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APPLICATION OF INNOVATIVE MEDICINAL FORMS IN MODERN PHARMACOTHERAPY OF INFLAMMATORY DISEASES THROAT AND UPPER RESPIRATORY TRACTS

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The aim of the research is to justify the use of innovative dosage forms in modern pharmacotherapy of inflammatory diseases of the throat and upper respiratory tract.

Research methods and materials. To conduct the research, the following methods were used: systematic and comparative analysis, generalization, statistical processing and synthesis to determine the predicted prospects for the use of innovative dosage forms in modern pharmacotherapy of inflammatory diseases of the throat and upper respiratory tract. The software and electronic resources of ATX (Anatomical-Therapeutically-Chemical), ATC (Anatomical Therapeutically Chemical Classification System), BSC (Biopharmaceutical Classification System), Vidal, Compendium, and the State Register of Medicinal Products of Ukraine were used to carry out the systematic and comparative analysis.

Research results. Inflammatory diseases of the throat and upper respiratory tract are among the most common in the modern world. The effectiveness of pharmacotherapy prevents the occurrence of complications of these diseases and the economic costs of both the patient and health care institutions.

In medical practice, the choice of the dosage form and its use determine the functional characteristics, the speed of development and the duration of the pharmacological effect, the spectrum of adverse reactions. The dosage form is a structural unit of pharmacotherapy and modern pharmaceutical production. According to the results of the study, the frequency of use of medicinal forms for the treatment of inflammatory diseases of the throat and upper respiratory tract according to the nomenclature of the State Formulary of aerosols and sprays is more than 50%; solid dosage forms – 36%, of which tablet preparations – 24%, granules and sachets for preparing solutions – 8.5%, liquid dosage forms – suspension and emulsion type solutions, syrups – 5.5%, lozenges, lozenges – 12%. In the segment of solid dosage forms, capsules make up 37%; tablets – 24%, granules and sachets for preparing solutions – 8.5%, orodispersible tablets – 12.5%, lozenges – 12%; medical fees -–5.95. Experimental and clinical studies have shown that the type of dosage form and the method of administration significantly affect the therapeutic effectiveness, determining the degree of its absorption and concentration in biological fluids. In modern medical practice, orodispersible tablets, as an innovative dosage form, are widely used to achieve an accelerated therapeutic effect by releasing active pharmaceutical ingredients in the oral cavity and affecting the mucous membranes of the oral cavity, throat and upper respiratory tract for the treatment of inflammatory processes. Orodispersible tablets are used both for local action and general action.

Conclusions. The advantages of orodispersible tablets as a promising dosage form are: ease of use for such patients in pediatrics, geriatrics, and psychiatry; increased bioavailability as a result of dispersion in the oral cavity and rapid absorption; no need to drink water; pleasant taste; increased safety of use due to low risk of suffocation during medication administration.

Regulatory requirements for the quality of pharmaceutical production of orodispersible tablets are distinguished by the fact that the term of disintegration and release of API must be clearly defined and acceptable for the availability of absorption in the oral cavity. From a regulatory point of view, the oral disintegration rate guidelines are currently being reviewed by the FDA, as these limits have been found to be limited for some orodispersible tablets that are firmly positioned in the pharmaceutical market.

It has been established that with the development of industrial pharmacy, orodispersible tablets have become a promising pharmaceutical form for oral drug delivery systems.

Key words: pharmacotherapy, inflammatory diseases of the throat and upper respiratory tract, dosage form, therapeutic effectiveness, innovative dosage forms, orodispersible tablets.

Коновалов Сергій, Воскобойнікова Галина. Застосування інноваційних лікарських форм у сучасній фармакотерапії запальних хвороб горла і верхніх дихальних шляхів

Мета дослідження – обґрунтування застосування інноваційних лікарських форм у сучасній фармакотерапії запальних хвороб горла і верхніх дихальних шляхів.

Методи і матеріали дослідження. Для проведення дослідження використано такі методи: системний і порівняльний аналіз, узагальнення, статистична обробка і синтез для визначенні прогнозованих перспектив застосування інноваційних лікарських форм у сучасній фармакотерапії запальних хвороб горла і верхніх дихальних шляхів. Для здійснення системного і порівняльного аналізу використано програмні та електронні ресурси ATX (Anatomical-Therapeutically-Chemical), ATC (Anatomical Therapeutically Chemical Classification System), BSC (Biopharmaceutical Classification System), Vidal, Compendium, Державного реєстру лікарських засобів України.

Результати дослідження. Запальні хвороби горла і верхніх дихальних шляхів є одними з найпоширеніших у сучасному світі. Ефективність фармакотерапії запобігає виникненню ускладнень цих захворювань і економічних витрат як пацієнта, так і закладів охорони здоров'я.

У лікувальній практиці вибір лікарської форми та її застосування визначають функціональні характеристики, швидкість розвитку та тривалість фармакологічного ефекту, спектр побічних реакцій. Лікарська форма є структурною одиницею фармакотерапії та сучасного фармацевтичного виробництва. За результатами дослідження частоти застосування лікарських форм для лікування запальних хвороб горла і верхніх дихальних шляхів, відповідно до номенклатури Державного формуляра, аерозолі і спреї становлять понад 50%; тверді лікарські форми – 36%, з них таблетовані препарати – 24%, гранули і саше для приготування розчинів – 8,5%, рідкі лікарські форми – розчини суспензійного і емульсійного типу, сиропи – 5,5%, пастилки, льодяники – 12%. У сегменті твердих лікарських форм капсули становлять 37%; таблетки – 24%, гранули і саше для приготування розчинів – 8,5%, ородисперсні таблетки – 12,5%, пастилки, льодяники – 12%; лікарські збори – 5,95. Експериментально-клінічні дослідження показали, що вид лікарської форми і спосіб введення суттєво впливають на терапевтичну ефективність, визначаючи ступінь її абсорбції та концентрації в біологічних рідинах. У сучасній медичній практиці ородисперсні таблетки, як інноваційна лікарська форма, знаходять широке застосування для досягнення пришвидшеного терапевтичного ефекту шляхом вивільнення активних фармацевтичних інгредієнтів у ротовій порожнині і впливу на слизові оболонки ротової порожнини, горла і верхніх дихальних шляхів для лікування запальних процесів. Ородисперсні таблетки застосовують як для місцевої, так і для загальної дії.

Висновки. Перевагами ородисперсних таблеток, як перспективної лікарської форми, є зручність застосування для таких пацієнтів у педіатрії, геріатрії, психіатрії; підвищена біодоступність як результат диспергування у ротовій порожнині та швидке всмоктування; відсутність необхідності запивати водою; приємний смак; підвищена безпека застосування за рахунок низького ризику задухи під час прийому ліків.

Регуляторні вимоги щодо якості фармацевтичного виробництва ородисперсних таблеток вирізняються тим, що термін розпадання і вивільнення АФІ має бути чітко визначеним і прийнятним для доступності всмоктування у ротовій порожнині. З регуляторної точки рекомендації щодо швидкості розпадання у ротовій порожнині наразі переглядаються FDA, оскільки зазначені рамки виявилися обмеженими для деяких препаратів у формі ородисперсних таблеток, які впевнено позиціонують себе на фармацевтичному ринку.

Встановлено, що з розвитком промислової фармації ородисперсні таблетки стали перспективною фармацевтичною формою для систем пероральної доставки ліків.

Ключові слова: фармакотерапія, запальні хвороби горла і верхніх дихальних шляхів, лікарська форма, терапевтична ефективність, інноваційні лікарські форми, ородисперсні таблетки.

Introduction. Inflammatory diseases of the throat and upper respiratory tract are among the most common in the modern world. The effectiveness of pharmacotherapy prevents the occurrence of complications of these diseases and the economic costs of both the patient and health care institutions.

The scientists summarize the research results and outline the prospects for systematizing and standardizing the tactics of treatment of acute tonsillopharyngitis. Thus, during the period 2011–2024, the creation of national and international clinical recommendations and systematic reviews was started in 2011: "Guidelines for the diagnosis and treatment of acute pharyngitis" (Toward Optimized Practice, Guidelines2 update), "Analysis of recommendations of international guidelines for the treatment of acute pharyngitis in adults and children" (review of 12 manuals, E. Chiapinni et al., 2011), "Guidelines for the management of acute sore throat" under the direction of P. Huovinen, (European Society for Clinical Microbiology and Infectious Diseases, ESMID, 2012), "Practical guide to the diagnosis and treatment of acute sore throat" (Infectious Diseases Society of America, IDSA, Stanford T. Shulman, 2012), "Antibiotic prescription strategies for acute sore throat: a prospective observational cohort study" [1].

According to the recommendations of the Canadian Medical Association (Alberta), viruses are the most common cause of acute pharyngitis, and therefore antibiotics are not indicated for treatment. Also, in a separate point, there is a recommendation not to use such drugs as antiseptic or antibacterial pastilles, sprays and antibacterial preparations for gargling,

due to the fact that they can contribute to the growth of resistance of the oropharyngeal flora [1].

Therefore, to prevent exacerbation of the inflammatory process, the use of alternative drugs and dosage forms is effective. According to the new recommendations of the Infectious Diseases Society of America, most infectious diseases of the throat are caused by viruses and should not be treated with antibiotics [1]. Recommended for use are non-steroidal anti-inflammatory drugs to control symptoms and prevent the development of complications associated with the spread of the inflammatory process.

The main goal of the recommendations published in the journal Clinical Infectious Diseases (September, 2012) [1] is to limit the use of antimicrobial drugs for the treatment of viral infections of the back of the pharynx, as well as timely detection and adequate treatment of pharyngitis caused by group A streptococci (group A streptococci), nonsteroidal anti-inflammatory drugs should be used as an adjunct to adequate antibacterial therapy for pharyngitis associated with BGSA to control pain and inflammation.

The European Society for Clinical Microbiology and Infectious Diseases published a guide for the diagnosis and treatment of patients with acute sore throat in the journal Clinical microbiology and infection (2012 18 (1) April 20) [1], regarding the use of clinical diagnostic criteria and laboratory diagnostics to identify possible bacterial infection with acute sore throat.

The work of scientists on the systematization of the lists of recommended drugs and the rational use of drugs and dosage forms for the treatment of inflammatory diseases of the throat and upper respiratory tract continues.

A balanced and justified approach to the appointment of antibacterial therapy is one of the conditions for restraining the evolution of antibiotic resistance, which is escalating. A sore throat in most cases is an example that is unlikely in the absence of antibiotic therapy. However, primary care physicians often continue to prescribe antibiotics for various conditions associated with sore throat. Local use of flurbiprofen in the form of lozenges and spray as an alternative, symptomatic means of therapy prevents the unnecessary prescription of antibacterial agents and, accordingly, reduces the burden of antibiotic resistance. If antibacterial therapy is clinically justified, flurbiprofen oromucosal spray and lozenges can improve the patient's quality of life from the very beginning of topical therapy and potentially shorten the duration of antibiotic use [2].

Scientific studies confirm the effectiveness of the use of propolis preparations in the form of aerosol forms, pastilles and lozenges, as propolis is safe and has an antiviral and immunomodulation effect; however, clinical trials aim to examine its effect on the pathological process caused by viral diseases, in combination with or without antiviral drugs or vaccines [3].

As alternative means of rational therapy for inflammatory diseases of the throat, combined preparations of dequalinium and lysozyme, as well as in combination with bupivacaine in the form of tablets that dissolve in the oral cavity, relieve the exacerbation of the inflammatory process and have a bactericidal effect have confirmed their pharmacotherapeutic effectiveness.

The aim of the research is to justify the use of innovative dosage forms in modern pharmacotherapy of inflammatory diseases of the throat and upper respiratory tract.

Research methods and materials. To conduct the research, the following methods were used: systematic and comparative analysis, generalization, statistical processing and synthesis to determine the predicted prospects for the use of innovative dosage forms in modern pharmacotherapy of inflammatory diseases of the throat and upper respiratory tract. The software and electronic resources of ATX (Anatomical-Therapeutically-Chemical), ATC (Anatomical Therapeutically Chemical Classification System), BSC (Biopharmaceutical Classification System), Vidal, Compendium, and the State Register of Medicinal Products of Ukraine were used to carry out the systematic and comparative analysis.

Research results and their discussion. From the point of view of biopharmaceutics, the dosage form and route of administration are one of the most important pharmaceutical factors that ensure the bioavailability of drugs. In medical practice, the choice of the dosage form and its use determine the functional characteristics, the speed of development and the duration of the pharmacological effect, the spectrum of adverse reactions. The dosage form is a structural unit of pharmacotherapy and modern pharmaceutical production, therefore the most important task in the development and industrial production of the dosage form is to ensure bioavailability, optimal conditions for the release and subsequent absorption of the active pharmaceutical ingredient (API) to achieve a therapeutic effect.

From the point of view of rational pharmacotherapy, the dosage form is considered as a means of transporting a medicinal substance - an active pharmaceutical ingredient into the body to ensure maximum bioavailability and therapeutic effectiveness, taking into account the convenience of introducing

medicinal substances in a natural way and the safety of use.

For the treatment of infectious and inflammatory diseases of the throat and upper respiratory tract, the following dosage forms are used: aerosols, sprays, sachets and granules for dissolution, lozenges, tablets.

According to the results of the study of the frequency of use of medicinal forms for the treatment of inflammatory diseases of the throat and upper respiratory tract in accordance with the nomenclature of the State Formulary, the data are shown in the diagrams in Fig. 1, Fig. 2.

Aerosols and sprays make up more than 50%; solid dosage forms – 36%, of which tablet preparations – 24%, granules and sachets for preparing solutions – 8.5%, liquid dosage forms – suspension and emulsion type solutions, syrups – 5.5%, lozenges – 12%.

In the segment of solid dosage forms, capsules make up 37%; tablets – 24%, granules and sachets for preparing solutions – 8.5%, orodispersible tablets – 12.5%, lozenges – 12%; medical fees – 5.95.

Experimental and clinical studies have shown that the type of dosage form and the method of administration significantly affect the therapeutic effectiveness, determining the degree of its absorption and concentration in biological fluids. That is why 70–80% of all medicines are administered orally.

In general, practical experience shows that the most common and convenient forms for use are tablets, more than 50% of all ready-made medicines.

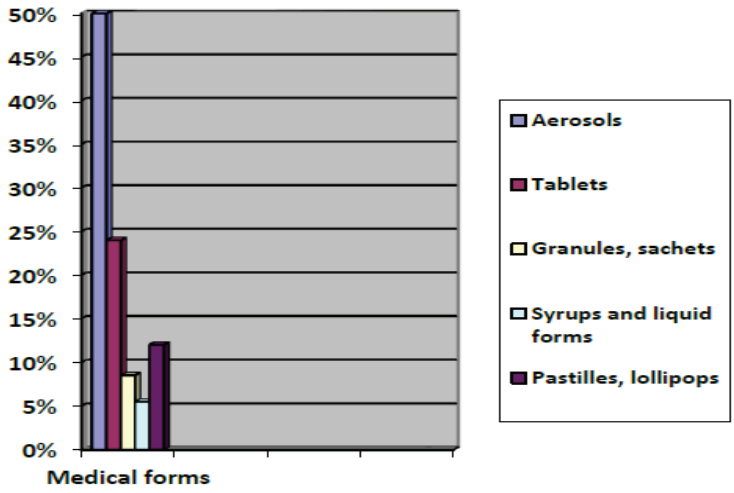

Fig. 1. Diagram of the frequency of use of medicinal forms for the treatment of inflammatory diseases of the throat and upper respiratory tract according to the nomenclature of the State Formulary (2024)

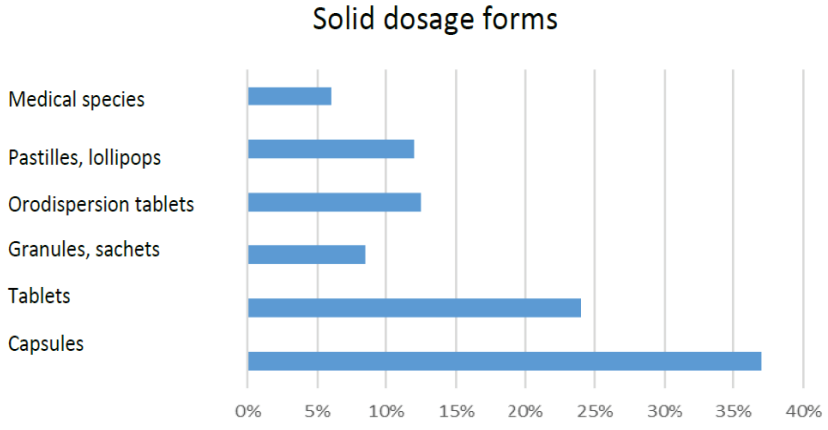

Fig. 2. Diagram of the frequency of use of solid dosage forms for the treatment of inflammatory diseases of the throat and upper respiratory tract according to the nomenclature on the global pharmaceutical market

That is why the assortment and industrial production of tablets around the world is growing annually and is constantly being improved, thanks to the use of innovative and computer technologies. Three-dimensional (3D) printing technologies are constantly being applied to new areas, laying the foundations for industrial pharmacy innovation. As far as pharmaceutical sciences are concerned, 3D-printed drugs are becoming attractive, innovative tools in personalized medicine.

For example, solid oral dosage forms, tablets, can be printed in a wide range of dosages, release profiles, geometries and sizes by simple modification of the digital model, thus providing patients with individualized options for rational pharmacotherapy. Various 3D printing technologies have been applied in pharmaceutical manufacturing to produce solid oral dosage forms with a wide range of properties, new approaches to 3D printed drug development, from digital design to final product, short- and long-term potential applications of 3D-printed drugs and their appropriate regulation, taking into account the challenges of industrial implementation [4].

Innovative tablet forms, such as orodispersible tablets, are confidently positioned in the segment of ready-made dosage forms on the world pharmaceutical market and have found effective use in the treatment of inflammatory diseases of the throat and upper respiratory tract, as well as in complex pharmacotherapy of inflammatory diseases in otolaryngological practice.

In modern medical practice, orodispersible tablets are widely used in order to achieve an accelerated therapeutic effect by releasing active pharmaceutical ingredients in the oral cavity and affecting the mucous membranes of the oral cavity, throat and upper respiratory tract for the treatment of inflammatory processes. Orodispersible tablets are used both for local action and general action.

According to the results of clinical studies, evidence-based medicine provides information that the therapeutic effect of orodispersible tablets occurs earlier, compared to tablets soluble in the stomach, therefore they are acceptable for the treatment of infectious and inflammatory processes of the oral cavity, throat, upper respiratory tract, analgesia, if necessary quickly achieve a therapeutic effect.

Depending on their composition, orodispersible tablets can be absorbed faster by the enzymes of the oral cavity due to the high dissolution rate and low weight of the tablet.

The introduction of orodispersible tablets, by foaming rather than dissolving, were developed for pediatric practice to make it more pleasant for children to take vitamin preparations.

At the current stage, the idea of developing, industrially introducing and bringing to the pharmaceutical market drugs in the form of orodispersible tablets has been adapted by the pharmaceutical industry and combined with the technology of drug delivery systems using microparticles that are released when dissolved in the oral cavity. Dissolving has become a more effective method than foaming as manufacturing processes have improved and ingredients such as mannitol have become available to improve binding and reduce dissolution time. The process of developing orally dispersible tablets was initiated by R.P. Scherer Corporation [en] (hereafter Catalent Pharma Solutions) and Cima Labs in the US, as well as Takeda Pharmaceutical in Japan.

The advantages of using orodispersible tablets as a promising dosage form for the treatment of inflammatory diseases of the throat and upper respiratory tract are: convenient for use in pediatric practice and gerontology; do not require drinking water and are suitable for travelers or busy people who do not always have access to water; taste adjustment; increased safety due to the low risk of suffocation while taking medication; increased bioavailability – rapid absorption and therapeutic action in the oral cavity, throat and upper respiratory tract;

At the same time, there are disadvantages of this dosage form: since these are innovative drugs, they have a high cost due to more complex technological production; low strength in blister packaging; limited ability to deliver high concentrations of the active substance.

From a regulatory point of view, orodispersible tablets fall under the scope of the United States Pharmacopoeia (USP) and belong to the method of disintegration in the oral cavity, and must dissolve in less than 30 seconds [5]. These guidelines are currently being reviewed by the FDA, as these guidelines have been found to be too strict for some types of orodispersible tablets that are marketed in the pharmaceutical market.

At the current stage, tablet forms that dissolve in the oral cavity – orodispersible tablets as a dosage form of tablets are available from a limited number of over-the-counter and prescription drugs. Regulatory requirements for the quality of pharmaceutical production of orodispersible tablets are distinguished by the fact that the term of disintegration and release of API must be clearly defined and acceptable for the availability of absorption in the oral cavity.

Orodispersible tablets (ODTs) emerged at the current stage of the development of pharmaceutical sci-

ence as an improved oral drug delivery system and can be considered one of the most significant inventions among all new drug delivery systems. Their implementation significantly improves patient compliance, ease of use, bioavailability and accelerates the onset of action [5].

So, as a medicinal form, orodispersible tablets combine practicality and convenience of use, they quickly dissolve in the oral cavity, the API is quickly released, which accelerates the therapeutic effect.

Because orodispersible tablets have an earlier therapeutic effect than gastro-dissolving tablets, they are an alternative form of medication for patients who suffer from dysphagia, for patients who may refuse to take medication, and for patients who require medication in this form is more convenient.

With the development of industrial pharmacy, orodispersible tablets have become a promising pharmaceutical form for oral drug delivery systems.

Orodispersible tablets ensure the dissolution and release of active pharmaceutical ingredients (APIs) in the oral cavity and achieve a therapeutic effect by affecting the mucous membranes of the oral cavity and upper respiratory tract with local action, as well as general action (analgesic, anti-inflammatory drugs).

The disintegration test of many orodispersible tablet preparations shows satisfactory results up to 1–2 minutes.

At the same time, APIs in the form of orodispersible tablets must be bioavailable, so they must be released into biological fluids and fermented by oral cavity enzymes, or absorbed through the mucous membranes of the oral cavity and upper respiratory tract to achieve a therapeutic effect. Therefore, the form of orodispersible tablets is biopharmaceutically acceptable for API classes I-III of the biopharmaceutical classification system. AFI of the first class of BSK and with high solubility and a high degree of penetration; BSK Class III API with high solubility and low penetration.

APIs with high biopharmaceutical solubility are substances whose highest dose recommended by WHO dissolves in 250 ml or less of an aqueous medium in the pH range of 1.2 – 6.8. All other substances are considered to have low solubility.

Modern manufacturers use the following methods of obtaining orodispersible tablets: the method of direct pressing, direct pressing using preliminary granulation; formation method; lyophilization method. Innovative approaches are distinguished by the introduction of new technological techniques, engineering and excipients.

The method of obtaining orodispersible tablets with a combination of forming and pressing methods and the introduction of water-insoluble and soluble excipients into the composition (Ziplets-technology, P. Bornago, Eurand, Italy).

Innovative approaches include the method of obtaining orodispersible tablets by pressing a mixture of microspheres and granules (G. Venkatesh et al. US 20050232988 A1); microcapsule pressing and film coating, AdvaTab tablets (Kyowa Hakko Kogyo, Japan), formation of nanocrystal emulsions (Nanocrystal-technology) followed by lyophilization (Elan Corporation).

The method of obtaining orodispersible tablets by pressing granules using the technology of granulation of excipients that differ in compression (WowTab-technology, Yamanouchi Ph. Techn. Inc. Japan).

The method of obtaining orodispersible tablets by cryoscopy lyophilization with the formation of matrix tablets (Zydis-technology, R. P. Scherer, Inc.).

Conclusions. The advantages of orodispersible tablets as a promising dosage form are: ease of use for such patients in pediatrics, geriatrics, and psychiatry; increased bioavailability as a result of dispersion in the oral cavity and rapid absorption; no need to drink water; pleasant taste; increased safety of use due to low risk of suffocation during medication administration.

Regulatory requirements for the quality of pharmaceutical production of orodispersible tablets are distinguished by the fact that the term of disintegration and release of API must be clearly defined and acceptable for the availability of absorption in the oral cavity. From a regulatory point of view, the oral disintegration rate guidelines are currently being reviewed by the FDA, as these limits have been found to be limited for some orodispersible tablets that are firmly positioned in the pharmaceutical market.

It has been established that with the development of industrial pharmacy, orodispersible tablets have become a promising pharmaceutical form for oral drug delivery systems.

Prospects for further research are the substantiation of the formulation of pharmaceutical compositions of anti-inflammatory effect of orodispersible tablets for inflammatory diseases of the throat and upper respiratory tract.

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