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EVALUATION OF THE EFFECTIVENESS OF THE TREATMENT OF ONYCHOMYCOSIS OF THE FOOT IN HIV-INFECTED PEOPLE ON THE BACKGROUND OF ANTIRETROVIRAL THERAPY

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The aim of this study was to evaluate the effectiveness of treatment of onychomycosis of the feet in HIV-infected patients depending on the effectiveness of antiretroviral therapy (ART).

Patients and methods. *96 HIV-infected patients with onychomycosis of the feet were under observation.*

The diagnosis of HIV infection was established according to the International Classification of Diseases of the 10th revision (ICD-10) and verified by the detection of specific serological and molecular biological markers of HIV. The number of CD4⁺-lymphocytes and viral load (copies/ml) were recorded in all patients.

Considering the effectiveness of ART, HIV-infected patients with onychomycosis of the feet were divided into four groups. Group I included patients with virological and immunological ART success; to the II group – patients with a decrease in viral load without an increase in the number of CD4⁺-lymphocytes or with an increase in the level of CD4⁺>500 cells/μl without a decrease in viral load; to the III group – patients with an immunological response, but without a decrease in the viral load; to IV group – persons with virological and immunological failures of ART. Thus, 30 people were under observation in the 1st group; in the II group – 20; in the III group – 11; in the IV group – 35 patients.

From the systemic antifungal therapy, HIV-infected patients of the I group received terbinafine 250 mg per day for 12 weeks. Patients of the II group received itraconazole 200 mg 2 times a day according to the scheme of pulse therapy on the 1st, 5th and 9th weeks of treatment. In groups III-IV, patients were prescribed fluconazole at a dose of 150 mg once a week for 6 months.

The results. *On the 6th month of observation, the effectiveness of antifungal therapy for onychomycosis of the feet in patients with virological and immunological successes of antiretroviral therapy was significantly higher than in patients with virological and immunological failures of antiretroviral therapy ($p<0.01$).*

At the 12th month of observation, the mycological, clinical and full effectiveness of antifungal therapy for onychomycosis of the feet was statistically significantly higher in the case of virological and immunological success of antiretroviral treatment, compared to the group of patients in whom such a result of etiotropic therapy of HIV infection could not be achieved ($p<0.01$).

Conclusions. *Evaluation of the effectiveness of antifungal therapy for onychomycosis of the feet in HIV-infected patients in groups formed depending on the effectiveness of antiretroviral treatment showed the best results in the group with a successful option of using antiretroviral drugs and the worst in the group with a negative result of such treatment. In representatives of the group with a lack of positive dynamics of one of the indicators (viral load or the number of CD4⁺-lymphocytes), the combined therapy of onychomycosis of the feet showed intermediate results.*

Keywords: *HIV infection; mycoses of the skin and its applications; antiretroviral therapy.*

Cutaneous mycoses and mycoses of skin appendages remain a relevant global health problem, primarily due to the tendency toward worldwide spread involving various age groups of the population. Mycoses occupy leading positions in the structure of dermatoses of different origins, second only to pyodermas in prevalence. The current situation is mainly associated with an increase in the number of patients with secondary immunodeficiency states, which develop under the influence of physical and chemical factors (ionizing radiation, immunosuppressive therapy, chemotherapy), modern lifestyle conditions (physical inactivity), nutritional disorders, autoimmune diseases, malignant neoplasms, defects of neurohumoral regulation

(stress), intoxications, infectious diseases, as well as natural physiological processes occurring in the human body (advanced age, pregnancy) [1].

In the context of HIV infection, mycoses represent a major cause of morbidity and mortality [2, 3]. In most cases, fungal infections in HIV-infected patients manifest as dermatomycoses [4, 5]. At the AIDS stage, mycoses of the skin and its appendages are observed in 46–80 % of cases [6, 7].

Timely diagnosis and treatment of cutaneous mycoses in HIV-infected patients are of critical importance, as failure to eliminate the pathogen leads not only to its further dissemination but also to the development of fungal sensitization, toxic-allergic reactions, and impairment of local immune defenses. In addition, this contributes to the development of mixed infectious skin lesions due to activation of opportunistic microflora [8, 9].

The diversity of nosological forms of mycoses of the skin and its appendages in HIV-infected patients necessitates further in-depth investigation of each individual form, with determination of their etiological and clinical characteristics. In the era of widespread use of antiretroviral therapy (ART), it is particularly relevant to assess its impact on the etiological and clinical features of various nosological forms of cutaneous mycoses and mycoses of skin appendages in HIV-infected patients.

The aim of the study was to evaluate the effectiveness of treatment of onychomycosis of the feet in HIV-infected patients depending on the effectiveness of antiretroviral therapy (ART).

Patients and Methods

A total of 96 HIV-infected patients with onychomycosis of the feet were enrolled in the study. The patients were aged 23 to 59 years (mean age 40.6±2.1 years), including 54 men and 42 women.

The diagnosis of HIV infection was established in accordance with the International Classification of Diseases, 10th Revision (ICD-10), and confirmed by the detection of specific serological and molecular biological markers of HIV. For preliminary HIV diagnosis, immunochemical and enzyme-linked immunosorbent assay (ELISA) test systems were used to detect antigen–antibody complexes in blood serum. In all patients, CD4+ T-lymphocyte counts and plasma HIV viral load (copies/mL) were measured.

Depending on the effectiveness of ART, HIV-infected patients with onychomycosis of the feet were stratified into four groups. Group I included patients with both virological and immunological success of ART. Group II comprised patients with a decrease in viral load without a concomitant increase in CD4+ T-lymphocyte count, or an increase in CD4+ T-lymphocyte count (>500 cells/μL) without a decrease in viral load. Group III included patients with an immunological response in the absence of virological suppression. Group IV consisted of patients with both virological and immunological failure of ART. Accordingly, Group I included 30 patients, Group II – 20 patients, Group III – 11 patients, and Group IV – 35 patients.

Etiotropic antifungal therapy consisted of systemic and topical antimycotic agents combined with instrumental nail debridement. Based on published data demonstrating the high efficacy, safety, and accessibility of combination therapy for onychomycosis [10–12], all 96 HIV-infected patients received combined systemic (terbinafine, itraconazole, or fluconazole) and topical antifungal treatment.

When selecting a systemic antifungal agent, primary consideration was given to the type of causative pathogen; therefore, different antifungal drugs were preferred across the four groups formed according to ART effectiveness. In Group I, in which only dermatophytes were isolated, terbinafine was prescribed as systemic therapy at a dose of 250 mg once daily for 12 weeks. In Group II, where yeasts (Candida spp.) predominated, and less frequently non-dermatophyte filamentous fungi, dermatophytes, and mixed infections were identified, patients received itraconazole at a dose of 200 mg twice daily using a pulse-therapy regimen during weeks 1, 5, and 9 of treatment. In Groups III and IV, where non-dermatophyte filamentous fungi predominated, with yeasts (Candida spp.) and mixed infections detected less frequently, fluconazole was administered at a dose of 150 mg once weekly for 6 months.

Topical treatment methods included application of a nail lacquer (5 % amorolfine) once weekly to the affected nail plate until complete nail regrowth, as well as instrumental nail debridement performed prior to initiation of therapy and subsequently at intervals of once every 6 weeks.

Statistical analysis was performed using Pearson's χ^2 test, Fisher's exact test, and Student's t-test. Data processing was carried out using Microsoft Windows, Word, and Excel, as well asSTATISTICA software, version 6.1.

Results and Discussion

The etiological agents of onychomycosis of the feet differed among the study groups. In Group I, onychomycosis was caused exclusively by dermatophytes. In Group II, dermatophytes, yeasts, non-dermatophyte filamentous fungi, and mixed infections were identified, with a predominance of yeasts. In Group III, dermatophytes, yeasts, non-dermatophyte filamentous fungi, and mixed infections were also detected, with mixed infections being the dominant form. In Group IV, yeasts, non-dermatophyte filamentous fungi, and mixed infections were identified, with a predominance of non-dermatophyte filamentous fungi (Table 1).

Table 1

Characteristics of onychomycosis of the feet in the study groups (etiological spectrum and clinical forms)

Indicator	Group I (n=30)	Group II (n=20)	Group III (n=11)	Group IV (n=35)
Clinical forms of onychomycosis	DLSO (n=28) WSO (n=2) PSO (n=0) TDO (n=0)	DLSO (n=6) WSO (n=4) PSO (n=9) TDO (n=1)	DLSO (n=4) WSO (n=1) PSO (n=5) TDO (n=1)	DLSO (n=2) WSO (n=0) PSO (n=1) TDO (n=32)
Etiological agents of onychomycosis	Dermatophytes (n=28) Yeasts (n=0) Non-dermatophyte filamentous fungi (n=0) Mixed infection (n=0)	Dermatophytes (n=1) Yeasts (n=14) Non-dermatophyte filamentous fungi (n=26) Mixed infection (n=0)	Dermatophytes (n=2) Yeasts (n=3) Non-dermatophyte filamentous fungi (n=1) Mixed infection (n=5)	Dermatophytes (n=0) Yeasts (n=2) Non-dermatophyte filamentous fungi (n=25) Mixed infection (n=8)

Note: DLSO – distal lateral subungual onychomycosis; WSO – white superficial onychomycosis; PSO – proximal subungual onychomycosis; TDO – Total dystrophic onychomycosis.

Onychomycosis of the feet in the study groups was represented by the following clinical forms: In Group I, distal lateral subungual onychomycosis and white superficial onychomycosis were observed, with a marked predominance of the former. In Groups II and III, distal lateral subungual, white superficial, proximal subungual, and total dystrophic onychomycosis were identified. Proximal subungual onychomycosis predominated in Group II, whereas total dystrophic onychomycosis was the dominant form in Group III. In Group IV, total dystrophic onychomycosis was most commonly diagnosed, while distal lateral subungual and proximal subungual onychomycosis were detected only in isolated cases.

As part of systemic antifungal therapy, HIV-infected patients in Group I received terbinafine at a dose of 250 mg once daily for 12 weeks. Patients in Group II were treated with itraconazole at a dose of 200 mg twice daily according to a pulse-therapy regimen during weeks 1, 5, and 9 of treatment. In Groups III and IV, patients were prescribed fluconazole at a dose of 150 mg once weekly for 6 months.

Terbinafine is an allylamine antifungal agent with a broad spectrum of activity against fungal infections of the skin, hair, and nails caused by dermatophytes such as Trichophyton (e.g., T. rubrum, T. mentagrophytes, T. verrucosum, T. tonsurans, T. violaceum), Microsporum (e.g., Microsporum canis), Epidermophyton floccosum, as well as yeasts of the genus Candida (e.g., Candida albicans) and Pityrosporum. At low concentrations, terbinafine exhibits fungicidal activity against dermatophytes, molds, and certain dimorphic fungi. Its activity against yeasts may be either fungicidal or fungistatic, depending on the species.

Terbinafine specifically interferes with an early stage of sterol biosynthesis in the fungal cell. This results in ergosterol deficiency and intracellular accumulation of squalene, leading to fungal cell death. The mechanism of action of terbinafine is mediated through inhibition of the enzyme squalene epoxidase in the fungal cell membrane. When administered orally, the drug accumulates in the skin at concentrations sufficient to exert a fungicidal effect [13].

Itraconazole is a synthetic antifungal agent belonging to the triazole class. It has a broad spectrum of activity, mediated by disruption of ergosterol synthesis, a key component of fungal cell membranes, through inhibition of lanosterol 14α-demethylase, a cytochrome P450-dependent enzyme. It is active against dermatophytes (Trichophyton spp., Microsporum spp., Epidermophyton floccosum), yeasts including Candida spp. (e.g., C. albicans, C. glabrata, C. krusei), molds (Cryptococcus neoformans, Aspergillus spp., Histoplasma spp., Paracoccidioides brasiliensis, Sporothrix schenckii, Fonsecaea spp., Cladosporium, Blastomyces dermatitidis), and several other microorganisms [14].

Fluconazole is another triazole antifungal agent with potent activity against fungi, specifically inhibiting fungal sterol synthesis. Its mechanism targets fungal cytochrome P450-dependent enzymes. Fluconazole is active against various Candida spp. strains (including those causing systemic candidiasis), Cryptococcus neoformans (including central nervous system infections), and Microsporum spp. It is also effective against pathogens of endemic mycoses, including Blastomyces dermatitidis, Coccidioides immitis (including CNS infections), and Histoplasma capsulatum [15].

The effectiveness of antifungal therapy was assessed through clinical examination and mycological evaluation at 6 and 12 months after initiation of treatment. Mycological cure of onychomycosis of the feet was defined as negative results on both microscopy and culture. Clinical cure corresponded to the appearance of healthy nails. Complete

cure was defined as achieving both mycological and clinical cure.

At the 6-month follow-up, treatment outcomes in HIV-infected patients were as follows: in Group I, mycological cure was achieved in 22 patients (73.3±8.1 %), and clinical and complete cure in 20 patients (66.7±8.6 %); in Group II, mycological cure was observed in 12 patients (60.0±11.0 %), and clinical and complete cure in 10 patients (50.0±11.2 %); in Group III, mycological cure was recorded in 6 patients (54.5±15.0 %), clinical cure in 5 patients (45.0±15.0 %), and complete cure in 4 patients (36.4±14.5 %); in Group IV, mycological cure was achieved in 13 patients (37.1±8.2 %), and clinical and complete cure in 11 patients (31.4±7.8 %).

Importantly, the efficacy of antifungal therapy for onychomycosis of the feet was significantly higher in patients with both virological and immunological success of ART compared to those with virological and immunological failure (p<0.01, Table 2)

At the 12-month follow-up, the following outcomes of antifungal therapy were observed in HIV-infected patients. In Group I, mycological cure was achieved in 23 patients (76.7±7.7 %), while clinical and complete cure were observed in 21 patients (70.0±8.4 %). In Group II, mycological cure was diagnosed in 13 patients (65.0±10.7 %), and clinical and complete cure in 11 patients (55.0±11.1 %). In Group III, mycological cure was recorded in 7 patients (63.6±14.5 %), clinical cure in 6 patients (54.5±15.0 %), and complete treatment effectiveness in 5 patients (45.5±15.0 %). In Group IV, mycological eradication was achieved in 15 patients (42.9±8.4 %), while clinical and complete cure were observed in 12 patients (34.3±8.0 %). Statistical analysis demonstrated a significant dependence of treatment effectiveness for onychomycosis of the feet in HIV-infected patients on ART outcomes (Table 2). Specifically, mycological, clinical, and complete effectiveness of antifungal therapy was significantly higher in patients with virological and immunological success of antiretroviral treatment compared with those in whom such outcomes of etiological HIV therapy were not achieved (p<0.01, Table 3).

We demonstrated that even in the presence of an undetectable viral load, the clinical presentation of onychomycosis in HIV-infected patients differs significantly from that observed in seronegative individuals. According to some authors, more than 30% of patients with HIV infection develop onychomycosis at CD4+ T-lymphocyte counts of approximately 500 cells/mm³ [16]. In HIV-infected patients, impaired cell-mediated immune responses facilitate local fungal invasion; therefore, lesions may be atypical, extensive, and more severe compared with those

Table 2

Effectiveness of antifungal therapy for onychomycosis of the feet in different groups of HIV-infected patients at the 6-month follow-up

Treatment effectiveness	Group								Pearson's χ^2 test (p<0.05)
	I (n=30)		II (n=20)		III (n=11)		IV (n=35)		
	n	M%±m%	n	M%±m%	n	M%±m%	n	M%±m%	
Mycological cure	22	73.3±8.1*	12	60.0±11.0	6	54.5±15.0	13	37.1±8.2	χ^2=6.907; df=2
Clinical cure	20	66.7±8.6*	10	50.0±11.2	5	45.5±15.0	11	31.4±7.8	χ^2=6.434; df=2
Complete cure	20	66.7±8.6*	10	50.0±11.2	4	36.4±14.5	11	31.4±7.8	χ^2=7.598; df=2

Note – difference is statistically significant compared with Group IV (p<0.01)

Table 3

Effectiveness of antifungal therapy for onychomycosis of the feet in different groups of HIV-infected patients at the 12-month follow-up

Treatment effectiveness	Group								Pearson's χ^2 test (p<0.05)
	I (n=30)		II (n=20)		III (n=11)		IV (n=35)		
	n	M%±m%	n	M%±m%	n	M%±m%	n	M%±m%	
Mycological cure	23	76.7±7.7*	13	65.0±10.7	7	63.6±14.5	15	42.9±8.4	χ^2=6.907; df=2
Clinical cure	21	70.0±8.4*	11	55.0±11.1	6	54.5±15.0	12	34.3±8.0	χ^2=6.434; df=2
Complete cure	21	70.0±8.4*	11	55.0±11.1	5	45.5±15.0	12	34.3±8.0	χ^2=7.598; df=2

observed in HIV-negative patients [17]. Immunosuppression leads to uncontrolled proliferation of dermatophytes, with clinical specimens often revealing abundant hyphae and arthroconidia. Our findings correspond to a patient population that, according to the Centers for Disease Control and Prevention (CDC) classification, did not meet the criteria for AIDS at the time of sample collection.

Thus, assessment of the effectiveness of antifungal therapy for onychomycosis of the feet in HIV-infected patients stratified according to the effectiveness of antiretroviral therapy demonstrated the best outcomes in the group with successful ART and the poorest outcomes in the group with unsuccessful ART. In patients showing no positive dynamics in one of the key indicators (viral load or CD4+ T-lymphocyte count), combined therapy for onychomycosis of the feet yielded intermediate results.

Analysis of the effectiveness of antifungal treatment for onychomycosis of the feet in HIV-infected patients depending on ART outcomes indicates the need for optimization of antiretroviral regimens in order to select more effective treatment strategies.

Thus, dermatomycoses represent characteristic clinical manifestations of HIV infection and are expressed by a wide range of nosological forms, including various combinations thereof. The etiological and clinical features of onychomycosis of the feet depend on the adequacy of the selected ART regimen. Successful ART is associated with a significant increase in the effectiveness of antifungal therapy for onychomycosis of the feet.

Conclusions

1. When selecting an antimycotic agent for the treatment of onychomycosis of the feet in HIV-infected patients, the spectrum of antifungal activity against the identified pathogen should be taken into account. Thus, in cases of onychomycosis of the feet caused by dermatophytes, terbinafine is the drug of choice; when non-dermatophyte fungi (yeasts, non-dermatophyte filamentous fungi), dermatophytes, or their combinations are isolated, itraconazole is recommended; in onychomycosis of the feet caused by non-dermatophyte fungi (yeasts, non-dermatophyte filamentous fungi) or in cases of mixed infection, fluconazole is advisable.

2. The use of antimycotic agents with regard to their antifungal spectrum against the identified pathogen, prolongation of treatment duration, and administration of adequate antiretroviral therapy regimens increase the effectiveness of comprehensive treatment of onychomycosis of the feet in HIV-infected patients. The overall effectiveness of treatment at 6 and 12 months of follow-up was 46.9% and 51.0%, respectively.

3. Evaluation of antifungal therapy effectiveness demonstrated the best outcomes in patients with successful antiretroviral therapy and the poorest outcomes in those with unsuccessful ART. In patients lacking positive dynamics in one of the key parameters (viral load or CD4+ T-lymphocyte count), combined therapy for onychomycosis of the feet yielded intermediate results.

4. Antifungal therapy for onychomycosis of the feet in HIV-infected patients should be comprehensive and prolonged and must be administered in conjunction with adequate antiretroviral therapy. Comprehensive treatment of onychomycosis of the feet caused by non-dermatophyte fungi (non-dermatophyte filamentous fungi, yeasts) or mixed infections should include itraconazole at a dose of 200 mg twice daily using a pulse-therapy regimen during weeks 1, 5, and 9 of treatment, or fluconazole at a dose of 150 mg once weekly for 6 months, in combination with topical nail lacquer application (5% amorolfine) once weekly and instrumental nail debridement at intervals of once every 1.5 months. Comprehensive therapy of onychomycosis of the feet caused by dermatophytes should include terbinafine at a dose of 250 mg once daily for 12 weeks or itraconazole at a dose of 200 mg twice daily using a pulse-therapy regimen during weeks 1, 5, and 9 of treatment, combined with topical application of 5% amorolfine nail lacquer once weekly and instrumental nail debridement every 1.5 months.

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ОЦІНКА ЕФЕКТИВНОСТІ ЛІКУВАННЯ ОНІХОМІКОЗІВ СТОП У ВІЛ-ІНФІКОВАНИХ НА ФОНІ АНТИРЕТРОВІРУСНОЇ ТЕРАПІЇ

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РЕЗЮМЕ. ***Мета роботи*** *– оцінити результативність лікування оніхомікозів стоп у ВІЛ-інфікованих залежно від ефективності антиретровірусної терапії (АРТ).*

Пацієнти і методи. *Під спостереженням перебувало 96 ВІЛ-інфікованих хворих із оніхомікозами стоп.*

Діагноз ВІЛ-інфекції встановлювали згідно з міжнародною класифікацією хвороб 10-го перегляду (МКХ-10) та верифікували виявленням специфічних серологічних і молекулярно-біологічних маркерів ВІЛ. Усім хворим реєстрували кількість CD4⁺-лімфоцитів і вірусне навантаження (копій/мл).

Зважаючи на ефективність АРТ, ВІЛ-інфіковані хворі з оніхомікозами стоп були поділені на чотири групи. До І групи входили пацієнти з вірусологічним та імунологічним успіхами АРТ; до ІІ групи – пацієнти зі зниженням вірусного навантаження без збільшення числа CD4⁺-лімфоцитів або з підвищенням рівня CD4⁺>500 кл/мкл без зниження вірусного навантаження; до ІІІ групи – пацієнти з імунологічною відповіддю, але без зниження вірусного навантаження; до IV групи – особи з вірусологічною та імунологічною невдачами АРТ. Таким чином, у І групі під спостереженням перебувало 30 осіб; у ІІ групі – 20; у ІІІ групі – 11; у IV групі – 35 хворих.

Із системної антифунгальної терапії ВІЛ-інфіковані хворі І групи отримували тербінафін по 250 мг на добу протягом 12 тижнів. Пацієнти ІІ групи отримували інтраконазол по 200 мг 2 рази на добу за схемою пульс-терапії на 1-й, 5-й та 9-й тижні лікування. У ІІІ-IV групах хворим призначали флуконазол у дозі 150 мг 1 раз на тиждень протягом 6 місяців.

Результати. На 6-й місяць спостереження ефективність протигрибкової терапії оніхомікозів стоп у пацієнтів з вірусологічним та імунологічним успіхами АРТ була достовірно вищою, ніж у хворих з вірусологічною та імунологічною невдачами АРТ (p<0,01).

На 12-й місяць спостереження мікологічна, клінічна та повна ефективність антифунгальної терапії оніхомікозів стоп виявилася статистично вагомо вищою у разі вірусологічного та імунологічного успіхів антиретровірусного лікування, порівняно з групою хворих, в яких такого результату етіотропної терапії ВІЛ-інфекції досягти не вдалося (p<0,01).

Висновки. *Оцінка ефективності протигрибкової терапії оніхомікозів стоп у ВІЛ-інфікованих хворих у групах, сформованих залежно від ефективності антиретровірусного лікування, показала найкращі результати у групі з успішним варіантом використання антиретровірусних препаратів і найгірші – у групі з негативним результатом такого лікування. У представників групи з відсутністю позитивної динаміки одного з показників (вірусного навантаження чи кількості CD4⁺-лімфоцитів) комбінована терапія оніхомікозів стоп продемонструвала проміжні результати.*

Ключові слова: *ВІЛ-інфекція, мікози шкіри та її додатків, антиретровірусна терапія.*

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