

Modern approaches to the treatment of acute cystitis: traditional herbal formulations
in modern dosage forms

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medicinal forms

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RESUME

The informational and analytical study of traditional and contemporary approaches to the treatment of acute cystitis was conducted. It was done with a view to optimize the techniques of rational therapy with innovative dosage forms of herbal preparations. We revealed the continuity of traditional and contemporary approaches to the rational phytotherapy of various diseases. Current approaches are characterized by: clinical use of standardized herbal medicines, expansion and diversification through the creation of new dosage forms, the tendency to optimize the methods of prevention and treatment of diseases due to the combined use of different formulations of the same medicines.

Keywords: phytotherapy, acute cystitis, chronic cystitis, Urolesan, optimization of treatment methods, modern medicinal forms, drops, capsules, encapsulation of substances of plant origin.

SUMMARY

The analysis of traditional and modern approaches to the treatment of acute cystitis, taking into account the optimization of rational therapy methods using innovative dosage forms of herbal preparations. Revealed the continuity in traditional and modern approaches to the rational herbal medicine of various diseases. Modern approaches are characterized by: the use of standardized herbal preparations in clinical practice; expanding their assortment due to the creation of new dosage forms; a trend towards optimization of methods of prevention and treatment of diseases through the combined use of different dosage forms of the same drug. On the example of capsules of the drug "Urolesan" it is shown

Key words: herbal medicine, acute cystitis, chronic cystitis, urolesan, optimization methods of treatment, modern dosage forms, drops, capsules, encapsulation of substances of plant origin.

Cystitis - (from the Greek Κύστις - bladder) - inflammation of the mucous membrane of the bladder, accompanied by a violation of its function. Distinguish between primary and secondary, acute and chronic, infectious (specific or nonspecific) and non-infectious (chemical, thermal, toxic, allergic, medicinal, radiation, alimentary, etc.) cystitis. Secondary cystitis develops against the background of diseases of the bladder (stones, swelling) and / or bladder obstruction of various etiology, as well as chronic inflammatory diseases of the genital organs [5]. Acute cystitis is an acute inflammation of the lining of the bladder, usually caused by an infection. Urinary tract infections are second only to acute respiratory infections in prevalence [9, 35].

26–36 million cases of acute cystitis are registered annually [30]. The incidence in adult men is extremely low, at 6–8 cases per 10,000 men aged 21–50; frequency

the occurrence of the disease in women is 50 times higher [13, 31] and, for example, at the age of 20–40 years, acute cystitis is detected in 25–35% of women [37], which in general is about 5% of the total morbidity in the population [13]. In older age groups (60 years and older), uncomplicated community-acquired urinary tract infections (BMIs) occur among both sexes with approximately the same frequency [13, 31].

The causes of BMI are most often *E. coli* [27] (approximately in 80–90% of cases [5]), in 10–15% of cases - *Staphylococcus saprophyticus*, only in 1–3% of cases in the urine of patients with cystitis *Proteus mirabilis* and *Klebsiella pneumoniae*, even less often *Enterobacter aerogenes*, *Pseudomonas* spp. [5]. In some cases, the causative agent of cystitis can be anaerobic microorganisms, chlamydia, ureoplasma [27].

The microbial flora in persons with complicated / hospital BMI (especially with catheter-associated lesions, diabetes mellitus, as well as in persons treated with broad-spectrum antibacterial drugs and systemic glucocorticoid therapy) is characterized by a lower specific gravity of *E. coli* (within 50–55%) and a significantly higher detection of other uropathogens (mainly *Candida albicans* and *Candida tropicalis*, as well as *Coccidioidomycosis*, *Blastomycosis*, and *Cryptococcus neoformans* in immunosuppressed patients) [5].

Of great importance in the development and maintenance of symptoms of acute cystitis is a violation of the urodynamics of the lower urinary tract, a change in the tone of the detrusor and urethra, manifested by frequent and difficult urination [5]. The main task of the treatment of cystitis as recurrent and chronic diseases is the sanitation of the lower urinary tract and the restoration of the natural protective antibacterial mechanisms of the urinary system. A large number of treatment methods and their combinations used for chronic cystitis in women indicate the absence of a universal method of therapy for this common disease [22].

Nonspecific infectious and inflammatory diseases of the genitourinary tract today account for about 2/3 of all urological pathology and represent a serious medical and socio-economic problem throughout the world [5, 13, 28, 36]. In this regard, the search for highly effective drugs for the prevention and treatment of diseases of the urinary tract is an urgent task in medicine of the present and future [5].

The purpose of this study: analysis of traditional and modern approaches to treatment acute cystitis taking into account the optimization of rational therapy methods using innovative dosage forms (DF) of herbal preparations.

Methods: information-analytical, historical.

1. Traditional approaches to the treatment and prevention of cystitis

When discussing traditional approaches, one should distinguish between truly traditional methods (that is, those adopted in traditional medicine, or, as it has become fashionable to say now, in complementary and alternative medical practice) and modern (so-called academic) means and methods, which, due to terminological confusion, are often called traditional, while actually traditional (based on the traditions of the peoples of the world) means and methods are called non-traditional.

In truly traditional (and folk) medicine, the generally accepted and practically the only method of treatment and prevention of acute and chronic cystitis is herbal medicine, which has come down to modern clinical practice in the form of official (registered in the prescribed manner) herbal preparations. As a rule, for the treatment of cystitis in folk and traditional medicine, plants are used that have anti-inflammatory, enveloping, phytoncidal (antimicrobial), antioxidant, diuretic, sedative-antispasmodic, analgesic and restorative types of action [11, 12, 15, 20, 21], and also their combinations, showing the effect of kinetic synergism [14, 17, 17].

An important traditional principle of herbal medicine is the use of liquid DF as preferred, and in some traditional medical cultures of the world - and the only one possible [11, 12, 14, 23, 25]. A rare exception in traditional herbal medicine

are solid LF powders from dried medicinal plants and soft external forms for the treatment of skin diseases and traumatic injuries - ointments [14, 16]. Historically, liquid DF was prepared in the form of aqueous (infusions, decoctions, vapors, explosions, water extracts) and alcoholic (medicinal vodka and wines, tinctures, extracts) extracts [14, 16, 23].

The advantages of liquid oral DF (solutions, emulsions, syrups, tinctures, liquid extracts, etc.), in comparison with solid ones, include a higher bioavailability and speed of the onset of the effect, as well as a pronounced local pharmaco-therapeutic effect on the mucous membranes of the oral cavity, esophagus, stomach and intestines. As a rule, in the presence of several DFs of the same drug, the treatment of acute cases of diseases begins with liquid DF, subsequently switching to more convenient solid formulations with a supportive and prophylactic purpose. In addition to the convenience of using solid formulations, their advantages over liquid formulations include the possibility of masking unpleasant taste and odor, protecting the mucous membrane of the gastrointestinal tract from irritating effects, ease of dosing, longer shelf life and milder requirements for storage conditions. Compared to alcohol-containing liquid formulations, solids have an advantage in the treatment of patients with liver disease, morbid addiction to alcohol, or after anti-alcohol treatment.

2. Modern ideas about the rational use of herbal preparations As a rule, modern herbal preparations are developed either on the basis of a ready-made traditional recipe, which has often passed the test of time for centuries, or they combine the experience of the traditional use of each herbal component with modern ideas about its chemical composition, as well as about the mechanisms and features of the development of one or another nosological form. diseases [16–20]. In any case, one of the advantages of herbal medicine is the biological effect of the drug not only on the affected organ, but also on the associated systems of the body, including with the aim of reducing the likelihood of chronic disease and reducing the side effects of synthetic drugs in combination therapy [16, 20, 24].

The most characteristic feature of modern rational herbal medicine is the use of standardized drugs registered in the established order in modern dosage forms, which ensure ease of use and reproducible therapeutic results [16, 20, 21, 24].

Liquid DFs still retain their importance in modern clinical practice and in the pharmacy assortment, along with soft (ointments, suppositories), but solid dosage DFs are now considered more convenient. In almost all pharmacotherapeutic groups of drugs, the dominant part of the assortment of pharmacies is made up of solid dosage forms, of which tablets are in first place in demand, and capsules are in second place, the share of which in the assortment of pharmacies is steadily growing [1–4, 6–8]. This explains the desire of well-known pharmaceutical companies to expand their own lines of drugs through the development and production of herbal preparations in new DF [2, 20, 26, 32].

The observed expansion of the product range significantly increases the possibility of choosing the optimal drugs, taking into account modern approaches to pharmacotherapy of various pathological conditions, individual characteristics of the course of the disease, the preferences of the doctor and the end user [2, 4, 7, 26].

The second important feature of modern herbal medicine is the emerging tendency to improve the methods of prevention and treatment of acute and chronic diseases through the combined or sequential use of the same herbal remedy in different DF. Based on the results of our own studies of the effectiveness of the solution and tablet form of "Novo-Passit" [32] and numerous literature data (including on the combined use of different DF at different stages of the pathological process) [2, 10, 20], it is possible to consider research on the development of technology for obtaining new DF of known drugs and the study of the features of their use in clinical practice.

3. Modern ideas about herbal medicine for cystitis

In modern clinical phytotherapy, the prescription of drugs for diseases of the genitourinary tract is usually based on antimicrobial, anti-inflammatory, litholytic, diuretic, antispasmodic, analgesic types of action and the ability to normalize the immune status and sexual function [29, 31, 33, 34].

Modern etiopathogenetic treatment of patients with acute cystitis and exacerbation of a chronic recurrent process in the bladder mucosa consists of antibacterial therapy in accordance with the sensitivity to pathogenic microflora, antispasmodic, diuretic, analgesic, anti-inflammatory therapy. In accordance with modern regulatory documents, the appointment of phytopreparations for diseases of the genitourinary tract is considered pathogenetic, since they reliably exhibit antimicrobial, phytoncidal, anti-inflammatory, diuretic, antispasmodic, analgesic effect [5].

From our point of view, the optimal approach to the treatment and prevention of cystitis will be the inclusion of all types of phytotherapy in the scheme of therapeutic and prophylactic measures - etiotropic, pathogenetic, symptomatic and auxiliary (in order to increase the effectiveness and safety of treatment, including with the combined use of pharmacological and phytotherapy) [20, 24]. Of particular importance in such therapy are multicomponent herbal preparations based on traditional prescriptions, including those in innovative DF. The latter include drugs obtained through the use of nanotechnology, modern extraction and other equipment, as well as modern excipients. In particular, the use of traditional and the appearance on the market of new stabilizers, adsorbents of active substances, disintegrants, diluents,

One of the striking examples of the second birth in a new dosage form of an already well-known herbal preparation is Urolesanum, a unique formulation of which has roots in Russian traditional and folk medicine [17–19, 31].

4. Evaluation of the rationality of the use of the drug "Urolesan" for the treatment of acute cystitis and prevention of its recurrence

4.1. Brief characteristics of the drug.

"Urolesan" belongs to the pharmacotherapeutic group "herbal antispasmodic agent"; ATX code G04BC. The drug was developed and registered in the USSR in the 80s of the last century; currently produced in Ukraine. Passed the necessary registration and re-registration procedures in Russia, has many years of experience in clinical use [5] and today is still perceived by specialists as a reliable and safe urolithic and uroseptic, and its sales are growing from year to year [17–19].

"Urolesan" is easily absorbed and quickly reaches the liver, urinary tract and kidneys with blood flow, quickly relieves attacks of renal and hepatic colic and normalizes the smooth muscle tone of the upper and lower urinary tract and gallbladder [5]. Its therapeutic breadth and reliability are assessed as high largely due to the implementation in the formulation of the two most commonly used principles of Eastern herbal medicine - kinetic synergism and duplication of unidirectional types of activity using ingredients of different chemical structures and different mechanisms of their action [14, 17, 19]. A detailed analysis of the mechanisms of action of biologically active substances from the standpoint of modern concepts of the chemical composition of ingredients was carried out by us earlier [17–19].

For more than 30 years, this herbal preparation has been considered one of the best, i.e. effective, safe and well-sold agents for the treatment of urinary and cholelithiasis, urinary diathesis, acute and subacute calculous pyelonephritis and chronic cholecystitis, biliary dyskinesia. According to NO PANT (www.naturoprof.ru), the most popular official indications for the use of the drug since its registration have been various forms of urolithiasis, as well as acute and chronic pyelonephritis [19–21]. This year, based on the results of new clinical trials, as well as post-registration

studies carried out at the Kharkiv Medical Academy of Postgraduate Education, the Dnepropetrovsk Medical Academy of the Ministry of Health of Ukraine [5, 31] and the staff of the Department of Urology and Andrology, Moscow State University. M.V. Lomonosov (2011–2012) [5], additional indications for use were added to the Instruction for the Medical Use of the Drug (hereinafter - the Instruction). Urolesan (oral drops) is now officially recommended as a complex therapy for acute cystitis.

4.2. Innovative dosage forms

Traditionally, the drug was produced in a liquid dosage form "drops" (approved for use from 18 years old), a little over a year ago, a syrup was introduced to the market (approved for use from 6 years old), this year - the most modern dosage form - capsules (tab. 1). With the help of modern technological methods and an original combination of excipients, the developers managed to obtain a free-flowing substance from the liquid DF of the drug "Urolesan". The substance is stable and technological, well encapsulated in gelatin capsules, as a result of which the patient receives a solid dosage of LF, which has the corresponding advantages and features of action, compared to a liquid one (see above). The innovativeness of such developments is undeniable,

Very interesting additions were made to the "Instructions for the medical use of the drug" "Urolesan" in an innovative formulation. In particular, in accordance with the approved "Instruction", taking capsules is indicated in the complex therapy of acute and chronic infections of the urinary tract and kidneys (cystitis, pyelonephritis), urinary and cholelithiasis, chronic cholecystitis, biliary dyskinesia of the hyperkinetic type.

Table 1

Pharmaceutical equivalence of liquid and solid dosage forms of Urolesan

Уролесан®, жидкость (1 доза), содержание в г		Уролесан®, капсулы (1 капсула), содержание в г		Назначение ингредиента
Моркови дикой плодов экстр. жидкий	0,00184	Моркови дикой плодов экстр. жидкий	0,00184	Действующее вещество
Хмеля шишек экстракт жидкий	0,00633	Хмеля шишек экстракт жидкий	0,00633	
Душицы травы экстракт жидкий	0,00146	Душицы травы экстракт жидкий	0,00146	
Масло пихты	0,02550	Масло пихты	0,02550	
Масло мяты перечной	0,00746	Масло мяты перечной	0,00746	
Масло касторовое	0,03515	Масло касторовое	0,03515	Носитель эфирных масел и растворитель, обладающий фармако-терапевтической активностью
Трилон Б	0,00002	Трилон Б	0,00002	Стабилизатор
–	–	Неуцилин UFL2	0,02711	Адсорбент действующих веществ и разбавитель
–	–	Магния карбонат тяжелый	0,13196	
–	–	Тальк	0,00638	Антифракционное вещество
–	–	Таблетоза-80	0,05010	Разбавитель
–	–	Крахмал картофельный	0,00562	Разрыхлитель

4.3. Optimization of treatment methods for acute and chronic cystitis

Taking into account the results of the studies [5, 31] and modern trends in the ecologization of medico-pharmaceutical activities, clinicians proposed new treatment regimens (phytotherapy) for acute cystitis and supportive therapy using various dosage forms of "Urolesan" - solution and capsules as the most convenient and practical LF with good bioavailability for long-term and effective treatment.

In particular, at present, in the treatment of cystitis, the sequential (step-by-step) use of drops and capsules can be considered optimal according to the following scheme:

Stage 1: Drops (during the first 5-7 days from the onset of the disease - according to the instructions) - for quick relief of pain, discomfort and dysuric phenomena (acute period), including as

additional treatment to standard therapy;

Stage 2: Capsules (from the 5-7th day of illness to 1 month) - as a supportive comfortable (if necessary, long-term) therapy, which reduces the risk of recurrence of cystitis in the future.

The research results were reflected in the Instructions for the medical use of both DFs of the drug "Urolesan", and the developed optimized methods received the official status of Methodological Recommendations of the Moscow Department of Health [5] and can be used in modern clinical practice.

conclusions

1. The carried out information and analytical research made it possible to establish continuity in traditional and modern approaches to rational herbal medicine of various nosological forms of diseases.

2. The traditional approaches identified by us should include: herbal medicine based on empirically established rational, effective and safe combinations of ingredients, taking into account their kinetic synergy, as well as the use of liquid dosage forms of herbal preparations.

3. Modern approaches to rational herbal medicine are characterized by the use in clinical practice of standardized herbal preparations based on traditional formulations and expanding their range through the creation of new dosage forms. Optimization of methods of prevention and treatment of diseases through the combined use of various dosage forms of the same drug is becoming a significant area of rational herbal medicine.

4. It has been established that the use of well-known and popular herbal preparations in new dosage forms (on the example of capsules of the drug "Urolesan") allows to optimize methodological approaches to the treatment of acute cystitis and the prevention of its recurrence in modern clinical practice.

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