH. 2014]. A significance level of $p \leq 0.05$ was considered statistically significant.

Results

Findings of the patients suffering from **CRHS** before conducting treatment suggested that the inclusion of immunomodulatory agents in the complex treatment plan was necessary. In this particular case, by using a 5% Lazolex gel, we achieved a positive therapeutic effect in all the cases of 54 patients suffering from **CRHS**. The average course of the treatment included 6-8 days. On the 10th-13th day after starting the treatment with Zovirax (control group-27 patients) and Lazolex (main group-27 patients), we performed blood and saliva tests to find out immunological indicators of the patients once more.

We defined the clinical effectiveness of the used medications by the following criteria: significant improvement - **I** [reduction of relapse duration and 2-fold increase of remission duration]; moderate improvement - **II** [increased interval of remission by 1-1.5 times]; No effect - **III** [patient required inpatient treatment]. In the first two criteria, the treatment results were considered successful.

27 patients were treated with Lazolex, of which we achieved significant improvement in 19 cases (70.3%; mild and moderate form), in 6 patients we obtained improvement (22.2%; mild and moderate form), and in 2 patients (7.5%; severe form) i.e. no satisfactory effect was achieved. The other 27

patients were treated with Zovirax. We achieved significant improvement in 12 cases (44,4%; mild and moderate form), in 11 patients we obtained moderate improvement (40,7%, mild and moderate form), and in 4 patients (14,8%, severe form) i.e. no satisfactory effect was achieved. (see **picture N1, N2**).
Our observation revealed that local therapy with the drug Lazolex 5% gel helps to relieve subjective complaints and accelerate reparative-regenerative processes of the skin and mucous membrane.

In particular: in the control group, the mild form of the disease lasted 7.3 days, the moderate severity form lasted 8.6 days, and the severe form - 11.4 days. In the main group, the duration of the mild form of the disease was 5.1 days, the moderate severity form lasted 6.2 days, and the severe form was 8.1 days. The study revealed that the duration of the treatment in the main group was an average of 6.5 days, and in the control group - 9.1 (see **Table N2**).

We processed the immunological data obtained after the treatment according to the severity of the course of the disease and the clinical effect (see **Table N3**). Changes in immunological indicators as a result of treatment appeared to be directly correlated with the severity of the disease. In mild and moderate cases, Lazolex significantly improved the immunological parameters of the patients, zovirax, on the other hand, corrected immunological indicators only in the case of a mild form.

Discussion

Topical anti-inflammatory and keratoplastic agents have an important place in the scheme of treatment of recurrent stomatitis. The number of such drugs is very large, but most of them cannot provide fast, painless, and effective epithelization of the mucous membrane of the oral cavity, vermillion, and the surrounding area. Topical treatment greatly aids in the repair of damaged tissues, however, it is often ineffective in prolonging the period between relapses.
Based on all of the above, it is relevant to create a new natural, plant-based topical anti-inflammatory, keratoplastic, and antiviral medications and to study its effectiveness in chronic recurrent stomatitis.
Intensive research is being continued in our country, using ancient medicinal recipes and the latest approaches of biotechnology, to search for ecologically pure endemic plants, to prepare new natural medicinal preparations, and to implement them in medical practice. Based on such studies, an extract of the pericarpium of an unripe walnut – LAZOLEX, which has passed all the necessary pre-clinical studies, was created in Georgia. Its antiviral (anti-herpes virus), anti-inflammatory, and keratoplastic effects have been approved. [N. Alavidze et al.,2013; www.iveriaparhma.com].
Determination of the state of various indicators of immunity during chronic recurrent herpes stomatitis is of great practical importance, as it allows a prognosis of the course and outcome of the infection. It is known that timely and pathogenetically justified therapy can achieve almost complete recovery in case of impairment of the homeostatic mechanism. In the case of irrational treatment of patients, the undesirable changes in the immune system indicators may last for a long time, which increases the probability of a slow recovery from the disease and the possibility of other complications arising from the activation of other pathogenic factors.

Conclusion

Comparative clinical analysis showed us that Lazolex 5% gel is characterized by well-expressed antiviral action. We achieved significant improvement in 19 patients (70.37%), moderate improvement in 6 patients (22.22%), and slightly expressed effect in 2 patients (7.41%); while, after using Zovirax 3% ointment: significant improvement was observed in 12 patients(44.4%), moderate improvement - in 11 (40.7%), slight effect - in 4 patients (14.8%).

As a result of immunological studies, it was revealed that the changes in immunological parameters as a result of Lazolex treatment of the patients with chronic recurrent herpes stomatitis are directly correlated with the severity of the disease.

After administering Lazolex in patients with a mild form of **CRHS**, all immunological parameters - (Lyz, sIgA, Pi, T-RES/T-Sen) - returned to normal and statistically did not differ significantly from the same data of healthy controls, except for the ability of leukocytes to synthesize interferons, while administering Zovirax did not affect the immunological parameters at all. After treatment with Lazolex in the moderate form of **CRHS**, the level of lysozyme and sIgA in saliva, as well as the index of immunoregulation, were normalized, while treatment with Zovirax did not affect the immunological indicators at all.

Recognition

Georgian medication, Lazolex 5% gel, does not cause local and general toxic effects, does not irritate the mucous membrane, and does not have mutagenic, embryotoxic, or allergic effects. It can be successfully used in the complex treatment of chronic recurrent herpetic and aphthous stomatitis in the form of topical applications as an anti-inflammatory, antiviral, and reparative regeneration stimulating agent [www.iveriapharma.com/index.php/products/lazolex].

The native drug Lazolex was used by us for the first time in the treatment of chronic recurrent stomatitis. We are the first to confirm the clinical effectiveness of this medication [Gogotishvili M. et al. 2014]. The drug was found to have an antiviral as well as immunomodulating effect. However, its antiviral effect appears to be weaker than that of Zovirax, and its immunomodulatory effect is stronger than that of Zovirax. The immunomodulating effect of Lazolex is especially evident in mild and moderate forms of the disease.

Probably the antiviral effect of the preparation is the result of its effective immunoregulatory activity, although further research is needed to confirm this.

Thus, due to its antiviral and immunomodulating properties, the drug Lazolex can be successfully used not only for chronic recurrent herpetic stomatitis but also for other viral and chronic inflammatory diseases of the oral cavity.

Table N1. Immunological indicators of patients with chronic recurrent herpetic stomatitis

Indicators	Herpetic stomatitis severity rate (A – mild B – moderate C – severe)				Healthy (n=30)
	total (n=54)	A (n=21)	B (n=22)	C (n=11)	
aIFN(U/ml)	*25.03±3.75	*27.85±4.27	*25.96±4.22	*21.3±3.47	**41.33±4.14**
gIFN(U/ml)	*12.33±4.5	*17.23±5.24	*12.23±2.68	*#^8.23±2.68	**28.09±4.25**
T-RES/T-Sen	*1.69±3.37	*2.13±3.28	*1.56±3.1	*1.44±2.8	**2.28±4.5**
Pi	*3.9±0.41	*4.52±1.01	*3.8±1.23	*3.06±1.19	**5.33±2.94**
sIgA(gr/l)	*0.26±0.13	*0.39±0.024	*0.36±0.39	*#^0.21±0.055	**0.76+0.054**
Lyz(%)	*33.7±4,20	*38.6±2.44	*34.8±2.05	*#26.89±11.8	**41.11±4.28**

A sign (*) indicates a significant difference compared to practically healthy volunteers).

A sign (#) indicates a significant difference compared to the data of patients with a mild form).

A sign (^) indicates a significant difference compared to the data of patients with an average form).

Table N2. The duration of the treatment in patients with CRHS according to the severity of the disease

CRHS Severity Rate	Duration of relapse (days)	
	Control group	Main group
Mild	7,3	5,1
Moderate	8,6	6,2
Severe	11,4	8,1
Median	9,1	6,5

Table N3. Immunological parameters in patients suffering from chronic recurrent herpetic stomatitis according to the severity of the disease and the results of the treatment

(10 -13 days after treatment)

Severity of the disease	A. Mild				B. Moderate				C. Severe				Before treat-ment	Healthy
Treatment with Zovirax cream (daily, for 10 days)														
Result	[I]	[II]	[III]	სულ	[I]	[II]	[III]	სულ	[I]	[II]	[III]	Total	n=27	n=30
	n=6	n=6	0		0	n=9	n=2		0	0	n=4			
aIFN (U/ml)	34.0± 2.73	28.11 ± 4.45	–	***31.05 ± 3.59**	–	26.22 ± 3.07	15.67 ± 4.30	***20.9± 3.68**	–	–	12.78 ± 4.46	**12.78 ± 4.46**	*25.03± 3.75	**41.33± 4.14**
gIFN (U/ml)	21.56 ± 3.50	17.22 ± 5.78	–	***19.39 ± 4.64**	–	15.11 ± 5.39	12.78 ± 4.46	***13.9± 4.92**	–	–	9.67± 3.70	**9.67± 3.70**	*12.33± 4.5	**28.09± 4.25**
T-RES/T-Sen	2.06± 1.01	2.09± 0.95	–	**2.07+ 0.98**	–	1.67± 0.70	1.56± 0.68	**1.61± 0.69**	–	–	1.39± 0.85	**1.39± 0.85**	*1.69± 3.37	**2.28± 4.5**
Pi	4.78± 2.22	4.52± 1.01	–	**4.65+ 1.61**	–	4.22± 1.85	4.00± 2.29	***4.11± 2.07**	–	–	3.28± 1.67	**3.28± 1.67**	*3.9± 0.41	**5.33± 2.94**
sIgA	0.73± 0.025	–	–	**0.73± 0.025**		0.31± 0.02	–	**0.31± 0.020**	–		0.10± 0.020	**0.10± 0.020**	*0.26± 0.13	**0.76± 0.054**
Lyz	39.67 ± 4.00	37.33 ± 3.04	–	**38.5± 3.52**	–	35.44 ± 2,22	35.89 ± 2.57	**35.66 ± 2.39**	–	–	29.11 ± 5.30	**29.11 ± 5.30**	*33.7± 4,20	**41.11± 4.28**
Treatment with Lazolex gel (daily, for 10 days)														
Result	A[I]	[II]	[III]	სულ	[I]	[II]	[III]	სულ	[I]	[II]	[III]	სულ	n=27	n=30
	n=10	0	0		n=9	n=2	0		0	n=4	n=2			
aIFN (U/ml)	36.67 ± 2.59	–	–	**36.67± 2.59**	30.02±6.43	28.44 ± 4.82	–	***29.3+ 5.62**	–	18.56 ± 4.03	18.56	**18.56 ± 4.03**	*25.03± 3.75	**41.33± 4.14**
gIFN (U/ml)	23.0± 2.91	–	–	**23.0± 2.91**	19.67±4.00	18.56 ± 4.03	–	***19.1+ 4.01**	–	9.89± 4.25	11.0	**10.4± 4.47**	*12.33± 4.5	**28.09± 4.25**
T-RES/ T- Sen	2.44± 1.42	–	–	**2.44± 1.42**	1.87± 0.50	1.82± 0.59	–	**1.84+ 0.54**	–	1.20± 0.61	1,11	**1.15± 0.65**	*1.69± 3.37	**2.28± 4.5**
Pi	5.11± 2.75	–	–	***5.11± 2.75**	4.56± 2.24	4.33± 2.34	–	***4.44+ 2.29**	–	4.22± 1.85	3,67	**3.94± 1.79**	*3.9± 0.41	**5.33± 2.94**
sIgA	0.77± 0.028	–	–	***0.77± 0.028**	0.75± 0.025	0.32± 0.021	–	**0.53+ 0.23**	–	0.76± 0.065	0.10	**0.43± 0.042**	*0.26± 0.13	**0.76± 0.054**
Lyz	43.22 ± 6.85	–	–	***43.22 ± 6.85**	39.22± 4.85	36.67 ± 2,59	–	**37.9+ 3.72**	–	28.56 ± 4.50	23.0	**25.78 ± 5.20**	*33.7± 4,20	**41.11± 4.28**

In the graph of the treatment results, the treatment evaluation criteria are given in Roman numerals (I, II, III)

(- P<0.05) indicates the reliability of the difference in comparison with the control group data***Picture N1. Female , 30 yrs. Labial herpes before treatment (mild form).**

Picture N1. Female , 30 yrs. Labial herpes after treatment with a LAZOLEX gel (mild form).

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ქრონიკული მორეციდივე ჰერპესული სტომატიტის კომპლექსურ მკურნალობაში პრეპარატ ლაზოლექსისა და ზოვირაქსის გამოყენების ეფექტურობის კლინიკო-იმუნოლოგიური შესწავლა

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აბსტრაქტი

დღესდღეობით ჩვენს ქვეყანაში - საქართველოში გრძელდება ინტენსიური კვლევები ეკოლოგიურად სუფთა ენდემური მცენარეებისგან დამზადებული ახალი ნატურალური სამკურნალო პრეპარატების მოძიების. კომპანია „ივერია-ფარმაში" იკვლევენ სამამულო პრეპარატ „ლაზოლექს" (ნედლ კაკლის პერიკარპიუმის ექსტრაქტს), რომელმაც უკვე გაიარა კლინიკამდელი ლაბორატორიული კვლევები და მიეწოდა კლინიცისტებს, როგორც ანტი ჰერპესული საშუალება.

ჯანმრთელ მოხალისეებზე ჩატარებულმა კვლევებმა აჩვენა ლაზოლექსის დადებითი იმუნოტროპული ეფექტი. ამიტომ, ჩვენ აუცილებლად ჩავთვალეთ, რომ შეგვესწავლა პრეპარატის ანტივირუსული და მისი იმუნომოდულირებადი მოქმედების ეფექტი კლინიკის პირობებში, კონკრეტულად ქრონიკული მორეციდივე ჰერპესული სტომატიტების დროს.

გამოვლინდა, რომ პაციენტის იმუნური სისტემა დაკავშირებულია ჰერპესული პროცესის მიმდინარეობის სიმძიმესთან, ანუ - უფრო ძლიერი იმუნოსუპრესია ვლინდება გართულებული (მძიმე) ფორმის პაციენტებთან. პრეპარატმა გამოავლინა მისი ორმაგი მოქმედების ეფექტურობა პაციენტებში, როგორც ანტივირუსული თვისებებით, ასევე იმუნოტროპულობით. ზოვირაქსისა და ლაზოლექსის პარალელური კვლევების შედეგად დაფიქსირდა ორივე პრეპარატის მაღალი აქტივობა. თუმცა, გამოჩნდა, რომ ლაზოლექსის აღნიშნული თვისებები უფრო მეტად აუმჯობესებს პაციენტის მკურნალობის ხარისხს: ადგილობრივად ქსოვილის აქტიური რეგენერაცია, დაავადების გამწვავების პერიოდის შემცირება და რემისიის გახანგრძლივება.

ჩატარებული კლინიკურ-ლაბორატორიული კვლევების საფუძველზე რეკომენდირებულია პრეპარატის აქტიური გამოყენება სტომატოლოგიურ პრაქტიკაში.

საკვანძო სიტყვები: ჰერპესული სტომატიტი, ლაზოლექსი.