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ЕЖЕМЕСЯЧНЫЙ НАУЧНЫЙ ЖУРНАЛ

Медицинские новости Грузии

საქართველოს სამედიცინო სიახლენი

GEORGIAN MEDICAL NEWS

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GMN: Georgian Medical News is peer-reviewed, published monthly journal committed to promoting the science and art of medicine and the betterment of public health, published by the GMN Editorial Board since 1994. GMN carries original scientific articles on medicine, biology and pharmacy, which are of experimental, theoretical and practical character; publishes original research, reviews, commentaries, editorials, essays, medical news, and correspondence in English and Russian.

GMN is indexed in MEDLINE, SCOPUS, PubMed and VINITI Russian Academy of Sciences. The full text content is available through EBSCO databases.

GMN: Медицинские новости Грузии - ежемесячный рецензируемый научный журнал, издаётся Редакционной коллегией с 1994 года на русском и английском языках в целях поддержки медицинской науки и улучшения здравоохранения. В журнале публикуются оригинальные научные статьи в области медицины, биологии и фармации, статьи обзорного характера, научные сообщения, новости медицины и здравоохранения. Журнал индексируется в MEDLINE, отражён в базе данных SCOPUS, PubMed и ВИНИТИ РАН. Полнотекстовые статьи журнала доступны через БД EBSCO.

GMN: Georgian Medical News – საქართველოს სამედიცინო სიახლენი – არის ყოველთვიური სამეცნიერო სამედიცინო რეცენზირებადი ჟურნალი, გამოიცემა 1994 წლიდან, წარმოადგენს სარედაქციო კოლეგიისა და აშშ-ის მეცნიერების, განათლების, ინდუსტრიის, ხელოვნებისა და ბუნებისმეტყველების საერთაშორისო აკადემიის ერთობლივ გამოცემას. GMN-ში რუსულ და ინგლისურ ენებზე ქვეყნდება ექსპერიმენტული, თეორიული და პრაქტიკული ხასიათის ორიგინალური სამეცნიერო სტატიები მედიცინის, ბიოლოგიისა და ფარმაციის სფეროში, მიმოხილვითი ხასიათის სტატიები.

ჟურნალი ინდექსირებულია MEDLINE-ის საერთაშორისო სისტემაში, ასახულია SCOPUS-ის, PubMed-ის და ВИНИТИ РАН-ის მონაცემთა ბაზებში. სტატიების სრული ტექსტი ხელმისაწვდომია EBSCO-ს მონაცემთა ბაზებიდან.

WEBSITE

www.geomednews.com

К СВЕДЕНИЮ АВТОРОВ!

При направлении статьи в редакцию необходимо соблюдать следующие правила:

1. Статья должна быть представлена в двух экземплярах, на русском или английском языках, напечатанная через **полтора интервала на одной стороне стандартного листа с шириной левого поля в три сантиметра**. Используемый компьютерный шрифт для текста на русском и английском языках - **Times New Roman** (**Кириллица**), для текста на грузинском языке следует использовать **AcadNusx.** Размер шрифта - **12**. К рукописи, напечатанной на компьютере, должен быть приложен CD со статьей.

2. Размер статьи должен быть не менее десяти и не более двадцати страниц машинописи, включая указатель литературы и резюме на английском, русском и грузинском языках.

3. В статье должны быть освещены актуальность данного материала, методы и результаты исследования и их обсуждение.

При представлении в печать научных экспериментальных работ авторы должны указывать вид и количество экспериментальных животных, применявшиеся методы обезболивания и усыпления (в ходе острых опытов).

4. К статье должны быть приложены краткое (на полстраницы) резюме на английском, русском и грузинском языках (включающее следующие разделы: цель исследования, материал и методы, результаты и заключение) и список ключевых слов (key words).

5. Таблицы необходимо представлять в печатной форме. Фотокопии не принимаются. **Все цифровые, итоговые и процентные данные в таблицах должны соответствовать таковым в тексте статьи**. Таблицы и графики должны быть озаглавлены.

6. Фотографии должны быть контрастными, фотокопии с рентгенограмм - в позитивном изображении. Рисунки, чертежи и диаграммы следует озаглавить, пронумеровать и вставить в соответствующее место текста **в tiff формате**.

В подписях к микрофотографиям следует указывать степень увеличения через окуляр или объектив и метод окраски или импрегнации срезов.

7. Фамилии отечественных авторов приводятся в оригинальной транскрипции.

8. При оформлении и направлении статей в журнал МНГ просим авторов соблюдать правила, изложенные в «Единых требованиях к рукописям, представляемым в биомедицинские журналы», принятых Международным комитетом редакторов медицинских журналов - http://www.spinesurgery.ru/files/publish.pdf и http://www.nlm.nih.gov/bsd/uniform_requirements.html
В конце каждой оригинальной статьи приводится библиографический список. В список литературы включаются все материалы, на которые имеются ссылки в тексте. Список составляется в алфавитном порядке и нумеруется. Литературный источник приводится на языке оригинала. В списке литературы сначала приводятся работы, написанные знаками грузинского алфавита, затем кириллицей и латиницей. Ссылки на цитируемые работы в тексте статьи даются в квадратных скобках в виде номера, соответствующего номеру данной работы в списке литературы. Большинство цитированных источников должны быть за последние 5-7 лет.

9. Для получения права на публикацию статья должна иметь от руководителя работы или учреждения визу и сопроводительное отношение, написанные или напечатанные на бланке и заверенные подписью и печатью.

10. В конце статьи должны быть подписи всех авторов, полностью приведены их фамилии, имена и отчества, указаны служебный и домашний номера телефонов и адреса или иные координаты. Количество авторов (соавторов) не должно превышать пяти человек.

11. Редакция оставляет за собой право сокращать и исправлять статьи. Корректура авторам не высылается, вся работа и сверка проводится по авторскому оригиналу.

12. Недопустимо направление в редакцию работ, представленных к печати в иных издательствах или опубликованных в других изданиях.

При нарушении указанных правил статьи не рассматриваются.

REQUIREMENTS

Please note, materials submitted to the Editorial Office Staff are supposed to meet the following requirements:

1. Articles must be provided with a double copy, in English or Russian languages and typed or compu-ter-printed on a single side of standard typing paper, with the left margin of **3** centimeters width, and **1.5** spacing between the lines, typeface - **Times New Roman** (**Cyrillic**), print size - **12** (referring to Georgian and Russian materials). With computer-printed texts please enclose a CD carrying the same file titled with Latin symbols.

2. Size of the article, including index and resume in English, Russian and Georgian languages must be at least 10 pages and not exceed the limit of 20 pages of typed or computer-printed text.

3. Submitted material must include a coverage of a topical subject, research methods, results, and review.

Authors of the scientific-research works must indicate the number of experimental biological species drawn in, list the employed methods of anesthetization and soporific means used during acute tests.

4. Articles must have a short (half page) abstract in English, Russian and Georgian (including the following sections: aim of study, material and methods, results and conclusions) and a list of key words.

5. Tables must be presented in an original typed or computer-printed form, instead of a photocopied version. **Numbers, totals, percentile data on the tables must coincide with those in the texts of the articles.** Tables and graphs must be headed.

6. Photographs are required to be contrasted and must be submitted with doubles. Please number each photograph with a pencil on its back, indicate author's name, title of the article (short version), and mark out its top and bottom parts. Drawings must be accurate, drafts and diagrams drawn in Indian ink (or black ink). Photocopies of the X-ray photographs must be presented in a positive image in **tiff format**.

Accurately numbered subtitles for each illustration must be listed on a separate sheet of paper. In the subtitles for the microphotographs please indicate the ocular and objective lens magnification power, method of coloring or impregnation of the microscopic sections (preparations).

7. Please indicate last names, first and middle initials of the native authors, present names and initials of the foreign authors in the transcription of the original language, enclose in parenthesis corresponding number under which the author is listed in the reference materials.

8. Please follow guidance offered to authors by The International Committee of Medical Journal Editors guidance in its Uniform Requirements for Manuscripts Submitted to Biomedical Journals publication available online at: http://www.nlm.nih.gov/bsd/uniform_requirements.html
http://www.icmje.org/urm_full.pdf
In GMN style for each work cited in the text, a bibliographic reference is given, and this is located at the end of the article under the title "References". All references cited in the text must be listed. The list of references should be arranged alphabetically and then numbered. References are numbered in the text [numbers in square brackets] and in the reference list and numbers are repeated throughout the text as needed. The bibliographic description is given in the language of publication (citations in Georgian script are followed by Cyrillic and Latin).

9. To obtain the rights of publication articles must be accompanied by a visa from the project instructor or the establishment, where the work has been performed, and a reference letter, both written or typed on a special signed form, certified by a stamp or a seal.

10. Articles must be signed by all of the authors at the end, and they must be provided with a list of full names, office and home phone numbers and addresses or other non-office locations where the authors could be reached. The number of the authors (co-authors) must not exceed the limit of 5 people.

11. Editorial Staff reserves the rights to cut down in size and correct the articles. Proof-sheets are not sent out to the authors. The entire editorial and collation work is performed according to the author's original text.

12. Sending in the works that have already been assigned to the press by other Editorial Staffs or have been printed by other publishers is not permissible.

Articles that Fail to Meet the Aforementioned Requirements are not Assigned to be Reviewed.

ავტორთა საყურადღებოდ!

რედაქციაში სტატიის წარმოდგენისას საჭიროა დავიცვათ შემდეგი წესები:

1. სტატია უნდა წარმოადგინოთ 2 ცალად, რუსულ ან ინგლისურ ენებზე,დაბეჭდილი სტანდარტული ფურცლის 1 გვერდზე, 3 სმ სიგანის მარცხენა ველისა და სტრიქონებს შორის 1,5 ინტერვალის დაცვით. გამოყენებული კომპიუტერული შრიფტი რუსულ და ინგლისურენოვან ტექსტებში - **Times New Roman (Кириллица)**, ხოლო ქართულენოვან ტექსტში საჭიროა გამოვიყენოთ **AcadNusx.** შრიფტის ზომა – 12. სტატიას თან უნდა ახლდეს CD სტატიით.

2. სტატიის მოცულობა არ უნდა შეადგენდეს 10 გვერდზე ნაკლებს და 20 გვერდზე მეტს ლიტერატურის სიის და რეზიუმეების (ინგლისურ, რუსულ და ქართულ ენებზე) ჩათვლით.

3. სტატიაში საჭიროა გაშუქდეს: საკითხის აქტუალობა; კვლევის მიზანი; საკვლევი მასალა და გამოყენებული მეთოდები; მიღებული შედეგები და მათი განსჯა. ექსპერიმენტული ხასიათის სტატიების წარმოდგენისას ავტორებმა უნდა მიუთითონ საექსპერიმენტო ცხოველების სახეობა და რაოდენობა; გაუტკივარებისა და დაძინების მეთოდები (მწვავე ცდების პირობებში).

4. სტატიას თან უნდა ახლდეს რეზიუმე ინგლისურ, რუსულ და ქართულ ენებზე არანაკლებ ნახევარი გვერდის მოცულობისა (სათაურის, ავტორების, დაწესებულების მითითებით და უნდა შეიცავდეს შემდეგ განყოფილებებს: მიზანი, მასალა და მეთოდები, შედეგები და დასკვნები; ტექსტუალური ნაწილი არ უნდა იყოს 15 სტრიქონზე ნაკლები) და საკვანძო სიტყვების ჩამონათვალი (key words).

5. ცხრილები საჭიროა წარმოადგინოთ ნაბეჭდი სახით. ყველა ციფრული, შემაჯამებელი და პროცენტული მონაცემები უნდა შეესაბამებოდეს ტექსტში მოყვანილს.

6. ფოტოსურათები უნდა იყოს კონტრასტული; სურათები, ნახაზები, დიაგრამები - დასათაურებული, დანომრილი და სათანადო ადგილას ჩასმული. რენტგენოგრამების ფოტოასლები წარმოადგინეთ პოზიტიური გამოსახულებით **tiff** ფორმატში. მიკროფოტოსურათების წარწერებში საჭიროა მიუთითოთ ოკულარის ან ობიექტივის საშუალებით გადიდების ხარისხი, ანათალების შეღებვის ან იმპრეგნაციის მეთოდი და აღნიშნოთ სურათის ზედა და ქვედა ნაწილები.

7. სამამულო ავტორების გვარები სტატიაში აღინიშნება ინიციალების თანდართვით, უცხოურისა – უცხოური ტრანსკრიპციით.

8. სტატიას თან უნდა ახლდეს ავტორის მიერ გამოყენებული სამამულო და უცხოური შრომების ბიბლიოგრაფიული სია (ბოლო 5-8 წლის სიღრმით). ანბანური წყობით წარმოდგენილ ბიბლიოგრაფიულ სიაში მიუთითეთ ჯერ სამამულო, შემდეგ უცხოელი ავტორები (გვარი, ინიციალები, სტატიის სათაური, ჟურნალის დასახელება, გამოცემის ადგილი, წელი, ჟურნალის №, პირველი და ბოლო გვერდები). მონოგრაფიის შემთხვევაში მიუთითეთ გამოცემის წელი, ადგილი და გვერდების საერთო რაოდენობა. ტექსტში კვადრატულ ფჩხილებში უნდა მიუთითოთ ავტორის შესაბამისი N ლიტერატურის სიის მიხედვით. მიზანშეწონილია, რომ ციტირებული წყაროების უმეტესი ნაწილი იყოს 5-6 წლის სიღრმის.

9. სტატიას თან უნდა ახლდეს: ა) დაწესებულების ან სამეცნიერო ხელმძღვანელის წარდგინება, დამოწმებული ხელმოწერითა და ბეჭდით; ბ) დარგის სპეციალისტის დამოწმებული რეცენზია, რომელშიც მითითებული იქნება საკითხის აქტუალობა, მასალის საკმაობა, მეთოდის სანდოობა, შედეგების სამეცნიერო-პრაქტიკული მნიშვნელობა.

10. სტატიის ბოლოს საჭიროა ყველა ავტორის ხელმოწერა, რომელთა რაოდენობა არ უნდა აღემატებოდეს 5-ს.

11. რედაქცია იტოვებს უფლებას შეასწოროს სტატია. ტექსტზე მუშაობა და შეჯერება ხდება საავტორო ორიგინალის მიხედვით.

12. დაუშვებელია რედაქციაში ისეთი სტატიის წარდგენა, რომელიც დასაბეჭდად წარდგენილი იყო სხვა რედაქციაში ან გამოქვეყნებული იყო სხვა გამოცემებში.

აღნიშნული წესების დარღვევის შემთხვევაში სტატიები არ განიხილება.

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CONCEPTUAL AND THEORETICAL EXPLORATION OF TREATMENT OF PATIENTS WITH ONYCHOMYCOSIS

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Abstract.

The last decades regarding diseases of fungal etiology are characterized by a tendency towards changes in the understanding of the etiology and clinical picture of such lesions, and accordingly, the development of new treatment methods is necessary. The goal of our work was to optimize medical care for patients with onychomycosis through the use of therapeutic agents that improve the structure of the nail plates.

Materials and methods: The study involved 147 patients with various forms of onychomycosis of the hands and feet aged 23 to 79 years. Patients in the main group were offered to use a systemic antifungal drug with a drug that contains biotin and improves the structure and speed of nail plate growth. Patients in the control group used only a systemic antifungal drug. Examination of patients was performed with microscopic examination of pathological material (pieces of nail fragments), cultural study, PCR, epiluminescence surface microscopy of affected nail plates, dermatoscopy, determination of nail plate damage index.

Results: At the beginning of treatment, the most common clinical manifestations of onychomycosis were as follows: hyperkeratotic changes were observed in 44 patients (47.3%) of the main group and in 30 patients (55.6%) of the control group; onycholysis in the form of partial or complete detachment of the nail plates from the nail bed was observed in 26 patients (28.0%) with combined therapy and in 38 patients (70.4%) of the control group; destruction of the nail plates to their complete absence was observed in 4 patients of the main group and in 3 patients of the control group; color change was observed in almost all patients of both groups - 96.8% of the main group and in 96.3% of the control group; Surface deformation is also a characteristic sign of onychomycosis and at the beginning of treatment it was observed in a weak degree of severity in 41 patients (44.1%), in a moderate degree - in 26 (27.9%), in a significant degree - in 19 patients (20.4%). As for the patients of the control group, the largest number of them had moderate surface deformation in 25 patients (46.3%), then 14 patients (25.9%) with significant changes in the form of transverse and longitudinal striations, there were no surface changes at all in 11 patients. Such a symptom as a change in the free edge was completely absent in 10 patients (18.5%) of the control group and in 24 patients (25.8%) of the main group. The highest percentage of changes among the main group – 29.0% was observed in patients with moderate degree of delamination in 27 patients, absence – in 19 patients (20.0%), and insignificant in the form of slight partial delamination in 23 patients (24.7%). As a result of the treatment, it was found that the growth rate of nail plates in patients receiving complex therapy was 1.4 times (0.77±0.02 cm) higher than in patients in the control group, whose average growth rate was 0.53±0.03 cm.

Conclusions: A comprehensive method of treating patients with onychomycosis involving both antifungal agents and agents that improve the structure of the nail plates and accelerate their regrowth provides mycological elimination and a positive clinical outcome in patients: achieving mycological remission at 10-12 weeks in 89.1% of patients with comprehensive treatment, which is 19.5% more than in patients with traditional treatment. The developed method ensures the restoration of the normal structure of the nail plate in 96.8% of patients (respectively, in 81.5% of patients using traditional treatment).

Key words. Onychomycosis, treatment, morphology, nail plate, antimycotics.

Introduction.

The last decades are characterized by the successes of infectious medicine [1] despite the tragic consequences of the Covid pandemic [2,3], in particular with regard to pathological conditions of bacterial [4-6], viral [7,8] and fungal etiology [9,10]. Regarding the latter, there is a tendency to changes in the understanding of the etiology and clinical picture of such lesions: the role of mixed infection has increased, widespread, acute inflammatory and eczematized forms have become more widespread [11,12]. This is due to a significant decrease in the body's immune defenses, general population aging, the tendency to population migration, and some iatrogenic factors [1,13,14]. Penetration of fungi into the nail area is preceded by damage or destruction of the structures that limit them. Important factors that precede the penetration of pathogenic mycelium include mechanical injuries to the nail plate, exposure to chemicals (constant contact with synthetic detergents, degreasers, and water), wearing tight, narrow shoes made of synthetic materials (creating a moist and warm environment that promotes the growth and reproduction of fungi), individual characteristics of sweating (with a predominance of the sympathetic type of the vegetative system), various deformations and anatomical

features of the foot (flat feet, narrow interdigital spaces, and the associated poor aeration of the foot), and the speed of regrowth of the nail plates [15,16].

In this regard, many methods of treatment of onychomycosis have been developed - a disease that is, in principle, considered curable. The main principles of treatment of patients with onychomycosis, which are followed by most clinicians, are [17,18]: a method of treatment of onychomycosis based on the etiology, clinical form of onychomycosis and the presence of concomitant pathology; treatment of fungal lesions of several nail plates without involvement of the nail matrix in the pathological process with local antimycotics; treatment of subtotal and total onychomycosis with a long duration of the disease, expressed by hyperkeratosis with the involvement of systemic antimycotics. However, in practice, the treatment of onychomycosis faces a large number of difficulties caused by treatment errors or patient characteristics. Frequent lesions of slowly growing toenails, a long history of the disease, pronounced hyperkeratosis, the presence of contraindications, and concomitant pathology make treatment with both local and systemic drugs ineffective [17].

The goal of our work was to optimize medical care for patients with onychomycosis through the use of therapeutic agents that improve the structure of the nail plates.

Materials and Methods.

The study involved 147 patients with various forms of onychomycosis of the hands and feet aged 23 to 79 years. Patients were divided into two groups: the main and the control group. All patients, after reading the patient's personal sheet, gave written consent to participate in the study. The groups of patients receiving treatment were formed according to the principle of random sampling. Patients in the main group were offered to use a systemic antifungal drug with a drug that contains biotin and improves the structure and speed of nail plate growth. Patients in the control group used only a systemic antifungal drug; patients in both groups were prohibited from using any other antifungal medications. The final basis for inclusion in the study group was obtaining a positive microscopic result of a mycological study. Patients who had received systemic antifungal drugs within the last month or local antifungal drugs within the last week, had contraindications to the use of systemic antifungal drugs, as well as patients receiving corticosteroid and cytostatic drugs, and pregnant women were excluded from participation in the study. Previous treatment of onychomycosis was performed only in 21 patients, and in 17 of them the prescribed therapy was ineffective, and in 4 patients the disease relapsed or re-infection occurred (Table 1).

Mycological examination of patients included microscopic examination of pathological material (pieces of nail fragments) and culture. PCR was performed using a reagent kit with primers to determine the presence of DNA specific to Trichophyton rubrum, and PCR with panfungal primers.

Epiluminescence surface microscopy of affected nail plates was performed using a Dermlite II Pro HR dermatoscope (USA) and an Omnivision video dermatoscope (Korea). Dermatoscopy photographs were taken using a Sony α-58 digital camera, which was connected to the dermatoscope with an adapter ring and a Sony photo adapter, which allowed the use of automatic image analysis systems [19,20].

To assess the degree of nail plate damage by onychomycosis, the nail plate damage index (NPDI), which is calculated by the total number of points of individual clinical structural signs of changes in the nail plates in onychomycosis. The number of points in the range from 0 to 3 was awarded to the selected signs. NPDI was calculated according to seven clinical criteria: a scratched surface, a change in the free edge, nail hyperkeratosis, uneven nail color, the presence of cavities, the presence of tunnels, nail atrophy. The index value in patients with onychomycosis with different degrees of severity of the process was divided into the minimum NPDI – from 1 to 4 points; moderate NPDI – from 5 to 10 points; pronounced degree NPDI – from 11 to 21 points.

Patients were monitored for 16 weeks. Patients in the main study group were prescribed a systemic antifungal drug depending on the type of pathogen (terbinafine for dermatophytic onychomycosis and itraconazole for onychomycosis of other etiology, dosage according to the instructions) and the drug Volvit 5 mg 1 time per day before meals throughout the entire course of treatment with a systemic antifungal drug. Patients in the control group received therapy with a systemic antifungal drug depending on the type of pathogen (terbinafine for dermatophytic onychomycosis and itraconazole for onychomycosis of unknown etiology, dosage according to the instructions) for 6 weeks for onychomycosis of the hands and 12 weeks for onychomycosis of the feet.

The effectiveness of the studied complex was assessed based on the results of clinical and mycological studies. Clinical

Table 1. *Distribution of patients according to clinical and anamnestic data.*

Data	**Patient groups**	
	Main group, (n = 93)	**Control group, (n=54)**
Total number of patients	93	54
Sex:		
- male	47	27
- female	46	27
Age, years	55.7± 1.3	54.1± 2.9
Previous treatment:		
- was held	14	7
- was not held	79	47
Localization of the lesion:		
- feet	61	34
- brushes	10	5
- feet and hands	22	15
Comorbidities*: total	92	39
- varicose veins	20	5
- chronic eczema	6	1
- dyshidrosis	5	3
- candidiasis of large folds	9	1
- psoriasis	12	6
- diabetes mellitus	7	1
- gastrointestinal tract pathology	19	12
- damage to the cardiovascular system	9	9
- chronic diseases of ENT organs	4	2
- genital candidiasis	18	4

Note: * – more than one comorbidity may occur in one patient.

evaluation of the method included assessment of complaints, dynamics of objective manifestations of the disease. Mycological efficacy consisted in the elimination of fungi. To assess the dynamics of nail plate regrowth in patients of both groups, the length of the nail plate was measured using a ruler (from the proximal nail plate to the distal edge) from the beginning of the study and at the second, fourth, sixth, eighth, twelfth and sixteenth weeks of treatment.

All patients were assessed for subjective signs of the disease (itching, pain), data from an objective examination (measurement of the length of the nail plate from the proximal nail plate to the distal end, wetting, hyperemia, peeling, dry skin, cracks) and mycological negativity. Registration of objective signs of nail plate damage before, during and after treatment was carried out according to the following parameters: distal damage, lateral damage, total with involvement of the germinal zone, total without involvement of the germinal zone, subungual hyperkeratosis, onycholysis, change in the growth rate of a healthy nail plate. The severity of the sign was assessed on the following scale from 0 to 3, where 0 is the absence of the sign, 3 is a significant degree of severity. The severity values of individual symptoms before treatment, after 1, 2, 4, 6, 8, 10, 12 weeks, and at the end of therapy (16 weeks) were used to calculate the total values, and then the reduction in their severity was determined by regressive dependence on treatment.

Statistical processing of the obtained results, as well as their graphic display was carried out using the standard Microsoft Excel 2007 application package on a personal computer. In the case of normal distribution, the parametric Student-Fisher method was used. The obtained values of the arithmetic mean (M), the standard deviation (δ), the error of determining the arithmetic mean (m), determined the level of reliability of the differences (p) of the group means, which were compared using the Student test (t). In the case of non-normal distribution of the results, the non-parametric method (Mann-Whitney U-test) was used.

Results.

During the work, it was found that the area of fungal infection in patients of the main and control groups was distributed as follows: in 39 patients (26.5%) half of the nail was affected, and in 39 patients (26.5%) more than half of the nail was affected, less than half of the nail in 29 patients (19.7%), total nail damage in 33 patients (22.5%) and absence of nail plates due to atrophy in 7 patients (4.8%) (Table 2).

Objective examination revealed in 61 patients (41.5%), the distal-lateral form (Table 3), which was diagnosed and began with the appearance of yellowish, gray-brown, or grayish-yellowish spots and stripes in the distal-lateral part of the nail. Over time, the spots spread from the free edge to the root of the nail and to the entire nail plate. In patients with a long history of onychomycosis, the distal-lateral form turned into a total form. This diagnosis was established in 64 patients (43.5%). The nail plates of these patients were dirty-gray in color, thickened, partially or completely destroyed on the free edge. Significant subungual hyperkeratosis was observed.

7 patients (4.8%) had a superficial white form of onychomycosis. In patients with this form of the disease, in the vast majority of cases, the process was localized on the nail plates of the feet, where white spots with clear boundaries appeared, mainly in the proximal parts. Sometimes we observed a total lesion of the nail plate. In these cases, the configuration of the nail was preserved, but superficial destruction of the plate above the spots was noted. The surface of the nail was loose and easily scraped off in the form of a powdery mass.

Table 2. *Distribution of patients by area of nail damage in patients of the studied groups and the average index of nail plate damage by groups.*

Indicator		**Number of patients**	
		Main group, n = 93	**Control group, n = 54**
Area of injury	Less than half of the nail	18	11
	Half a nail	22	17
	More than half of the nail	25	14
	Total nail damage without matrix involvement	19	5
	Total nail lesion involving the matrix	5	4
	Absence of a nail due to atrophy	4	3
Average indicator of NPDI per patient		**10.7 ± 0.3**	**10.8 ± 0.7**

Table 3. *Distribution of patients by the form of nail damage in patients of the studied groups.*

Form of lesion	**Number of patients**	
	Main group, n=93	**Control group, n=54**
Distal-lateral	39	22
Surface white	5	2
Total	41	23
Proximal	8	7

The remaining 15 patients (10.2%) had a proximal form of onychomycosis. In this case, the process began in the proximal part of the nail fold. The proximal subungual form was diagnosed in patients who received previous therapy for onychomycosis. In this case, the nail plates were dirty yellow in color, easily crumbling both from the sides and from the free edge.

Among 147 patients of the studied groups, the results of the conducted cultural study were distributed as follows: positive in 73 (49.7%) patients and negative in 74 patients (50.3%). The majority were pure dermatophyte cultures – in 53 (72.6%) patients, in second place Candida spp. – in 10 patients (13.7%), then mixed dermatophyte-yeast culture – in 6 patients (8.2%), and in last place Aspergillus – in 4 patients (5.5%).

The pathological process was localized on the nail plates of the feet only in a larger number of patients – 92 patients (62.6%), only on the hands – in 18 (12.2%), on the hands and feet – in 37 (25.2%). During the study, it was found that nail lesions on the hands were observed mainly in women. The number of affected nails in the majority of patients (117 – 79.6%), who were under observation, ranged from 3 to 10, and in almost half of the patients from both groups (71 patients – 48.3%) the infection covered 5–7 fingers. Up to four nail plates were affected in 19 patients (12.9%), of which 13.9% of the patients in the main group and 11.1% of the control group. Infected up to 8-10 nail plates were found in 27 patients (18.4%), with a higher percentage (19.4%) of patients belonging to the main group,

and a lower percentage – 16.7% to the control group. Infected more than 10 nails were noted in 30 patients (20.4%), of which 22 (23.7%) patients from the main group and 8 (14.8%) patients from the group receiving only systemic antifungal treatment, including one patient from the main group who had all 20 nails infected.

It should be noted that the duration of the course of dermatosis by the time the patients sought medical help ranged from 2 months to 15 years, of which from 2 months to 1 year in 29 patients (19.7%): in 22.6% of patients in the main group and in 14.8% of patients in the control group. The duration of the disease from 1 to 5 years was observed in almost half of the patients from both groups - 73 (49.7%), of which in 48.4% of patients receiving combination therapy and 51.9% of patients with monotherapy with a systemic antifungal. From 5 to 10 years in 41 patients (27.9%), of which in 24 (25.8%) patients from the main group and 17 (31.5%) patients from the control group. Three (3.2%) patients from the main group and one (1.9%) from the control group had been suffering from onychomycosis for more than 10 years.

With the installation results of NPDI was found that severe duration was observed in 54 patients (58.1%), of which 37 (39.8%) were patients from the main group and 17 (31.5%) were patients from the control group. Moderate severity was observed in 89 patients (60.5%) of both groups (58.1% of patients from the main group and 64.8% of patients from the control group), and only three patients had a minimal severity (2.0%), which was 4 points, but we had to include these patients in the treatment with systemic antifungal drugs, because the nails of 4 toes were involved in the pathological process with manifestations of changes in the free edge and partial distal onycholysis. Average NPDI was at the same level in both groups (Table 2).

Early after treatment, in both the main group and the control group, the most pronounced symptoms were peeling, dryness, and cracks, and the least pronounced were wetting. A week after the start of treatment, there was a slight positive trend in patients in both groups, which concerned only acute inflammatory symptoms. In 5 patients (5.4%) with athlete's foot from the main group who used the study drug (Volvit), itching, hyperemia, and weeping decreased. The manifestations of fresh vesicular elements ceased, the previously existing vesicles and papules flattened and peeled off (Figure 1).

Two weeks after the start of treatment, soreness (subjective manifestation of acute inflammatory process) in patients of the control group decreased by 13.0%, in the main group - by 16.1%. In all patients, symptoms of inflammation (erythema, weeping) significantly decreased. However, in patients of the control group, a slowdown in the resolution of dryness, peeling, and healing of cracks was noted. As for itching, it completely disappeared in 9 patients (16.7%) who received only systemic antifungal and in 17 patients (18.3%) of the main group. Hyperemia of the skin significantly decreased in 18 patients (19.4%) and completely disappeared in 21 patients (22.6%) who received combined therapy. As for patients who took only systemic antifungal, hyperemia decreased in 10 patients (18.5%) and in 10 patients the skin of the feet restored a healthy color. Two patients (3.7%) from this group had significantly pronounced hyperemia. The symptom of peeling gradually disappeared in patients of

Figure 1. *Patient, 46 years old. Diagnosis: Onychomycosis of the feet, total dystrophic form before treatment (a) and one week after the start of treatment (b).*

both groups. In 17 (18.3%) patients from the main group and 9 patients (16.7%) from the control group. A significantly pronounced symptom of peeling remained in 9 patients (9.7%) from the main group and in 8 (14.8%) from the control group. Wetting, as one of the symptoms of inflammation, remained in a weak degree of severity only in three patients (3.2%) from the main group and in 11 patients (20.4%) from the group that received only monotherapy with a systemic antimycotic. Cracks healed after two weeks in 15 patients from the main group and in 2 patients from the control group. The number of patients with manifestations of dryness decreased by 21.5% in the main group and by 18.5% in the control group.

At the 4th-6th week of treatment, there was a complete regression of hyperemia, peeling, dryness, healing of cracks and almost complete (6 patients – 6.5%) regression of subjective signs in patients of the main group and preservation of clinical manifestations (hyperemia, peeling, dryness, healing of cracks) in 11 patients (20.4%) of the control group, by the 8th week of treatment in a weak degree of severity and subjective signs in 9 patients (16.7%): in 4 (7.4%) patients, pain persisted and in 5 (9.3%) patients, itching persisted in a weak degree of severity. As for the oozing, it completely disappeared after 4 weeks in all patients in the main group and at week 6 in all patients who received only a systemic antifungal.

After 8 weeks, in 5 (5.4%) patients of the main group, pain persisted and in 1 (1.9%) patient, itching persisted to a weak

degree, which can be explained by the duration of the existing onychomycosis (12-15 years) and the presence of concomitant pathology in the form of varicose veins in patients, which significantly reduces microcirculation in the peripheral vessels of the lower extremities and thereby reduces the access of the prescribed systemic antifungal and biotin to the blood vessels of the terminal phalanges of the feet. Complete clinical recovery was observed in 87 patients (93.5%). Patients of the control group, then complete regression of clinical signs after 8 weeks occurred in 47 (87.0%) patients, mild itching remained in 7 patients (13.0%). Pain persisted until the 8th week in 4 patients (7.4%) of the control group. Slight hyperemia was noted in 2 patients (3.7%), barely noticeable peeling was in 3 patients (5.6%). Dryness and cracks remained in a weak degree of severity in 8 patients (14.8%).

At the 10th week of treatment, there was a complete regression of clinical symptoms such as itching, soreness, hyperemia, peeling, dryness, and healing of cracks in all 93 patients (100%) receiving combination therapy and an incomplete regression of these clinical manifestations in patients from the group receiving monotherapy with a systemic antifungal due to the preservation of soreness in 2 patients (3.7%), i.e., 52 patients received clinical recovery, which is 96.3%.

In two patients (3.7%) of the control group, pain persisted until week 12 of treatment. This can be explained by the presence of an ingrown nail and long-term hypertrophic onychomycosis in which thick hyperkeratotic masses constantly compressed the nail bed and maintained pain.

The most common clinical manifestations of onychomycosis (hyperkeratosis, onycholysis, nail discoloration, surface deformation, atrophic changes, and the presence of tunnels-cavities in the thickness of the nail plate) make it easy to assess the severity of onychomycosis and investigate the presence of clinical changes in the structure of the affected nail plates. At the beginning of treatment, hyperkeratotic changes were observed in 44 patients (47.3%) of the main group and in 30 patients (55.6%) of the control group. Onycholysis in the form of partial or complete detachment of the nail plates from the nail bed was observed in 26 patients (28.0%) with combined therapy and in 38 patients (70.4%) of the control group. Destruction of the nail plates to their complete absence was observed in 4 patients of the main group and in 3 patients of the control group. Color change was observed in almost all patients of both groups – 96.8% of the main group and 96.3% of the control group. Surface deformation is also a characteristic sign of onychomycosis and at the beginning of treatment it was observed in a weak degree of severity in 41 patients (44.1%), in a moderate degree – in 26 (27.9%), in a significant degree – in 19 patients (20.4%). As for the patients of the control group, the largest number of them had moderate surface deformation in 25 patients (46.3%), then 14 patients (25.9%) with significant changes in the form of transverse and longitudinal striations, there were no surface changes at all in 11 patients. Such a symptom as a change in the free edge was completely absent in 10 patients (18.5%) of the control group and in 24 patients (25.8%) of the main group. The highest percentage – 29.0% of changes among the main group were observed in patients with moderate degree of delamination in 27 patients, absence – in 19 patients (20.0%), and insignificant in the form of slight partial delamination in 23 patients (24.7%). As for the control group, in 10 (18.5%) patients no changes of the free edge were observed, which was characteristic of the clinical picture of the proximal type of nail plate lesion in onychomycosis. Partial delamination was in 16 patients (29.2%), moderate – in 21 patients (38.9%) and its absence was observed in 7 patients (12.9%). Thanks to dermatoscopic examination, we were able to detect longitudinal cavities in the thickness of hyperkeratotic masses, which had varying degrees of severity from thin, short (up to 2 mm) to 5 mm in diameter, which passed from the free edge to the proximal roller. Cavities in the thickness of the nail were detected in a small number of patients in both groups. This symptom was found in 15 patients (16.1%) of the main group and in 8 patients (14.8%) of the control group. Thus, at the beginning of treatment, the most pronounced symptoms were such as changes in color, free edge, surface, and the least pronounced were the destruction of the nail plate and the presence of cavities in the thickness of the nails (Table 4), which can be compared with the condition after 16 weeks (Table 5), when patients had not received antifungal therapy for a month.

In patients with monotherapy with systemic antifungals, clinical recovery occurred in 44 patients, which was 81.5%. Manifestations of hyperkeratosis, atrophy, delamination of 1/3 of the free edge and discoloration remained in 10 patients (18.5%). That is, clinical recovery occurred earlier in patients in the main group by 15.3% compared to the recovery time of patients in the control group.

Before the start of treatment, the main group included patients with different lengths of nail plates unaffected by pathological

Table 4. *Distribution of patients at the beginning of treatment by severity of clinical symptoms*.*

Clinical symptom	**Main group, n=93**				**Control group, n=54**			
	Symptom severity, scores				**Symptom severity, scores**			
	0	**1**	**2**	**3**	**0**	**1**	**2**	**3**
Hyperkeratosis	49	17	12	15	24	10	11	9
Onycholysis	28	20	18	17	16	13	10	15
Atrophy	89	0	2	2	51	0	1	2
Color change	3	38	29	23	2	25	19	8
Surface deformation	7	41	26	19	3	12	25	14
Changing the free edge	24	23	27	19	10	16	21	7
Tunnels in the thickness of the nail	78	6	5	4	46	5	3	1

*Note: * – one patient has more than one clinical symptom.*

Table 5. *Distribution of patients by severity of clinical symptoms 16 weeks after the start of treatment in patients of both groups.*

Clinical symptom	Main group, n=93				Control group, n=54			
	Symptom severity, scores				Symptom severity, scores			
	0*	1	2	3	0*	1	2	3
Hyperkeratosis	93(100)	-	-	-	51(94.4)	3	-	-
Onycholysis	93(100)	-	-	-	54(100)	-	-	-
Atrophy	92(98.9)	1	-	-	52(96.3)	2	-	-
Color change	92(98.9)	1	-	-	52(96.3)	2	-	-
Surface deformation	93(100)	-	-	-	53(98.1)	1	-	-
Changing the free edge	92(98.9)	1	-	-	51(94.4)	3	-	-
Tunnels in the thickness of the nail	93(100)	-	-	-	54(100)	-	-	-

*Note: * – personage of absolutely disappearance of symptom in 16 weeks.*

Table 6. *Distribution of patients depending on the length of the affected nail plates.*

Length of the nail plate not affected by mycelium,* cm	Number of patients			
	Main group, n = 93		Control group, n = 54	
	Abs.	%	Abs.	%
0 – 0.3	9	9.7	7	13.0
0.4 – 0.7	66	71.0	32	59.2
0.8 – 1.0	18	19.3	15	27.8

* – refers to an area of the nail plate without clinical signs of onychomycosis (change in structure, color, etc.).

Table 7. *Dynamics of nail plate regrowth in patients of the main group.*

Weekly	The main group, n = 93	
	Average nail length, cm	Average nail growth, cm
1	0.46 ± 0.02	–
2	0.47 ± 0.02	0.01 ± 0.004
4	0.59 ± 0.02	0.13 ± 0.01
6	0.72 ± 0.02	0.25 ± 0.01
8	0.84 ± 0.02	0.38 ± 0.01
10	0.96 ± 0.02	0.49 ± 0.02
12	1.07 ± 0.02	0.61 ± 0.02
16	1.23 ± 0.02	0.77 ± 0.02

Table 8. *Dynamics of nail plate regrowth in patients of the control group.*

Weekly	Control group, n = 54	
	Average nail length, cm	Average nail growth, cm
1	0.52 ± 0.05	–
2	0.52 ± 0.05	0
4	0.55 ± 0.04	0.03 ± 0.01
6	0.65 ± 0.04	0.14 ± 0.01
8	0.76 ± 0.04	0.25 ± 0.02
10	0.85 ± 0.04	0.33 ± 0.02
12	0.94 ± 0.04	0.42 ± 0.03
16	1.05 ± 0.04	0.53 ± 0.03

mycelium. The largest percentage was patients with a length of 0.4 to 0.7 cm (in 66 patients – 71.0%), the second largest number was patients with a length of 0.8–1.0 cm (in 18 patients – 19.3%), and the smallest percentage was patients (9.7%) with completely absent nail plates (atrophy) in 4 patients (4.3%) and preserved up to 3 mm in 5 patients (5.4%). As for the patients in the control group, the number of patients with different lengths of nail plates not affected by pathological mycelium was distributed as follows: the minimum length was in 13.0% - 7 patients (of which three had completely absent nail plates and four patients had only a small portion preserved), the average length was from 0.4 to 0.7 cm in 32 patients - 59.2%, and 15% were patients with a maximum length of 0.8–1.0 cm (Table 6).

Before the start of treatment, the average length of the nail plate, not affected by mycelium, of patients from the main group who received combination therapy was 0.46±0.02 cm; for patients in the control group who were treated with systemic antifungals only, the average length of the nail plate was 0.52±0.05 cm (p=0.0471). That realised in 0.77 ± 0.02 cm average nail growth for main group when it was 0.53 ± 0.03 cm in control group after 16 weeks (that is 1.4 times faster growth in main group). Data are presented in (Tables 7 and 8).

The dynamics of nail plate regrowth had a positive growth trend in patients of both groups (Figure 2). After 4-6 weeks of treatment the structure of the affected nail plates in all patients improved during the treatment: it acquired a pale pink color, the surface became shiny and smooth, the free edge of the nail plates flattened and thickened. The nails gradually acquired a normotrophic structure. This was especially noticeable in patients with onychomycosis of the hands. At this stage, patients with onychomycosis of the hands stopped the prescribed treatment program.

At week 16, the effectiveness of the treatment was monitored and it was found that in the main group of patients receiving combination therapy, the average nail length was 1.23 ± 0.02 cm, which is 0.16 cm more than in 12 weeks of treatment in their group. The average nail growth after 16 weeks in these patients was 0.77 ± 0.02 cm, which is 0.16 cm more than in the previous 12 weeks of treatment in their group.

At the end of treatment for 16 weeks in patients who used only systemic antifungal therapy, the average nail length was (1.05 ± 0.04) cm, and the average nail growth of these patients was

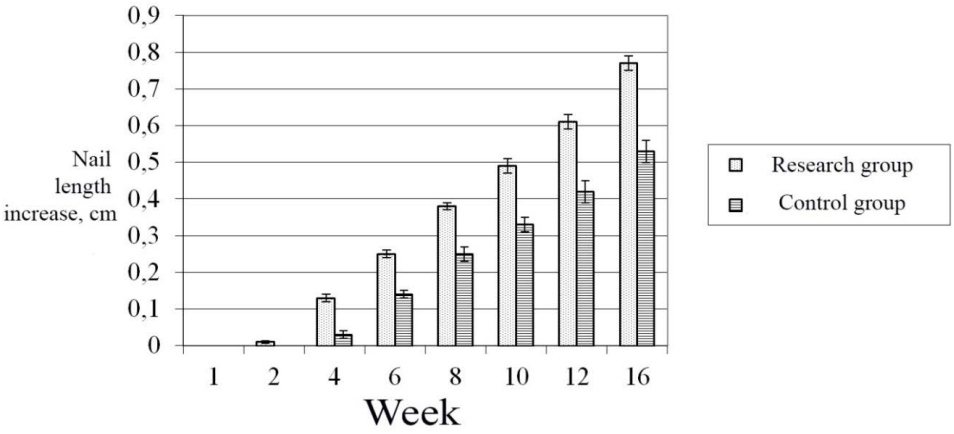

Figure 2. *Comparative dynamics of nail plate regrowth in patients of the studied groups.*

(0.53 ± 0.03) cm, which is 0.11 cm greater than in 12 weeks of treatment in their group (p=0.0482). The dynamics of nail plate regrowth in the process of sanogenesis is 0.18 cm less than the average nail growth in 16 weeks in patients with combined therapy. We associate the decrease in nail regrowth in the last 4 weeks and the nail growth rate in both groups (in patients of the main group - 0.16 cm and 0.11 cm - in patients of the control group) with the withdrawal of therapy.

Discussion.

Qualitatively conducted diagnostic measures allow obtaining the necessary data for choosing treatment tactics in modern medicine [21,22] in various fields [23,24], but classical methods remain relevant [25]. However, the extraordinary conditions of today [26,27] require new ways to solve medical problems of an educational [28], scientific [29] and practical nature [30].

Fungal and viral skin infections are common and typically are managed by family physicians, but can occur in the practice of any doctor, from dentists to gynecologists [31,32]. The success of treatment of patients with onychomycosis is due not only to the effectiveness of eliminating the pathogen, but also to the speed of regrowth of the nail plate and the normalization of its structure. Therefore, our proposal to include a drug containing biotin in the therapeutic complex, which improves the structure of the nail plate and increases the speed of its growth, is considered appropriate, and the results of the work confirm this.

Usually, local therapy used in the initial stages of the distal-lateral form of onychomycosis; in the superficial white form of onychomycosis; in the case of damage to less than half of the nail; in the case of the duration of the disease up to 5 years; in the presence of contraindications to systemic therapy [33]. It is believed that local therapy of onychomycosis allows you to create such a high concentration of the antifungal drug on the surface of the nail plate, which is impossible to create with its systemic administration, because this would cause a toxic effect on the patient's body. The main advantage of local therapy of onychomycosis is the absence of side and toxic effects observed with the use of systemic drugs. However, when applying the drug to the surface of the nail plate, it does not always reach the pathogen - the pathogenic fungus located in the nail bed, and even more so in the matrix. Therefore, local treatment of onychomycosis is always carried out in two stages: first, the affected parts of the nail are removed, then antifungal drugs are applied [34,35].

The more frequent nail damage in women, which was established in the course of our work, can be associated with the socio-domestic characteristics of women's lives (frequent contact with detergents, nail trauma during housework, etc.), as well as the fact that women often visit manicure rooms and infect their nails there. Almost all of our elderly patients noted a long duration of the disease, which usually proceeded in a latent form without any or minimal subjective symptoms. These patients were often forced to consult a doctor by an exacerbation of a pathogenetically significant concomitant pathology or the appointment of antibiotics, steroids, cytostatics for the treatment of intercurrent diseases, which contributed to the generalization and exacerbation of the mycotic process.

During the study, we noted the resistance of clinical symptoms to the prescribed monotherapy in patients with total forms of onychomycosis, which directly indicates the insufficiency of systemic antifungal therapy alone and the need to add a vitamin preparation containing biotin, which has a positive effect on the structure of the skin and its appendages (hair, nails) and a positive effect on the growth rate of nail plates [36,37].

Our work confirms published early data [36,37] that combination of biotin with other medicine is associated with further clinical improvement and has crucial perspective for implementation. Simultaneously our research has more patients with wide age range and wider spectrum of objective examination which prove that fresh hypotheses with significantly more detailed description of nail changes.

Despite more pronounced part of patients with comorbidities (Table 1) such as varicose veins, chronic eczema, psoriasis, genital candidiasis in main group suggested treatment realised in better outcome of therapy. Future selection of such patients in separate group with direct comparison and detection of influence named pathology in antifungal therapy could be one of possible development of suggested idea with better dynamics of nail plate regrowth in patients of the studied groups (Figure 1). That our result insists one more time for necessity to select optimal combination of medicine for treatment in case of comorbidities [5,38] and when one of pathology is infectious especially [6,13].

The characteristic signs of fungal nail lesions detected by dermatoscopic examination were a scratched surface, changes

in the free edge and color, onycholysis, the presence of cavities (tunnels) in the thickness of the nail plate, hyperkeratosis, partial or complete atrophy, which corresponds to both our previously published results [39] and literature sources [40,41]. Assessment of their severity makes it possible to assess the severity of the lesion and the dynamics of nail plate rehabilitation during treatment.

Conclusion.

A comprehensive method of treating patients with onychomycosis involving both antifungal agents and agents that improve the structure of the nail plates and accelerate their regrowth provides mycological elimination and a positive clinical outcome in patients: achieving mycological remission at 10-12 weeks in 89.1% of patients with comprehensive treatment, which is 19.5% more than in patients with traditional treatment; shortens the time and, accordingly, reduces the risk of side effects from long-term systemic antifungal therapy. The developed method ensures the restoration of the normal structure of the nail plate in 96.8% of patients (respectively, in 81.5% of patients using traditional treatment).

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Conflict of interest statement.

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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