GEORGIAN MEDICAL NEWS

ISSN 1512-0112

NO 1 (358) Январь 2025

ТБИЛИСИ - NEW YORK

ЕЖЕМЕСЯЧНЫЙ НАУЧНЫЙ ЖУРНАЛ

Медицинские новости Грузии

საქართველოს სამედიცინო სიახლენი

GEORGIAN MEDICAL NEWS

Monthly Georgia-US joint scientific journal published both in electronic and paper formats of the Agency of Medical Information of the Georgian Association of Business Press. Published since 1994. Distributed in NIS, EU and USA.

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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No 1 (359) 2025

Содержание:

GEORGIAN MEDICAL NEWS
No 1 (358) 2025

DIAGNOSTIC MANAGEMENT OF PATIENTS WITH ONYCHOMYCOSES

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Abstract.

Introduction: Onychomycosis is a fungal infection of the nail, causing discoloration and thickening of the affected nail plate, and is the most common nail infection worldwide. Microscopy and fungal culture are the gold standard techniques for onychomycosis diagnosis. At the same time, the culture method is long-term and requires significant costs. In this regard, a promising direction in laboratory diagnostics of onychomycosis is the detection of genetic markers of onychomycosis pathogens using polymerase chain reaction. The goal of current work is optimization of diagnostic care for patients with onychomycosis through the use of PCR, epiluminescent diagnostics and therapeutic agents that improve the structure of nail plates.

Material and methods: The work is based on the results of observations of 343 patients with fungal lesions of the nails of the hands and feet, which were on inpatient and outpatient treatment, as well as data from laboratory and instrumental studies. Mycological examination of patients included microscopic examination of pathological material (pieces of nail fragments) and cultural study. 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.

Results: After calculations using standard methods, it was determined that the sensitivity for PCR is 91.9%, for microscopy – 75.9%, for culture – only 44.3%. The specificity for PCR is 71.4%, for microscopy – 83.3%, for culture – 100.0%. The diagnostic accuracy rate for PCR was 90.3%, for microscopy – 76.3%, and for culture – 47.3%. The higher the sensitivity of the method, the more often pathological changes are detected with their help, and accordingly, the more effective it is. The excess of PCR sensitivity rates compared to microscopy by 16.0% and culture by 47.6% and the high specificity rate (71.4%) indicate the possibility of increasing the detection of patients with onychomycosis through the use of the molecular method of research.

Conclusions: The proposed algorithm for managing patients and a comprehensive method of treating patients with onychomycosis, involving both antifungal agents and drugs, contributes to obtaining a timely diagnosis and prescribing therapy aimed at improving the structure of the nail plates.

Key words. Onychomycosis, diagnostic management.

Introduction.

Human fungal infections are widely observed not only as opportunistic in patients with AIDS [1-3], they are a historically neglected area of disease research, yet they cause more than 1.5 million deaths every year [4]. Onychomycosis is a fungal infection of the nail, causing discoloration and thickening of the affected nail plate, and is the most common nail infection worldwide [5]. Microscopy and fungal culture are the gold standard techniques for onychomycosis diagnosis, but high false-negative rates have pushed for more accurate methods, such as histology and polymerase chain reaction (PCR) [5]. At the same time, the culture method is long-term and requires significant costs. In this regard, a promising direction in laboratory diagnostics of onychomycosis is the detection of genetic markers of onychomycosis pathogens using polymerase chain reaction, which will allow in a short time (within 24 hours) to obtain a highly specific result, the sensitivity of which is expected to be about 90-98%.

The use of molecular genetic methods for detecting pathogens of mycoses using specific primers will expand the possibilities for diagnosing onychomycosis in complex cases and thereby prescribe adequate antifungal therapy earlier, reduce the severity of the lesion, the development of complications, and accelerate the recovery process [6].

Other diagnostically important direction connected with morphological visualisation of variable pathological processes [7-13] but is not always possible to track morphological changes in the nail plates during visual examination of patients. Therefore, at the present stage, it is necessary to involve hardware research methods (dermatoscopy) to identify the first early characteristic signs and structural changes in the nail plates affected by the mycelium to assess the severity of onychomycosis and prescribe timely adequate therapy. Rapid regrowth of the nail plates accelerates mycological elimination and improves the clinical effectiveness of complex therapy, reduces the risk of side effects and reactions due to prolonged antifungal therapy [14]. Therefore, the development and use of complex methods of treatment of onychomycosis with the involvement of both antifungal drugs and pathogenetic agents that improve the regrowth and structure of the nail plates is relevant in modern dermatology.

The goal of our work is optimization of diagnostic care for patients with onychomycosis through the use of PCR, epiluminescent diagnostics and therapeutic agents that improve the structure of nail plates.

Materials and Methods.

The work is based on the results of observations of 343 patients with fungal lesions of the nails of the hands and feet, which were on inpatient and outpatient treatment, as well as data from laboratory and instrumental studies. Mycological examination of patients included microscopic examination of pathological

material (pieces of nail fragments) and cultural study. 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 were 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.

Statistical processing of the obtained results, as well as their graphic display were 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.

To develop a method for dermatoscopic examination of nail plates and determine the main clinical signs of fungal nail plate lesions, 160 people were examined and epiluminescent nail plate studies were performed. Of these, 138 patients with onychomycosis (diagnosis confirmed by microscopic examination and PCR): 79 (57.2%) women and 59 (42.8%) men, 32 people without clinical signs of nail plate mycelium lesions and negative microscopy and PCR results, of which 18 (56.3%) women and 14 men (43.7%). In the course of the study, a total of 2583 dermatoscopic images of nail plates were taken, of which 1943 images of nail plates affected by mycelium and 640 images of nails without fungal infection were analysed. Using the developed method of examining the nail plates, out of 138 patients, 35 patients (25.4%) showed only the initial manifestations of the introduction of a fungal infection into the nail plate, 10 patients (7.2%) showed signs of total lesion with matrix involvement, 38 (27.5%) showed signs of total lesion without matrix involvement, and 55 (39.9%) patients accounted for the majority with distal-lateral lesions. Particular attention was paid to patients with mycoses of the hands and feet, rubromycosis of smooth skin, since they are mostly at risk of spreading mycotic infection from the skin to the nail plates. Therefore, using dermatoscopy, 13 patients in this group received confirmation of the first changes in the nails, which remained unnoticed by doctors during visual examination of the nail plates, when the microscopic examination was still negative. Analysis of the obtained dermatoscopic images allowed to highlight the main dermatoscopic signs of a healthy nail plate, to determine the expected places of occurrence of pathological changes and to organize the main changes of the nail plates that are often found. The nail plate without any pathological changes has a pale pink or pale beige color, a flat, smooth, shiny surface without longitudinal or transverse striations, the presence of a free edge of the nail plates, a thickness of 1.0 to 1.5 mm in an adult on the hands and from 1.2 to 2.5 mm on the feet, preservation of its structure and density. Dermatoscopic examination of the nail plates allowed to highlight the main pathological changes of the nails, which can be divided into changes in the structure of the nail plates due to mechanical or chemical trauma; changes in the structure of the nail plates due to the presence of chronic dermatoses (psoriasis, lichen planus, eczema, scleroderma, etc.); changes in the structure of the nail plates when affected by a mycotic infection; changes in the color of the nail plate (congenital pigmentation disorders, bacterial infection); the appearance of formations of melanocytic genesis (nevi, melanoma); the appearance of formations of non-melanocytic genesis, which include warts, pyogenic granuloma, myxoid pseudocyst; vascular changes in the form of hemorrhages and changes in the vessels of the nail beds; changes in the nail plates due to acute somatic diseases.

Analysis of the results of standard methods for diagnosing onychomycosis (nail plate microscopy, culture) and the complexity of the developed PCR analysis using specific and panfungal primers was carried out in the study of 196 patients, of whom 166 complained of nail plate lesions and 30 patients without complaints of nail lesions and clinical manifestations of onychomycosis and with a negative microscopy result. Among the examined patients, there were 86 (43.9%) men and 110 (56.1%) women aged 23 to 79 years, the average age was 51.0± 0.7 years.

According to the results of microscopic studies of 166 patients, positive results were obtained in 67, which is 40.4%, the results of cultural sowing were even lower: 39 positive results were obtained, which is 23.5% of those examined. When studying 30 samples of nail plates of healthy individuals using standard research methods, negative results were obtained.

Using the PCR test specific for T. rubrum and the PCR test with panfungal primers, 166 patients with nail pathology were examined. The PCR result was positive in 81 patients, which is 48.8%. That is, PCR increases the detection of onychomycosis by 8.4% compared to single microscopy and by 25.3% compared to single culture, regardless of the type of fungus isolated. Analysis of the etiological structure of onychomycoses, carried out using PCR diagnostics and culture, showed a significant percentage similarity of both methods in identifying pathogens and the predominance of dermatophytes, especially T. rubrum among all detected pathogens (75.3% with PCR and 64.1% - by culture).

After calculations using standard methods, it was determined that the sensitivity for PCR is 91.9%, for microscopy – 75.9%, for culture – only 44.3%. The specificity for PCR is 71.4%, for microscopy – 83.3%, for culture – 100.0%. The diagnostic accuracy rate for PCR was 90.3%, for microscopy – 76.3%, and for culture – 47.3%. The higher the sensitivity of the method, the more often pathological changes are detected with its help, and accordingly, the more effective it is. The excess of PCR sensitivity rates compared to microscopy by 16.0% and culture by 47.6% and the high specificity rate (71.4%) indicate the possibility of increasing the detection of patients with onychomycosis through the use of the molecular method of research. Analysis of these data allowed us to propose a new algorithm for laboratory verification of onychomycosis. The proposed scheme of the new algorithm for the diagnosis of onychomycosis is shown in Figure 1.

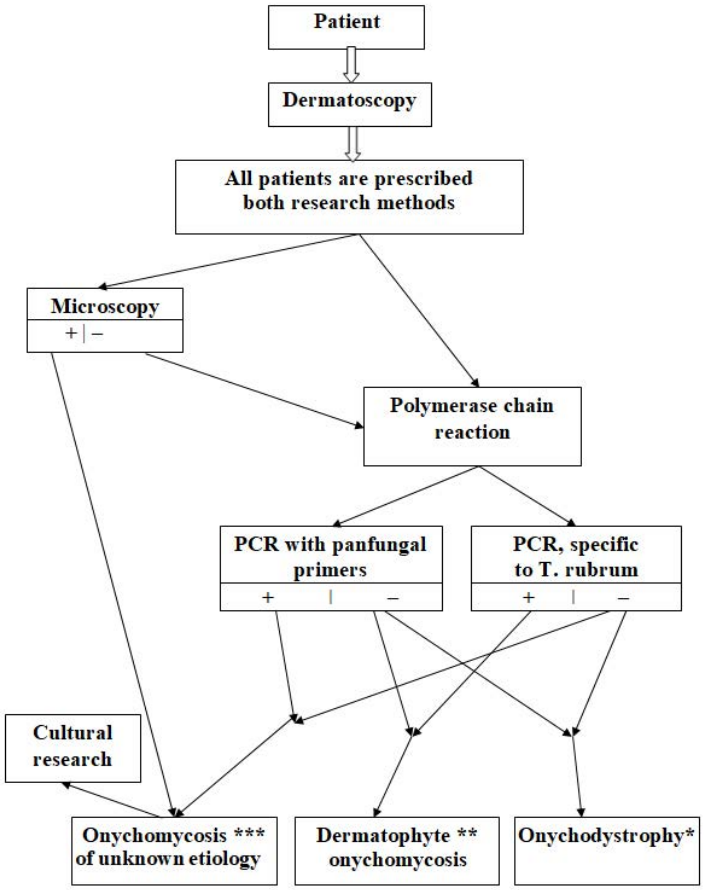

Figure 1. *New algorithm for laboratory diagnosis of onychomycosis.*

Note: **) re-examination is necessary; **) it is advisable to use terbinafine for treatment; ***) to clarify the nature of the pathogen, a culture study may be performed; in therapy, it is necessary to use broad-spectrum drugs (itraconazole).*

Discussion.

Onychomycosis is the most prevalent nail disease, representing nearly half of all clinically diagnosed onychopathies. Given the pervasive nature of the disease and that successful treatment depends on the proper identification of the causative organism, accurate and reliable methods of diagnosis are necessary [14]. The diagnosis of onychomycosis can be done easily for first point of view. One common method is to send a nail clipping to a laboratory for a pathologist to examine with a microscope where they can see the fungi within the nail. Another common method to diagnose onychomycosis is with a fungal culture. This is done by lightly scraping material from under the nail and sending it to a laboratory. It is a good idea to have testing done to make sure that the diagnosis is correct, because other nail problems can look similar to onychomycosis [15]. Nondermatophyte onychomycosis account for 2% to 12% of all nail fungal infections and can be caused by a wide range of fungi, mainly *Scopulariopsis brevicaulis, Aspergillus versicolor, A. flavus, A. niger, A. fumigatus, Fusarium solani, F. oxysporum and Scytalidium spp*. Among the predisposing factors are footwear, hyperhidrosis, local trauma, peripheral circulatory disease, and immunosuppression [16]. So, confirmation of fungal origin of onychopathy by mycological examination is essential [17].

The proposed algorithm allows you to diagnose onychomycosis, its etiology, and begin specific treatment within 24 hours.

A positive result of microscopy and a positive result of PCR specific for T. rubrum within 24 hours confirms the diagnosis of dermatophyte onychomycosis and becomes a recommendation for the appointment of therapy specific for dermatophytes (terbinafine).

A positive result of microscopy, a negative result of PCR specific for T. rubrum, and a positive result of PCR with panfungal primers confirms the diagnosis of onychomycosis and may be a recommendation for the appointment of systemic therapy with a broad-spectrum drug (itraconazole).

A negative result of microscopy and PCR specific for T. rubrum and a positive result of PCR with panfungal primers confirms the diagnosis of onychomycosis and can serve as a recommendation for the appointment of systemic therapy with a broad-spectrum drug (itraconazole). Negative results of microscopy and PCR analysis within 24 hours allow to exclude the diagnosis of onychomycosis of any etiology. Therefore, the new algorithm for laboratory diagnosis of onychomycosis using PCR provides the following: PCR can be performed as a method of laboratory diagnosis of onychomycosis of any etiology; PCR can be performed as a method of diagnosis of dermatophyte onychomycosis, allowing to establish or exclude this diagnosis in nail pathology within 24 hours; it is optimal to perform PCR simultaneously with microscopy, while the need for culture can be excluded.

The success of treating 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, it was considered appropriate 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.

The assessment of the effectiveness of treatment should be carried out on the basis of the results of clinical studies, the dynamics of nail plate regrowth and the results of mycological studies. Clinical evaluation of the method includes the assessment of complaints, the dynamics of objective manifestations of the disease. Mycological effectiveness consisted in the elimination of fungi.

In addition to assessing the subjective signs and symptoms of the acute inflammatory process, it is necessary to assess objective changes in the nail plates before the start of treatment and during therapy using epiluminescent diagnostics. It is necessary to pay attention to 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); due to their presence, it is easy to assess the severity of onychomycosis and investigate the presence of clinical changes in the structure of the affected nail plates.

Our results could be compared with other research were diagnosis of onychomycosis was histology was detected as the most sensitive single test for the diagnosis of onychomycosis, although its sensitivity (80.8%) but was not statistically different from smear (76.5%) [18]. Both histology and smear were significantly more sensitive than culture (53.2%). The most sensitive combination of tests, smear plus histology, was 97.8% sensitive with 98% negative predictive value [18].

In other work meta-analysis of the utility of culture, biopsy, and direct KOH examination for the diagnosis of onychomycosis was performed [19] to evaluate the diagnostic validity, performance, and accuracy of culture, nail clipping with Periodic Acid-Schiff (PAS)-staining (biopsy), and direct potassium hydroxide (KOH) examination for the study of onychomycosis and detected that values are lower for KOH and culture and higher for biopsy in moderate quality studies [19]. Periodic Acid-Schiff (PAS)-staining relates to classical methods [20,21] that a commonly used ancillary test for inflammatory and infectious dermatoses, yet infrequently changes the diagnosis [22,23]. Current appropriate use criteria from the American Society of Dermatopathology supports PAS staining when histopathologic features could be consistent with a dermatophyte infection [22] when other methodologies are limited.

So, despite the technical advantages of the traditionally used tests for the detection of the causative agents, none can be considered as a standard test alone from the viewpoint of their diagnostic utility for onychomycosis [24,25] as for other diseases connected with contamination. Therefore, several criteria are typically used for diagnostic validity studies because their simultaneous use can increase the sensitivity and specificity as we suggest in current work.

Conclusion.

The proposed algorithm for managing patients and a comprehensive method of treating patients with onychomycosis, involving both antifungal agents and drugs, contributes to obtaining a timely diagnosis and prescribing therapy aimed at improving the structure of the nail plates.

Funding: This research received no external funding

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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