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Athlete's Foot: A Common Fungal Infection in Athletes and Beyond. The Use of Terbinafine in Treating Tinea Pedis and Onychomycosis

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Abstract

Introduction: Tinea pedis is one of the most common skin conditions that often affects athletes, which is referred to by another name for the condition - Athlete's foot. It is a fungal infection that manifests itself with symptoms such as itching, redness, exfoliating skin and cracking of the epidermis. The foot skin infection can spread to the nails, so in this review we will discuss both conditions.

Terbinafine is an allylamine derivative with antifungal activity. It can be applied both superficially and orally. It is used to treat fungal infections, including tinea pedis and onychomycosis.
Aim of the study: The aim of this publication is to review the available literature to answer the question of whether terbinafine is an effective treatment for athlete's foot and onychomycosis.
Methods: Review of specialised literature in the field of dermatology and PubMed and Google Scholar databases by searching with keywords such as athlete's foot, tinea pedis, onychomycosis, terbinafine.
Conclusion: Tinea pedis and often associated onychomycosis are a medical problem affecting a wide social group. Topical or systemic drugs can be used to treat the aforementioned conditions. Terbinafine, which is a drug belonging to the allylamines, is effective in the treatment of tinea pedis and onychomycosis and has a high safety profile. There are terbinafine products on the market in various forms, e.g. emulsions, creams, film-forming solution, pills, so it is therefore easy to choose a suitable and convenient treatment. The use of lasers such as CO2 fractional laser or Nd:YAG laser seems to be beneficial in the complementary treatment of onychomycosis with terbinafine.

Keywords: Athlete's foot, tinea pedis, onychomycosis, terbinafine

Introduction:
Fungal infections of the skin and its appendages are a common health problem affecting the general population. Fungal infections can occur in hairless skin, mucous membranes, nails and hair. They are most often caused by dermatophytes. The source of infection may be a human, animal, infected object or the infection may be of geophilic origin (e.g. soil). The infection may spread from other locations on the skin [1,2]. There are predisposing factors for fungal infection include older age, chronic diseases and immunological disorders, high temperature and high humidity. In addition, wearing unvented footwear, poor hygiene, and use of swimming pools [1,2,3]. Fungal lesions have a variable picture, depending on the location. Dermatomycosis most often takes the form of an erythematous and exfoliative focus, spreading peripherally, often accompanied by translucency in the central part of the lesion.
The diagnosis of dermatophytosis is based on physical examination and mycological examination. For fungal culture, biological material should be collected from the potentially affected area. The collected material is also viewed under a microscope, usually with potassium hydroxide (KOH) [1,2].

'Athletes' foot'
This is another name for tinea pedis, a fungal infection of the skin of the foot, most commonly caused by dermatophytes. The lesions can be localised on the whole foot, but tinea pedis is distinguished between interdigital, moccasin-type, vesiculobullous, acute ulcerative tinea pedis. Predisposing factors are mechanical trauma, reduced immunity, diabetes, atherosclerotic processes in the vessels of the limbs. The lesions are most often of an erythematous and exfoliative nature, less often accompanied by maceration of the epidermis,

pustules, ulcerations. Thickening of the epidermis may result in epidermal rupture, which can be a gateway for bacterial infection. Fungal infection in the feet can spread to the nails.
Nail fungus most commonly manifests as discolouration of the nail surface, often yellow, thickening and distortion of the nail plate, subungual hyperkeratosis and onycholysis. The nail, destroyed by the disease process, may even break. Tinea pedis may also be accompanied by dermatophytosis of the hands and fingernails. Transmission of the infection most commonly occurs during nursing of the infected skin of the feet and toenails [1,2].
Infections caused by dermatophytes have been shown to be common in groups of athletes [4,5]. A meta-analysis on fungal infections among wrestlers showed that Trichophyton tonsurans was the most common aetiological agent [4]. In another study focusing on the most common infectious agents among athletes, dermatophytosis was shown to be one of the most common epidemic agents among athletes, indicating the prevalence of this condition. Trichophyton tonsurans was also identified as the most common aetiological agent in this study. Dermatophytosis is the highest risk among athletes involved in contact sports [5].
A Japanese study on a population of patients with tinea pedis and/or onychomycosis, showed that the conditions inside the shoe can be a risk factor for the development of tinea. High temperature, humidity inside the shoe and dew point were considered as these factors, which is dependent on the current environmental conditions and aura. It was shown that footwear such as boots favoured fungal infections, whereas footwear that did not cover the whole foot, such as flip-flops due to better ventilation, did not carry such a risk [3].

Antifungal agents

A distinction is made between antifungal drugs for use in organ mycoses and superficial mycoses, i.e. dermatophytosis [6]. In dermatophytosis, topical and systemic preparations are used. The most common choice for Athlete's foot is for superficial treatment using creams, ointments, sprays, etc. In the case of concomitant onychomycosis, special varnishes with an antifungal drug are also used. Onychomycosis is difficult to treat and treatment failures are often reported [1,2]. Azoles, allylamines, ciclopirox are most commonly used in the treatment of onychomycosis [2]. Systemic treatment is used in more severe, refractory forms. In systemic treatment, terbinafine, itraconazole and fluconazole are most commonly used. Combination treatment, i.e. a combination of systemic and topical treatment, can also be used. In order to avoid reinfection, footwear decontamination with formalin is recommended [1,2]. For onychomycosis, in addition to pharmacological treatment, surgical removal of the nail or laser treatment can be used [2,7,8,9,10].

Characteristics of terbinafine

Terbinafine is an antifungal drug belonging to the allylamines. It acts by inhibiting squalene epoxidase, thus preventing the formation of ergosterol, which is a building block of the fungal cell membrane. This results in the accumulation of squalene which causes fungal cell death [6,11]. Terbinafine has lipophilic and keratophilic properties and is well absorbed from the gastrointestinal tract. Because it accumulates in the stratum corneum and nail plate, among others, it is a good preparation for the treatment of fungal skin disorders. The drug is considered safe and does not often cause serious side effects, the most common side effects

being headache, gastrointestinal disorders and skin reactions. In rare cases, liver damage with elevation of liver enzymes may occur [11].

Methodology

The review was conducted based on publications available in PubMed and Google Scholar databases. Literature searches were performed using keywords such as ‘Athlete's foot’, ‘tinea pedis’, ‘onychomycosis’ and ‘terbinafine’. Priority was given to large sample trials and meta-analyses to provide the scientific quality of the findings shown. Specialised and up-to-date medical literature from the fields of pharmacology and dermatology was also used to enhance the content.

Terbinafine used orally and in combination with topical treatment

Terbinafine is a very well-studied drug that has been used for many years in clinical practice. It comes in the form of oral tablets and topical preparations. A study carried out to test the effect of terbinafine at a dose of 250 mg per day applied for a fortnight in patients with moccasin mycosis and tinea manuum showed that 6 weeks after treatment, up to 86% of patients had negative mycological findings and 71% were considered successfully treated (negative mycological findings and no or significantly reduced clinical symptoms). In comparison, only 7% of the placebo group had negative mycological results and no one in this group was considered successfully treated. No serious side effects of the drug were observed during the study. In conclusion, oral terbinafine was effective and safe in the treatment of moccasin mycosis fungoides [12]. In a published study on a group of patients with the hyperkeratotic variant of tinea pedis, the penetration and efficacy of oral terbinafine applied at a dose of 125 mg for 4 weeks was investigated. It was shown that up to 95% of patients had negative mycological findings 8 weeks after the end of treatment. In addition, clinical improvement, i.e. a reduction in symptoms such as epidermal peeling and pruritus, was achieved, with no serious side effects recorded [13]. In a study comparing the efficacy of terbinafine applied orally at a dose of 250 mg per day for three months to the use of a lacquer with 5% amorolfine or a lacquer with 30% resin for nine months in onychomycosis, it was found that 56% of terbinafine-treated patients achieved negative mycological results (negative microscopic examination with KOH and negative fungus culture), while only 13% of patients treated with topical resin and 8% treated with amorolfine achieved this result. In addition, as many as 16% of patients treated with terbinafine achieved full regrowth of a healthy nail, which was not observed in the other groups. This demonstrates the high efficacy of orally applied terbinafine [14]. On a population of patients with hyperkeratotic tinea pedis, the efficacy of oral terbinafine 250 mg per day for 2 weeks combined with the additional use of terbinafine cream and 10% urea ointment applied twice daily for 4 weeks was compared to an intervention involving oral placebo and topical application of terbinafine and 10% urea ointment for 12 weeks. The results of both interventions were found to be similar (negative mycological results were reported by 82% of those using oral and topical treatment and 78% of those using only topical treatment). The results suggest that oral use of terbinafine is effective and can significantly reduce the treatment time of hyperkeratotic tinea pedis [15].

In the Spanish SETTA study evaluating the efficacy of terbinafine in the treatment of tinea pedis and tinea unguium, patients with tinea pedis were prescribed 250 mg terbinafine per day orally for 2 weeks or surface formulations with terbinafine for 1 week, while patients with onychomycosis were prescribed 250 mg terbinafine per day for 12 weeks.
The results of the study indicate that terbinafine was highly effective, as 94% of patients with tinea pedis declared a significant improvement and 52.7% achieved a complete cure. Slightly worse results were obtained by patients with onychomycosis as only 33% achieved complete cure [16].
A US study analysing dermatophyte resistance to various antifungal drugs was published in 2023. It showed that 18.6% of dermatophyte samples submitted to the laboratory between 2021 and 2022 showed resistance to terbinafine with the majority of these being T. rubrum and T. indotineae species. This is probably related, among other things, to mutations in the gene encoding squalene epoxidase (e.g. mutation F397L). This information suggests that terbinafine may need to be switched to other therapies in the coming years [17]. Another worrying report comes from an article written by Indian researchers regarding the efficacy of terbinafine in the treatment of tinea corporis, tinea cruris and tinea faciei. Patients took terbinafine orally at a dose of 5mg/kg and a surface cream with 1% terbinafine twice daily. The entire therapy lasted four weeks and it was found that the cure rate (cure was defined as the disappearance of all skin lesions and a negative microscopic examination of the preparation) after two weeks of therapy was 2 %, while after four weeks it was 30.6 %, indicating a weak effect of terbinafine [18].

Terbinafine topical application

A meta-analysis comparing the efficacy of topical allylamines and azoles in the treatment of various forms of dermatomycosis, including tinea pedis, has been published. In the treatment of tinea pedis, azoles and allylamines were shown to be significantly more effective in treatment, the cures achieved were more durable and reinfection was less frequent compared to the placebo groups. In addition, allylamines have better efficacy than azoles in the treatment of tinea pedis (obtaining negative mycological findings) and patients treated with azoles are more likely to have a recurrence of tinea pedis compared to those treated with allylamines. It is concluded from the above that allylamines, which include terbinafine, are more effective in the treatment of tinea pedis than azoles [19]. In a study comparing the efficacy of a 1% terbinafine cream (applied twice daily for one week, followed by placebo for 3 weeks) with a 1% clotrimazole cream (applied twice daily for 4 weeks) in the treatment of tinea pedis, it was shown that 4 weeks after the start of the intervention, up to 94% of patients using terbinafine had a negative mycological examination, whereas only 73% in the clotrimazole group had such an effect. Effectively treated participants after 6 weeks were also in favour of terbinafine (90% vs. 73%) .Weekly therapy with terbinafine was therefore more effective than 4-week treatment with clotrimazole [20]. A similar study was conducted on patients with interdigital tinea pedis. In this study, terbinafine 1% was also applied for one week followed by a placebo cream for three weeks, while the second group applied clotrimazole 1% for four weeks. Both creams were applied twice daily. After one week of treatment, 84.6% of participants in the terbinafine treatment group achieved negative

mycological cultures, which was achieved by only 55.8% of participants in the clotrimazole treatment group, with statistical significance. Complete cure, i.e. negative mycological results and remission of clinical symptoms, was also better in the terbinafine group, but this was not statistically significant. At follow-up, the results of the two drugs were similar, but terbinafine enabled faster results [21].

A study comparing the efficacy of 1% and 3% topically applied terbinafine has been published. The emulsions were applied once daily for a period of 5 days. It was found that after 6 weeks, treatment efficacy (negative mycological test results, remission or presence of mild clinical symptoms) was achieved in 86% of participants using 1% terbinafine and in 68% using 3% terbinafine. Emulsion gel with 1% terbinafine was found to be a sufficient and effective concentration for the treatment of tinea pedis [22]. In a study of the efficacy of 1% terbinafine cream applied once daily for seven days in the treatment of interdigital tinea pedis, it was shown that, at the end of the study, 91.4 % of patients using this medication achieved negative mycological findings and 74.3 % achieved successful treatment (negative mycological findings and significant relief or complete remission of clinical symptoms). In addition, the cream was well tolerated and no serious adverse events were reported, indicating that therapy with 1% terbinafine cream in interdigital tinea pedis is highly effective and safe [23].
Another formulation that was tested was a 1% terbinafine spray, which was applied one time to the skin of the feet with a dose equivalent to 20 mg of terbinafine per foot. The control group had surface-applied terbinafine in the form of a 1% solution at the same dose. It turned out that the mycological findings, clinical effect and risk of reinfection were comparable for both groups. In favour of the use of the spray was the easier and non-contact application [24].
In a published meta-analysis comparing the efficacy of different topical antifungal drugs, terbinafine, regardless of the formulation used (e.g. cream, gel), was found to be effective in achieving negative mycological findings and good clinical outcomes and did not cause more adverse events than placebo. In addition, terbinafine showed a statistically non-significant superiority in effect over azoles and other allylamines in the control groups. The average treatment time for terbinafine was one week and for the active control groups an average of two weeks. In conclusion, terbinafine showed similar efficacy with a shorter required duration of use which may influence better patient compliance [25].

Terbinafine film-forming solution

Film Forming Solution in short FFS is a form of special alcohol-based solution that produces a thick film on the skin in which terbinafine is contained, capable of having a fungicidal effect over a long period of time, so that the number of administrations of the drug can be reduced. A study evaluating the use of terbinafine in the form of FFS at different concentrations in patients with tinea pedis has been published. Three study groups were set up, with participants using different concentrations of terbinafine FFS (1%, 5%, 10%); the control group used placebo. FFS was applied once to both feet. The effects of terbinafine FFS were satisfactory, the application of concentrations of 1% and 5% terbinafine being as effective as 10% terbinafine. All study groups achieved significantly better mycological results than the

placebo group and scored a reduction in clinical symptoms (e.g. itching and redness). Terbinafine FFS was well tolerated and did not cause serious side effects [26]. A similar study was conducted on a Chinese population, where the efficacy of 1% terbinafine FFS in a single application was evaluated for the treatment of tinea pedis. After 6 weeks, 86% of those using the drug had negative mycological findings, 69% reported a reduction in redness, 70% a reduction in pruritus. Terbinafine FFS was clearly more effective than placebo and treatment with it was well tolerated by patients [27]. As the study indicates, the use of terbinafine FFS is an effective and convenient form of treatment for tinea pedis.

The need for only one dose increases the chance that the patient will comply with medical advice [26, 27]. In a large study conducted in France and Germany, the efficacy and safety of terbinafine FFS at a concentration of 1% also applied as a single dose was evaluated. After a period of 6 weeks, 72% of patients treated with terbinafine had negative mycological findings, which was achieved by only 21% of the placebo group. The drug group had a significant clinical improvement compared to placebo with statistical significance. Terbinafine at 1% FFS concentration was effective and had a high safety profile, which influenced patient satisfaction with treatment [28].

Terbinafine and laser

The use of lasers is a relatively new treatment method for onychomycosis. Different lasers can be used in therapy, e.g. Nd:YAG and fractional laser. In the case of the fractional laser, additional surface-applied drugs (e.g. terbinafine) are used, which, probably due to laser therapy, penetrate better through the nail and show stronger antifungal effects [2]. In a study comparing the efficacy of 1% terbinafine ointment and CO2 fractional laser with orally taken itraconazole, the use of laser and terbinafine was shown to produce slightly better results than orally taken itraconazole and was not burdened by side effects. These results are promising, as such treatment may be an alternative for those poorly tolerating oral treatment [7]. In a study comparing the use of four sessions of the 1064 nm Nd-YAG laser with topical terbinafine in the treatment of onychomycosis, it was shown that 6-month therapy with terbinafine applied superficially twice daily was less effective after both 3 and 6 months of therapy. After 6 months, 50% of patients using terbinafine declared no improvement, while in the group using laser, 100% of patients showed improvement. Additionally, after 6 months, 20% of the laser-using participants had negative mycological findings, which contrasts with the fact that 100% of terbinafine-using patients had positive mycological results [8]. Another study compared the efficacy of using a long-pulse Nd laser with a wavelength of 1064 nm alone, oral terbinafine alone at a dose of 250mg per day and a combination of laser and terbinafine at a dose of 250mg per day. The intervention with the combination of laser therapy and terbinafine proved to be the most effective. This intervention resulted in complete elimination of the fungus after 24 weeks, which could not be achieved with laser and terbinafine used separately [9]. In 2017, a study was published that evaluated the efficacy of 12 sessions of fractional CO2 laser combined with 1% terbinafine cream applied for 6 months in patients with onychomycosis. After 3 months of treatment, 68.55% of patients achieved a clinical response in the form of a significant reduction in fungal lesions on the nail surface, and the Mycological Clearance Rate (MCR) was 74.19%. Among other things, the researchers

noted during the conduct of the experiment that participants under 50 years of age achieved better results with antifungal therapy, nails infected with Trichophyton rubrum and Trichophyton mentagrophytes prognosed better than those infected with Candida albicans. In addition, a thinner nail plate occupied by a fungal infection prognosticated a better cure, while total dystrophic onychomycosis was more difficult to cure than other types of onychomycosis. Overall, the use of CO2 laser and topical 1% terbinafine have been demonstrated to be effective in reducing clinical symptoms and improving mycological results [10].

Terbinafine in the treatment of onychomycosis

Tinea pedis is often accompanied by onychomycosis, as fungi residing on the skin can infect the nail or nails. Therefore, when discussing the efficacy of terbinafine in the treatment of tinea pedis, it is also worth focusing on onychomycosis as an accompanying disease entity [1,2].

In the treatment of onychomycosis, oral therapy is most effective. A study was conducted to compare the efficacy of continuous terbinafine therapy and pulse therapy. One group used terbinafine at a dose of 250 mg per day for 12 weeks, the other group received 500 mg of terbinafine daily for the first week of each four-week cycle. The dosing cycle (one week on medication followed by a three-week break) was repeated three times over a 12-week treatment period. Both groups reported clinical improvement and significant improvement in mycological findings and the differences between the continuous and pulsed medication groups were statistically insignificant [29]. There is a need to search for effective drugs for the treatment of onychomycosis that can be applied topically. This form of administration has potentially less risk of affecting the entire human organism. A study was conducted on the use of a topical solution of 10% terbinafine hydrochloride (MOB015B) in patients with moderate to severe onychomycosis, applied to the nails once daily for 28 days. The plasma concentration of MOB015B was approximately 2,000 times lower than after taking oral terbinafine - this shows how the use of the surface form of the drug results in lower systemic exposure. MOB015B was well tolerated, no serious side effects were observed, plasma levels were consistently low, i.e. terbinafine was not significantly absorbed into the human body [30]. In a study using topical terbinafine at a concentration of 10 per cent (MOB-015) once daily for 48 weeks for the treatment of distal subungual onychomycosis, it was shown that after 52 weeks of treatment, 69.9 % of participants using terbinafine achieved negative mycological results, while only 27.7 % of those in the placebo group did so ($p < 0.001$). However, the results were quite disappointing, as complete cure, defined as negative mycological results and the absence of clinical signs of mycosis fungoides, was achieved by only 4.5% of the study group and 0% of the placebo group. This indicates that MOB-015 is highly effective in eliminating fungi, but no satisfactory complete cure results could be achieved within the given application period [31].

A study was conducted using a lacquer with 10% terbinafine applied for 48 weeks (daily for four weeks, then once a week). Two control groups were formed in this experiment. One control group applied lacquer with palcebo, the other applied lacquer with 5% amorolfine once a week (the lacquer was washed off and the nail sawed before each application). The

complete cure rate (negative mycological examinations and no clinical symptoms) assessed after 60 weeks for terbinafine was 5.67%, for amorolfine 2.92% and for placebo 2.2%. Terbinafine in a 10% lacquer was significantly more effective than the placebo intervention, but the difference was statistically significant only when compared to placebo. Mycological cure after 60 weeks was achieved by 20.44% in the terbinafine group, 18.98% in the amorolfine group and 12.2% in the placebo group. Both antifungal drugs are effective in the treatment of onychomycosis with a slight advantage in favour of terbinafine [32]. A meta-analysis comparing the efficacy of monotherapy and multidrug therapy in the treatment of onychomycosis was conducted. It was found that the highest therapeutic efficacy was with oral continuous use of 250 mg of terbinafine for 12 to 16 weeks and 200 mg of itraconazole for 12 weeks. Continuous therapy produced better results than pulsed regimens of 500 mg terbinafine and 400 mg itraconazole.

The results of the meta-analysis showed that oral therapies are more effective than topical therapies, but are associated with more side effects and adverse events-topical therapies have lower efficacy but a higher safety profile [28]. In a study comparing the efficacy of different oral drugs in the treatment of onychomycosis, the best treatment efficacy was obtained for drugs such as albaconazole at 400mg, posaconazole at 200-400mg and terbinafine at 250-350mg. Terbinafine additionally showed a high safety profile, making it an effective and safe therapeutic option for onychomycosis [34].

Tinea pedis in patients with diabetes

An experiment was conducted on patients with diabetes to implement foot care to avoid the development of diabetic foot and associated ulcers. Patients at high risk of developing diabetic foot, with complications such as neuropathy, amputation status, circulation disorders in the lower limbs, among others, were analysed and completed a two-year foot care programme. This programme consisted of educating patients on how to care for their feet, removing calluses and monitoring skin conditions. In the context of tinea pedis, it turned out that the number of participants without tinea pedis increased from 14.8% to 37.5%. In patients with a history of ulceration, the number of patients free of tinea pedis increased from 0% to 34%. No effect of the intervention on onychomycosis was observed. The results of the study show the importance of proper foot hygiene in the prevention of tinea pedis [35]. In a Japanese study that analysed risk factors for the development of tinea pedis and onychomycosis, diabetes was shown to be an independent risk factor for the development of tinea pedis. The additional presence of lower ischaemia further increased the risk of tinea pedis. Diabetic neuropathy, on the other hand, was a risk factor for onychomycosis [36]. The results of the above studies show that the diabetic group requires close observation for onychomycosis and the use of prophylaxis and prevention [35,36].

Conclusion

Athlete's foot is a disease having a fungal aetiology, which manifests itself by various skin lesions, including redness, desquamation, accompanied by pruritus. Risk factors for its development are ageing, poor hygiene, inappropriate footwear, playing contact sports and many others. This causes the problem of tinea pedis to affect a large population. Effective

antifungal medications are available on the market to achieve satisfactory therapeutic results. These treatments are produced in various formulations so that the patient can easily choose a satisfactory agent. Terbinafine is a well-known treatment for tinea pedis and onychomycosis, which can be used systemically and topically. The results of the majority of studies show that it is effective in both reducing disease symptoms and eliminating the fungus. Unfortunately, there are reports of increasing fungal resistance to this agent, which should arouse the vigilance of physicians. Analysing the overall problem of tinea pedis, it is impossible to omit onychomycosis. It is much more difficult to treat, often requiring oral medication. An interesting direction in the treatment of onychomycosis are lasers, which seem to improve the effectiveness of local treatment, which is important for patients with contraindications to systemic treatment. A group of patients at particular risk are diabetics. Their feet are easily colonised by fungi and neuropathy as a consequence of diabetes is a risk factor for onychomycosis.
Researchers in the next few years should focus on the search for alternative substances in the face of increasing fungal resistance to current drugs and on improving topical treatment of onychomycosis. Onychomycosis often affects elderly and stressed individuals and prolonged oral treatment may adversely affect their bodies.

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Author's contribution:
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