

NAIL PLATE DAMAGE INDEX IN DERMATOSCOPIC EXAMINATION OF PATIENTS WITH ONYCHOMYCOSIS

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Abstract.

Introduction: The lack of uniform criteria for assessing the degree of damage to the nail plates of patients with onychomycosis does not allow for an objective assessment of the effectiveness of therapy and a comparative assessment of the results of treatment using different methods. In modern medicine, the use of instrumental methods of diagnosis and treatment is becoming more widespread. In particular, one of the options for obtaining information about the state of lesions is nail plate damage index (NPDI). However, the correspondence of the macroscopic appearance to the actual condition remains unclear.

Aim: The aim of our study was to determine the objectivity of nail plate damage index by comparing it with the degree of contamination with fungal structures.

Materials and methods: Patients with onychomycosis were examined with nail plate damage index (NPDI), Scoring Clinical Index of Onychomycosis (SCIO), and Onychomycosis Severity Index (OSI). To assess the degree of fungal contamination, scraping microscopy was performed. After assessing the degree of damage using NPDI, SCIO, OSI compared their results with the data of microscopic examination.

Results: When comparing the data of microscopic examination and external examination, it was found that, as a rule, with microscopic damage to 25% of the area, macroscopically observed change in nail color is observed, white or yellow spots/stripes appear (often near the free edge or on the sides), while the thickness of the nail is almost not disturbed. With damage from 25% to 50% of the area, the nail becomes dull, noticeably thickens, deforms and begins to crumble. Subungual hyperkeratosis (accumulation of horny masses) often occurs. With damage to more than 50% of the area, changes reach the matrix (nail growth zone). The nail plate collapses, exfoliates from the bed (onycholysis) or becomes thin and softened.

Conclusions: Definition of nail plate damage index at onychomycosis is an informative indicator with a high correlation with the area of contamination ($r=0.81$) and can be recommended for both diagnosis and monitoring of the treatment process.

Key words. Onychomycosis, dermatoscopy, microscopy, morphology, nail plate, pathology.

Introduction.

Infectious diseases are among the leading causes of severe conditions [1,2]. They control and management could significantly improve epidemiological indicators [3,4]. With

a normal objective examination, it is quite easy to suspect the presence of a fungal infection in the nails of patients, especially when changes in the nail plates are accompanied by mycotic lesions of the skin of the feet or hands, the presence of rubromycosis of smooth skin or candidiasis of large folds [5,6]. When the above diseases are absent or are in remission after antifungal treatment or permanent use of topical antifungal ointments by patients, the diagnosis becomes much more complicated. A slight deformation of the nail plates, a change in its color, the patient, and sometimes the doctor, may take for dystrophic changes due to a previous nail injury or wearing narrow shoes, but not for a fungal infection [7,8]. Differential diagnosis of onychomycosis presents some difficulties due to the fact that similar changes in the nail plates can be observed in patients with chronic dermatoses, such as psoriasis, eczema, lichen planus, lupus erythematosus, scleroderma, lichen planus, bullous dermatoses, etc., in which structural changes in the nail plates are observed [9,10].

The lack of uniform criteria for assessing the degree of damage to the nail plates of patients with onychomycosis does not allow for an objective assessment of the effectiveness of therapy and a comparative assessment of the results of treatment using different methods. In modern medicine, the use of instrumental methods of diagnosis and treatment is becoming more widespread [11,12]. Artificial intelligence tools are increasingly being introduced. In this case, digital images are often the basis for the use of AI [13,14]. But for AI, intelligence must receive objective criteria for the success and validity of its conclusions. One of the ways to implement AI in dermatology can be the analysis of digital images of affected areas, in particular nail plates. In particular, one of the options for obtaining information about the state of lesions is nail plate damage index (NPDI). However, the correspondence of the macroscopic appearance to the actual condition remains unclear. In addition, images for digital analysis can be obtained by epiluminescence microscopy, which allows to see at high magnification (from 10 to 50 times) structural changes in the nail plates that are not visible to the naked eye.

The aim of our study was to determine the objectivity of nail plate damage index by comparing it with the degree of contamination with fungal structures.

Materials and Methods.

Patients with onychomycosis who participated in the study (138 patients) underwent dermatoscopic examination of the nail

plates of the hands and feet before the start of treatment and an assessment of nail plate damage was made. Diagnosis was confirmed by microscopic examination and PCR. Mycological examination of patients for diagnostic confirmation method of onychomycosis 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.

To assess the degree of nail plate damage by onychomycosis, the nail plate damage index (NPDI) was used according to the method described in detail by us earlier [15]. 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 [15]. Inter-rater reliability of dermatoscopic assessments was provided by three examiners in a study where results were obtained by consensus. 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. During 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 analyzed. As comparison methods, we used Scoring Clinical Index of Onychomycosis (SCIO) and Onychomycosis Severity Index (OSI) scoring, which are common enough for taking into account the area of infection and the depth of penetration in fungal lesions [16]. OSI is calculated by multiplying the score for the area of the lesion (range 0-5) by the score for the proximity of the disease to the matrix (range 1-5). Ten points are added for the presence of a longitudinal stripe or spot (dermatophytoma) or for subungual hyperkeratosis greater than 2 mm. Mild onychomycosis corresponds to a score of 1 to 5; moderate - from 6 to 15; and severe - from 16 to 35 [17]. SCIO is used to determine treatment tactics, in particular, with a score of 1–3, local treatment is recommended (in combination with scraping/cutting off the affected edges); 3–6 points - local treatment can be used, but for nails that grow more slowly, systemic therapy is recommended; 6–12 points recommend systemic antifungal therapy (e.g., pulse-dosing of oral antifungal drugs) depending on whether it is a fingernail or a toenail. Scores of 12–20 suggest systemic therapy with possible combined approaches (adding local measures or keratinolytic therapy) [18].

To assess the degree of fungal contamination, scraping microscopy was performed. Sections were stained with Romanowski-Giemza and morphometry was performed according to previously published recommendations [13]. To quantify the degree of fungal damage, the area of the surface occupied by hyphae was measured; this value in percent reflects the proportion occupied by hyphae relative to the total surface. In

the areas occupied by hyphae, the volumetric density parameter (%) was also determined. This parameter reflects the spread and range of mycelium penetration and corresponds to the number and size of hyphae. Depending on the area of damage, during microscopic examination, the initial (mild) form was distinguished - the damage occupies up to 25% of the field of view, average (moderate) - 25% to 50% of the area is affected, and severe (advanced) - more than 50% of the area is affected. Total damage with 100% replacement by elements of the fungal structure was not observed in our study. After assessing the degree of damage using NPDI, SCIO, OSI compared their results with the data of microscopic examination.

The study was performed in accordance with the principles of the Helsinki Declaration of the World Medical Association "Ethical Principles of Medical Research Concerning Human Subjects" (2013) with written informed consent. Statistical processing of the data was performed using the Statistica for Windows 8.0 software package. Methods of descriptive statistics (determination of numerical characteristics of variables - arithmetic mean (M), mean sampling error (m), determination of the reliability of differences (p), which were tested via the Student-Fisher t-test in representative samples) were used. Correlation between indicators was assessed using Spearman's correlation coefficient (r). The difference in values between comparative indicators was considered significant at $p < 0.05$.

Results.

Of these, 138 patients with onychomycosis in whom the diagnosis was confirmed by microscopic examination and PCR, the distribution by gender was as follows. There were 79 women (57.2%), 59 men (42.8%). Using the method of examining nail plates developed by us, out of 138 patients, 35 patients (25.4%) showed only the initial manifestations of the introduction of fungal infection into the nail plate, 10 patients (7.2%) already had signs of total damage with matrix involvement, 38 (27.5%) patients had signs of total damage without matrix involvement, and 55 (39.9%) patients constituted the main percentage with distal-lateral damage. A significant percentage of patients (21.5%) considered their nails healthy before seeking medical attention. We paid special attention to dermatoscopy 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 in 13 patients of this group, we confirmed the first changes in the nails, when the microscopic examination was still negative, which remained unnoticed by doctors during visual examination of the nail plates.

According to the clinical sign, we obtained a characteristic dermatoscopic picture. Each examined patient with onychomycosis had certain and characteristic clinical changes of the nail plates only for him. The doctor assessed these changes and assigned points, then summed them up. The number of points obtained determined the NPDI value, and accordingly the severity of onychomycosis with visualisation on figures 1-7. Thus, in the range from 1 to 21 points, onychomycosis of any severity can be calculated (Figures 1-7).

A high NPDI index was observed in 41 patients (29.7%), moderate – in 78 (56.5%) patients, and the smallest number of

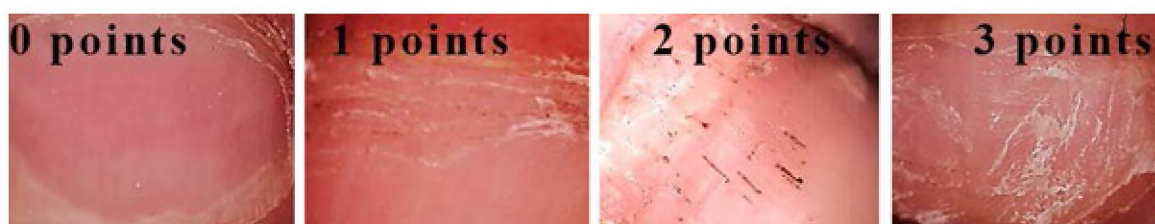


Figure 1. Unevenly outlined surface of the nail plate.

0 points There is no sign of unevenly outlined nail plate surface.

1 points The unevenly outlined surface occupies up to 30% of the nail plate in the form of longitudinal white and yellow wavy lines with brown dots in the structure and scales.

2 points The unevenly outlined surface occupies more than 30% of the nail plate in the form of brown, tan, and white longitudinal and transverse lines with multiple dots.

3 points The unevenly outlined surface occupies the entire nail plate in the form of oblique, longitudinal and transverse white lines.

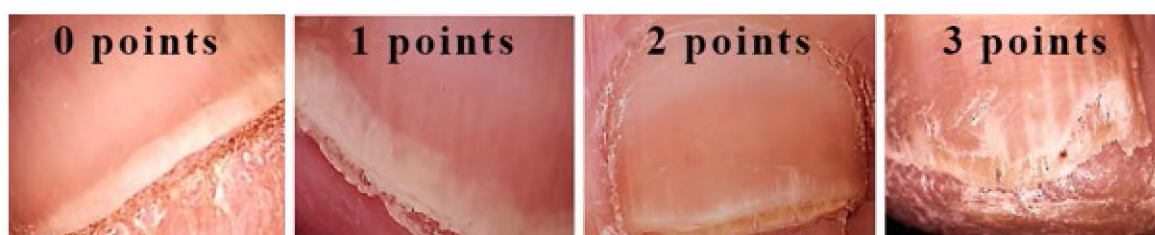


Figure 2. Free edge change.

0 points There are no changes in the free edge in the presence of subungual hyperkeratosis and significant changes in the distal nail bed: multiple cracks and layers of white scales, the capillary pattern is not visualized.

1 points Partial delamination of the free edge with preservation of the normotrophic structure of the nail plate.

2 points Delamination along the entire length of the nail plate in the form of transverse whitish and gray-yellow stripes with brown inclusions.

3 points Absence of a free edge in the total form of the lesion.

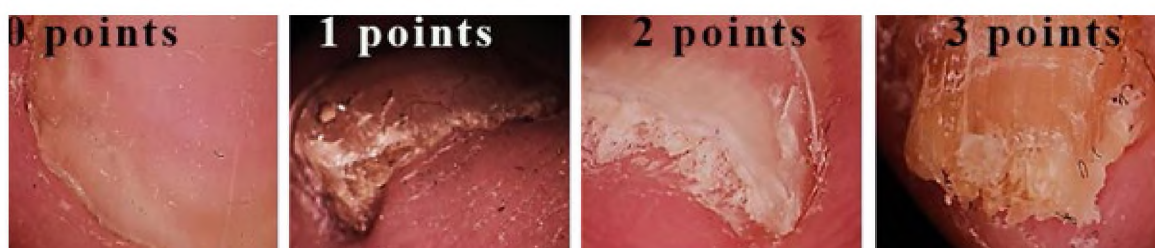


Figure 3. Nail plate hyperkeratosis.

0 points There is no sign of hyperkeratosis of the nail plate, but there are: a change in the color of the nail, the presence of a free edge and partial longitudinal striation with no parallelism of the gray stripes.

1 points Hyperkeratosis covers up to 30% of the nail plate.

2 points Hyperkeratosis occupies more than 30% of the nail plate and the process of nail destruction begins from the free edge.

3 points Hyperkeratosis covers the entire nail plate, the color is yellow-brown with significantly pronounced signs of surface damage, eponychia.

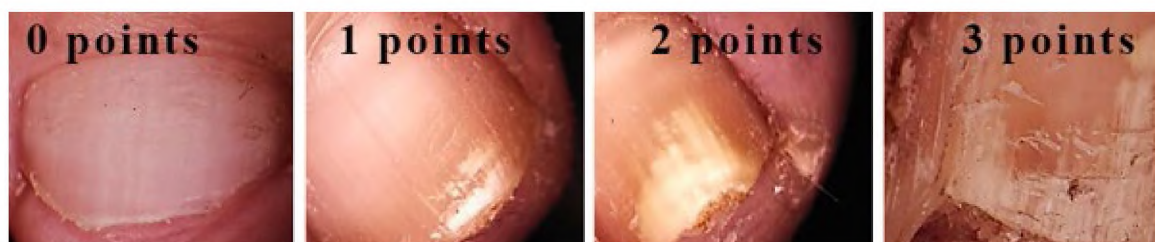


Figure 4. Uneven nail plate color.

0 points There is no unevenness in the color of the nail plate.

1 points Minor focal pigmentation of the nail plate in the form of white and yellow spots that occupy a small portion of the nail plate surface.

2 points Pronounced uneven coloration of the nail plate, occupying half of the surface of the nail plate.

3 points Multi-colored discoloration of the nail plate in the form of white, yellow and brown spots with significant surface destruction.



Figure 5. Cavities between the nail plate and the nail bed.

0 points Absence of cavities between the nail plate and the nail bed with the presence of other manifestations of nail onychomycosis.

1 points One small cavity between the nail plate and the nail bed.

2 points Two or more cavities between the nail plate and the nail bed are observed from the side of the lateral ridges.

3 points Complete detachment of the nail plate from the nail bed and held only in the proximal part of the nail.

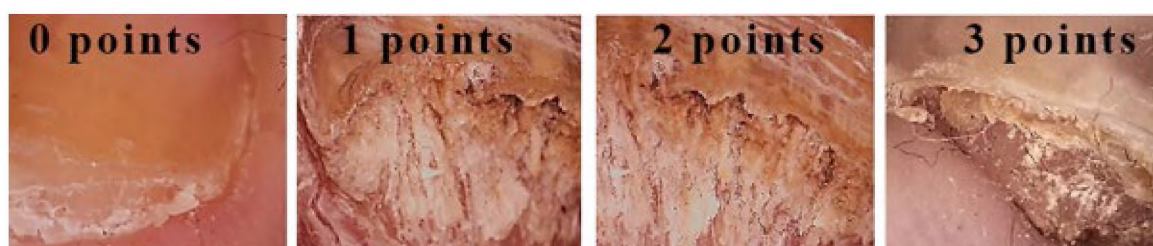


Figure 6. Tunnels in the thickness of the nail plate.

0 points There are no tunnels in the thickness of the nail plate in the presence of its thickening.

1 points The presence of up to two tunnels in the thickness of the nail plate in the form of longitudinal and transverse cavities in the thickness of the nail.

2 points The presence of three or more tunnels in the thickness of the nail plate.

3 points Complete detachment of the nail plate.

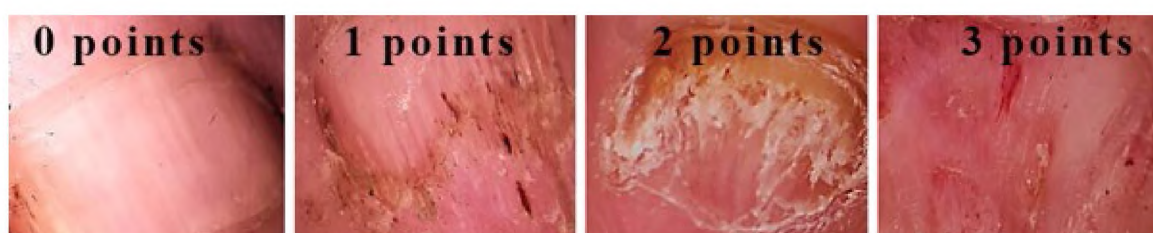


Figure 7. Nail plate atrophy.

0 points There is no atrophy of the nail plate, the entire plate is preserved.

1 points One-third of the nail plate is missing and there are a large number of longitudinal red and brown lines and pieces of the nail plate.

2 points Two-thirds of the nail plate is missing and longitudinal pink looped lines and white scales are visible on the exposed nail bed.

3 points Complete absence of the nail plate and visualization of hemorrhages, cicatricial changes, and fragments of the nail plate.

Table 1. The severity of nail plate lesions assessed by different methods.

Severity level	Nail plate damage index (NPDI)	Scoring Clinical Index of Onychomycosis (SCIO)	Onychomycosis Severity Index (OSI)
easy	19 (13.8 %)	16 (11.6 %)	18 (13.0 %)
moderate	78 (56.5%)	75 (54.3 %)	77 (55.8 %)
Heavy	41 (29.7%)	45 (32.6%)	43 (31.2 %)
Comparison of severity (number of points) obtained with NPDI, SCIO, OSI and microscopic examination (r)	0.81	0.74	0.77

patients was with a minimum index – 19 (13.8%). The average NPDI of the examined patients with onychomycosis was (10.7 ± 0.3) points. It should be noted that despite the different numbers, the groups were compared according to the degree of certainty of clinical symptoms. With a minimum severity (1–4 points), we usually considered the appointment of systemic antifungal drugs not justified, as a rule, only external antifungal therapy was required. With a moderate severity (5–10 points), the number of

affected nail plates and the presence of concomitant pathology were necessarily assessed. After that, a conclusion was made about the optimal volume of treatment, in particular the need for the appointment of a systemic antifungal drug. In severe cases (11–21 points), we used combination therapy, which included systemic (in the absence of contraindications) and external antifungal therapy. The average NPDI of the examined patients with onychomycosis was equal to 10.7 ± 0.3 .

When comparing the data of microscopic examination and external examination, it was found that, as a rule, with microscopic damage to 25% of the area, macroscopically observed change in nail color is observed, white or yellow spots/stripes appear (often near the free edge or on the sides), while the thickness of the nail is almost not disturbed. With damage from 25% to 50% of the area, the nail becomes dull, noticeably thickens, deforms and begins to crumble. Subungual hyperkeratosis (accumulation of horny masses) often occurs. With damage to more than 50% of the area, changes reach the matrix (nail growth zone). The nail plate collapses, exfoliates from the bed (onycholysis) or becomes thin and softened.

The results of comparing the assessment of the severity of signs of fungal damage carried out by different methods and their relationship with the microscopic structure are presented in Table 1.

Discussion.

Comparison of direct smear, culture and histology for the diagnosis of onychomycosis proves that the most sensitive combination of tests, smear plus histology, has 97.8% sensitive with 98% negative predictive value [19,20]. But direct smear combined with histological examination needs time for obtaining final results. Dermatoscopic examination of the nail plates led us to identify the main pathological changes in 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; change 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 rollers; changes in the nail plates due to acute somatic diseases [21,22].

The lack of uniform criteria for assessing the degree of damage to the nail plates of patients with onychomycosis makes it impossible to objectively assess the effectiveness of therapy and to conduct a comparative assessment of the results of treatment using different methods. Therefore, one of the most difficult problems in the diagnosis of onychomycosis is the selection of informative objective indicators that would fully characterize the pathological process. But no less problematic is the choice of quantitative assessment and the creation of an assessment scale that would allow giving the most complete quantitative description of qualitative indicators. Therefore, we set the goal of creating such an assessment scale that would allow objectively assessing the severity of the disease and, on this basis, making a decision on choosing a particular method of onychomycosis therapy. The severity of any pathological process is understood as the degree of severity of its subjective and objective symptoms. Both treatment tactics and prognosis depend on the correct interpretation of clinical indicators. Therefore, an accurate and correct assessment of the severity of any disease is an essential part of its treatment [23-25] as the transformation of clinical manifestations of common

pathological processes could be unexpected [26].

In the course of the study, using the developed method of dermatoscopic examination of nails, the main dermatoscopic signs of healthy nail plates were determined, and the main criteria for assessing the clinical form and severity of onychomycosis were identified with accordance to previously published work [27,28].

The use of epiluminescence microscopy in practice allows it to be used as a screening method and in the early stages of the disease to conduct an objective assessment of changes occurring in the nail plate, and to conduct differential diagnostics with other diseases that have nail pathology [29,30].

Dermatoscopic examination of affected nail plates allows you to assess the degree of need for systemic antifungals, select appropriate local therapy, and assess the effectiveness of the prescribed treatment in the process of sanogenesis and relative medical management [31,32] even in hard conditions [33] for adequate treatment [34,35]. At the same time, the proposed method allows calculating the damage not only when onychomycosis, but also in the listed pathological processes.

The authors of the manuscript acknowledge that the presented study has limitations due to its design and execution. The observational/retrospective and/or single-center nature does not provide grounds for causal conclusions and retains the risk of selection bias and residual confounding, despite the use of multivariate models, propensity matching, and other approaches to control for confounding factors. The sample size, lesion heterogeneity, and composition [N=138] limit the accuracy of the estimates and the portability of the results given the peculiarities of patient routing and care practices. To minimize the effects, measurements were standardized, raters were trained, blinded where possible, and sensitivity analyses were performed. The generalizability of the findings is limited by the context; confirmation requires prospective multicenter studies, reasonable power calculations, external validation, and adherence to Good Clinical Practice (GCP).

Conclusion.

Definition of nail plate damage index at onychomycosis is an informative indicator with a high correlation with the area of contamination ($r=0.81$) and can be recommended for both diagnosis and monitoring of the treatment process.

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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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