

Conservative Treatment of the Vesical Cervix Pathology by Liposome Complex with Dihydroquercetin (Taxifolin)

■ Introduction:

Vesical cervix pathology is one of the most frequently observed gynecological diseases in Russia which is diagnosed (depending on the region) in 38-49 % of cases. Modern diagnostics and appropriate treatment of the vesical cervix diseases play a significant role in the improvement of the life quality and female reproductive performance as well as in the preventive treatment of oncological diseases of the vesical cervix. Vesical cervix cancer remains one of the most acute problems and is the second in the structure of oncological diseases in the gynecology. In our country one woman dies of this pathology every 1.5 hour. Unfortunately, the number of new cases of the vesical cervix cancer tends to increase – at 2.1 % per year among patients of 30 years old and at 0.9% per year among patients over 30 years old. Thus, the necessity in early diagnosis and timely treatment of background and pre-cancer vesical cervix diseases is doubtless.

At treatment of vesical cervix pathologies we assumed that their pathologic behavior is significantly conditioned by the local violation of oxidation-reduction reactions and oxidative stress when the oxidation processes prevail over the restorative ones. In its turn this leads to cellular apoptosis and necrosis.

The response of the organism to oxidative stress is the activation of inflammation process which involves the neighboring healthy tissues. The level of inflammatory process directly depends on the intensity of oxidation reactions.

Stopping of oxidation processes and tissue regeneration are possible by using of antioxidants of exogenous origin. Their pharmacological effect is conditioned by their ability to bind free radicals and to reduce the intensity of oxidative processes.

As far as the main aim of the oxidative stress is a cell, the factor of antioxidant delivery immediately into the damaged cell is important. In this perspective, an undoubted interest is raised by liposomal systems based on phospholipids with their specific mechanism of interaction with cellular structures. Such liposomes can effectively interact with cellular membranes and provide for delivery of their internal content into the intracellular compartment.

■ Paper Execution:

This study was performed with the use of liposomal antioxidant-phospholipid complex (hereinafter referred to as the "*antioxidant Complex*") developed by Scientific company "Flamena" (Moscow, Russia, www.flamena.ru).

The selection of the *antioxidant Complex* is defined by the fact that each of its components – glycine, lecithin, dihydroquercetin (taxifolin) – is well known to the medical science. All of their important biological and pharmacological properties are

well-known. The antioxidant used therein is known worldwide and its properties are well studied. Its safety and effectiveness have been proved. Glycine is an endogenous material, a base for protein structures, including glutathione – an element of natural antioxidant protection for the organism. Highly purified egg lecithin with maximum content of phosphatidylcholine is a natural structural material of cell membranes.

The basic properties of the *antioxidant Complex* are frank local anti-inflammatory effect, restoration of the cell membranes, normalization of the cell metabolism and improvement of the cell-mediated immunity, regulation of the free-radical processes, higher reservoir properties and bioavailability within the local application. For the purposes of gynecology a special format in the form of abacterial gel with the bactericidal agent of natural origin immobilized into the system (Sanguiretrin) in bacteriostatic dosage. The medicine is equipped with disposable vaginal applicators; this offers an opportunity for its outpatient application.

This paper reflects the experience of using of the *antioxidant Complex* for the purposes of treatment of some generalized pathologies: vesical cervix ectopia, vesical cervix inflammatory process, atrophic colpitis, decubital ulceration, dysplasia of the 1-2 rate, dysplasia of the 2 rate, kraurosis and leukoplakia of the vulva.

In the majority of cases the treatment of the abovementioned pathologies is of invasive nature with the known combination of disadvantages and limitations. We conducted a fully conservative treatment and tried out the method of combined treatment when the *antioxidant Complex* was used after the invasive operations.

The treatment was conducted out of menstrual cycle. At detection of contamination by a specific infection, the antibacterial therapy was prescribed in accordance with the applicable standards.

In the in-patient department the manipulation was carried out in the following manner: after corresponding treatment with bactericidal agent solution, the vesical cervix is bared in the mirror, 1.5 – 2.5 ml of the *antioxidant Complex* was spread on the damaged section and then the woman stayed in a horizontal position for 20-30 minutes. The manipulation was conducted on a daily basis. The total course amounted to 10-20 days of daily application.

After the invasive manipulations, the *antioxidant Complex* was daily spread after stemming of a flow of blood within 10 days.

In some cases the *antioxidant Complex* was used outpatiently in the form of daily intravaginal manipulations through the vaginal applicators, in case of kraurosis - without applicators by applying it on the damaged sections.

Within 2011 in general 173 women aged 15 – 82 (average age was 28.4 ± 3.5) were examined and treated in several state medical institutions of Moscow and the Kirov Region.

The clinical examination included:

- history taking;

- general and gynecological exam;
- cytological examination;
- colposcopy (simple colposcopy, extended colposcopy, assay with 3 % acetic acid, Schiller test (2 — 3 % of the Lugol's iodine));
- examination for the presence of sexually-transmitted infections (chlamydia, herpes simplex virus, infectious warts hepatitis, cytomegalovirus);
- bacteriological swab seeding from the cervical canal;
- examination of the oophoron hormonal activity;
- PCR-diagnostics of the sexually-transmitted infections;
- gynecological exam using the mirrors.

The withdrawal of the material was carried out from the surface of the ectocervix and from the endocervix on separate microscope slides by special brush. The extended colposcopy with biopsy of the vesical cervix was carried out in order to get the diagnosis, the check colposcopy - on completing of the treatment course.

Based on the results of the conducted examination the following was revealed:

- ectopia of the vesical cervix, including with the transformation area - with 88 patients;
- inflammatory process of the vesical cervix (endocervicitis and ectocervicitis) - with 38 patients;
- atrophic colpitis - with 18 patients;
- kraurosis vulvae and leukoplakia of the vulva -with 6 patients;
- canker with abasement (decubital ulceration) - with 5 patients;
- dysplasia of the 1-2 rate - with 5 patients;
- dysplasia of the 2 rate - with 2 patients;
- dysplasia of the 3 rate - with 1 patient.

10 patients with the vesical cervix ectopia made up a control group which was not prescribed with the antioxidant treatment.

The check examination was conducted in 11 days after the beginning of treatment. The control included the gynecological exam, as well as the repeated swab withdrawal for flora, Schiller test and extended colposcopy. In the result of the examination of swabs for flora one should pay attention to the significant decrease of the white blood count, which is indicative of anti-inflammatory efficiency of the treatment.

■ Results:

Healing of the vesical cervix ectopia after the 10-day course treatment happened with 85% patients, which was characterized by the development of the normal stratified epithelium of the ectocervicitis, including after surgical treatment in 100% of cases. The period of epithelialization after cryo- and radio-wave destruction decreased at average 2 times against the usual regenerative process, i.e. within 1

menstrual cycle. 15 % of cases registered partial effect from treatment, which manifested itself as the marginal epithelialization. In the control group the period of the regenerative process was on average more than 2 months.

In the process of initial exam an individual event of an effective full medical treatment of a patient with dysplasia of the 1-2 rate was present. The repeated clinical event of full medical treatment after the course of 10 manipulations for dysplasia of the 1 rate with cicatrical changes became the reason to perform a special study on this subject, which completion is planned by the middle of 2012. At present, there were 7 cases of full medical treatment of dysplasia of the 1 and 1-2 rates with the *antioxidant Complex* during the 10-day treatment course.

We would like specially note the case of treatment of dysplasia of the 3 rate. The patient has been conducted the cone biopsy of the vesical cervix three times during 2 years. In the result of the last examination the dysplasia of the 3 rate was diagnosed, after the 10-day application of the *antioxidant Complex* dysplasia of the 2 rate was diagnosed. After the repeated 10-day treatment course the result corresponded to the vesical cervix ectopia, which was also proved clinically.

All 173 patients were gynecologically checked in 1 month and in the majority of cases in 6 months; this resulted in the fact that no pathological process of the vesical cervix was diagnosed in a single case.

It is important to note that no patient highlighted that she had uncomfortable sensations or discomfort feelings when using the *antioxidant Complex*.

■ **Resume:**

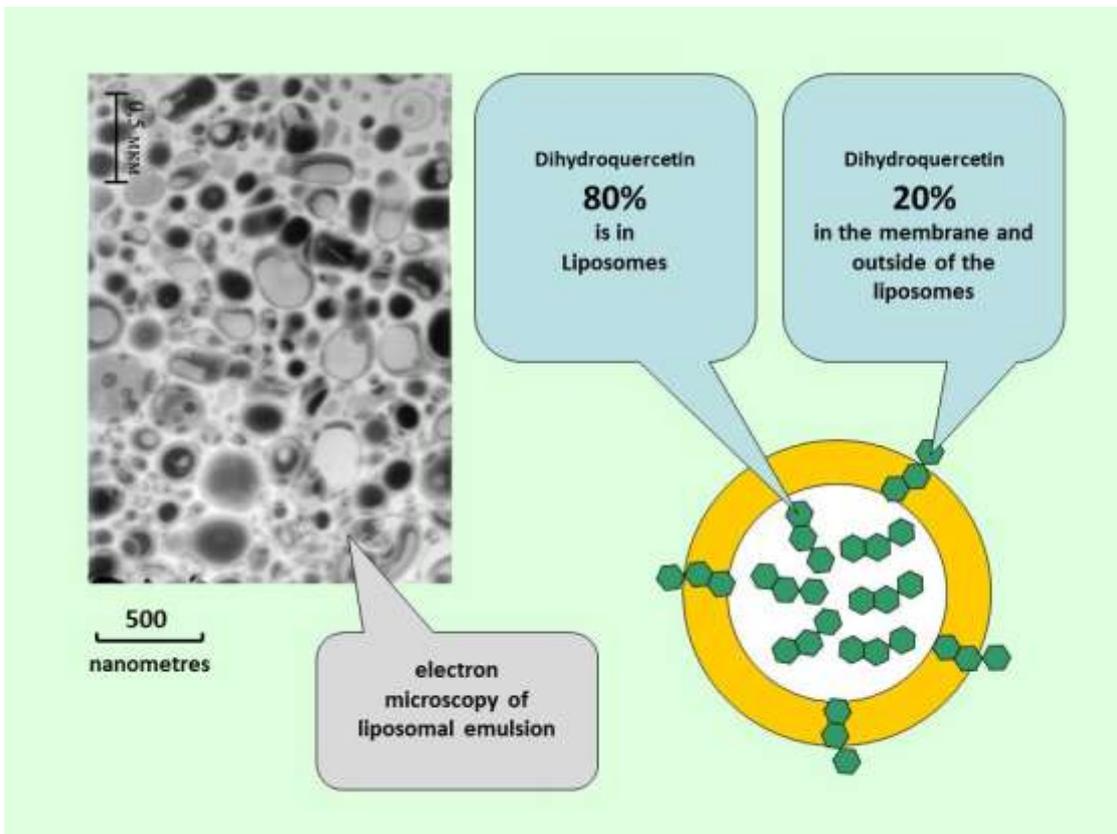
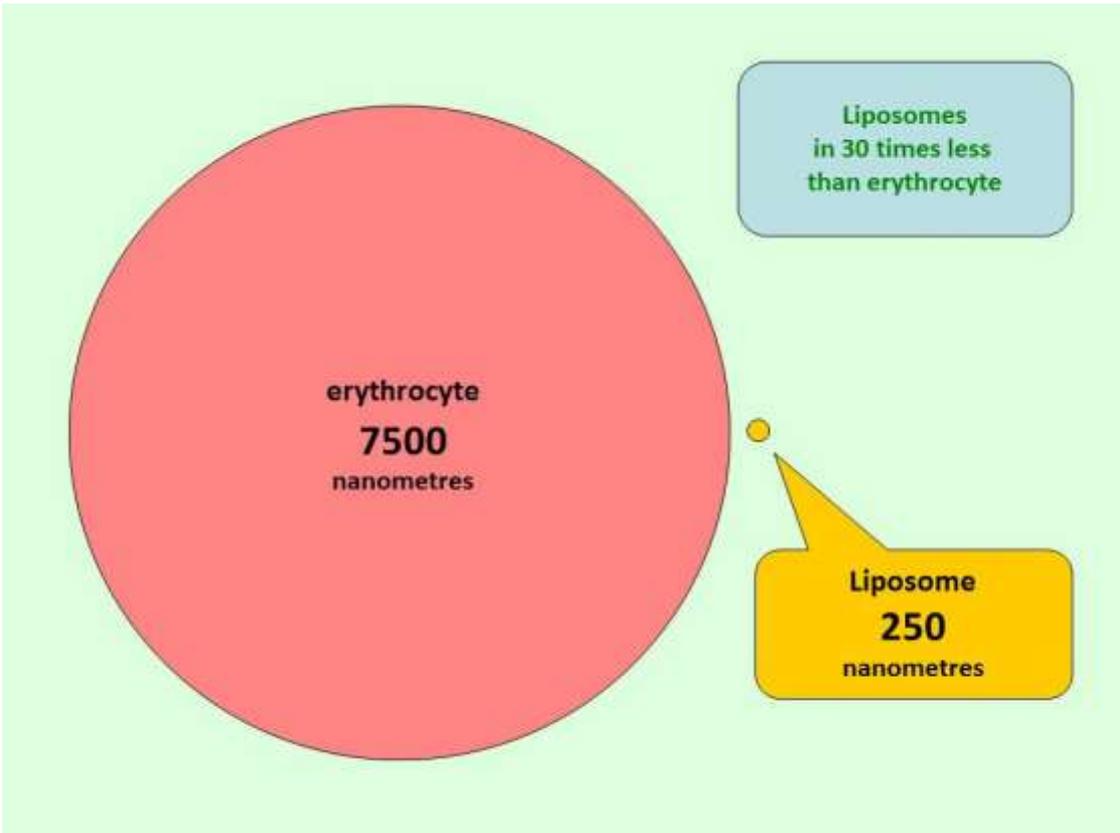
The use of conservative antioxidant treatment in the respect of the vesical cervix pathologies showed high effectiveness of the method. All the cases noted absence of clinical signs of the disease which was proved by laboratory studies.

■ **Conclusion:**

The clinical practice in this case fully confirmed the assumption about the significant influence of the oxidative stress on the development of different pathological processes. Its effective stopping by using of the *antioxidant Complex* provided the development of the non-invasive method for treatment of the vesical cervix pathologies and greatly decreasing of the period and increasing of the quality of rehabilitation after the invasive manipulations.

There is a point in speaking of the antioxidant treatment as a general system approach; moreover, the modern liposomal substances provide such an instrument.

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antioxidant Complex for use in gynecology



The typical example of the treatment without surgical treatment

the woman of 23 years, ectopia

after 10 days

