

## Application of Proteflazid in treatment of patients with recurrent genital herpes

**Fedotov V.P., Pogrebnyak L.A., Kokova V.A., Tarnavskaya N.N., Timofeyeva I.I.**  
**Dnipropetrovsk State Medical Academy**

The problem of herpes viral infections (HVI) in the last decade has gained special importance and attracted the attention of doctors of different specialties. A serious threat for human are 8 types of herpes, among them the leading place belongs to the herpes simplex virus (type 1,2). According to statistics, 30 to 50% of the population are the carriers of this virus in Europe, USA, Canada [1,4,5]. With each passing year due to environmental degradation, reduction of the compensatory capacity of the body and development of secondary immunodeficiency, there is a constant increase in the number of persons infected with the herpes simplex virus types (HSV) 1 and (HSV-2).

The infections caused by this virus are characterized by a number of features associated with a chronic carrier state and persistence of the pathogen in the body cells. The equilibrium is established between the microorganism and HSV, which is controlled largely by immunological mechanisms. Pathogenic mechanisms of latent viral infections to date have not been studied, so the ability to predict recurrence of herpes is very difficult. To a large extent this is clinically significant for the second type of HSV (so-called genital herpes). The importance of genital herpes (GH) as an urgent medical and social problem is associated with the increase in the spread, persistence in latent form, frequent reactivation [1-3,5].

Among patients addressing dermatologist, the patients with recurrent genital herpes (RGH) range from 2.1 to 15% [3, 4].

Equally important is the fact that HSV is characterized by a genetic ability to mutational processes mediated by DNA polymerase gene, which leads to the emergence of strains of the virus species and rapid development of resistance to the treatment.

As the global medicine does not have the means to achieve eradication of herpes infection, there are three main areas of antiviral therapy:

- Chemotherapy;
- Non-specific effects (interferon inducers, immunomodulators, interferons);
- Vaccine therapy.

But most of the major traditional schemes of GH therapy involve the use of expensive, and sometimes unsafe for the body drugs, mostly synthetic.

Our attention was drawn to a new drug with antiviral and immunomodulatory effects of domestic plant production (SMC "Ecopharm") – Proteflazid.

The composition of Proteflazid includes flavonoid glycosides, which are contained in the wild grasses of *Deschampsia caespitosa* L. And *Calamagrosis epigeios* L., which are capable of blocking the DNA polymerase activity in cells infected with Herpes simplex virus type 1 and 2. This leads to a reduced ability or complete blockade of viral DNA replication and as a result, prevents the growth of viruses. Simultaneously Proteflazid increases the production of endogenous alpha- and gamma-interferon, stimulates nonspecific activity macrophagal system, and also has apoptosis modulatory and antioxidant activity, and thereby improves mental and physical performance. All of these characteristics have been taken by us as a basis for the development of the treatment for patients with GH using Proteflazid.

We studied 34 patients (20 men and 14 women) aged 18 to 40 years with RGH. Assessment of the severity of herpetic process was carried out taking into account the frequency of exacerbations and duration of remission; basically, it was the patients with medium to severe virus infection: from 6 to 12 and more recurrent episodes per year. The age of disease was 1 -10 years.

Mostly, relapses of HG arose in autumn-winter period of time - 28 (82.2%) patients, much less - in spring and summer, 6 (17.2%) patients. The typical clinical course of the disease was observed in 30 (88.2%), nature of migratory rash - in 4 (11.8%). Clinical manifestations were presented as grouped vesicles with clear or turbid contents, located on erythematous-edematous background, erosions with polycyclic outlines, sometimes – superficial cracks. Eruptions are accompanied by subjective sensations: itching, tingling, tenderness. Men localized herpes on the genitals and perineum. They were limited, more often, on the inner layer of the foreskin, in the header groove, at least – on the head and trunk of the penis. Women have similar clinical changes observed in the inner surface and large labia minora, clitoris, at least – on the walls of the vagina or cervix. Herpetic lesions were confirmed by the nature of the cytological study.

All patients in the acute stage of the disease along with the basic therapy were administered Proteflazid under scheme:

- Week 1 – 5 drops 3 times a day;
- Week 2-3 – 10 drops 3 times a day;
- Week 4 – 8 drops 3 times a day.

The total period of the first course of treatment with Proteflazid *per os* in combination therapy was 28 days. Simultaneously with oral medication the topical treatment was used with a solution including Proteflazid – 14 days. For the preparation of the solution and its subsequent use as applications of 1.5 ml (30-35 drops) Proteflazid was diluted in 10 ml of saline.

Among all surveyed (34 subjects) the administration of Proteflazid according to subjective and objective evaluations was not accompanied by a characteristic complications. Only 3 (9%) patients on day 3-5 with topical formulation reported a slight burning sensation in the vesicular or erosive lesions. After 2-fold increase in the amount of solvent no burning sensation in the area of lesions where Proteflazid was applied with a saline until the end of therapy was observed.

Already on day 2-3 of the treatment the appearance of new lesions, tendency to epithelialization of erosions and decrease in the severity of subjective sensations ceased. Complete resolution of clinical manifestations of the disease with Proteflazid, was reported on day 5-7 of administration of the drug in 23 (69.1%) of the observed patients, day 8-9 – in 11 (30.9%). Clinical cure was observed in 25 (70.9%) patients in complex treatment that included Proteflazid, a significant improvement in 9 patients (29.1%). No lack of effect or worsening of the disease course when using Proteflazid was observed.

As a result of the treatment a positive therapeutic effect was ascertained. Evaluation of efficacy was carried out in 2 weeks and 1, 3 and 6 months after the end of treatment based on the clinical data (no disease recurrence) and results of cytology.

Recurrences of genital herpes were observed in 7 (20.1%) patients in 1-2 months. Therefore, in a month we repeated Proteflazid treatment (maintenance doses – 7-8 drops *per os* 3 times a day, every other day for a few months). In such a scheme the recurrent disease, the severity of which was minimal, was reported only in three patients (8.3%).

Thus, our data allow estimating Proteflazid (“SMC “Ecopharm”) as highly effective in treatment of recurrent genital herpes. The drug does not cause complications and is well tolerated and can be recommended for widespread use in treatment of this pathology. More preferably, according to our data, to prescribe Proteflazid for a month-long course in combination with topical application, with repeated course in maintenance doses to prevent the relapses and establish maximum control of persistent viral infection for 3-6 months.

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