PUB: 108/2011

INTERMITTENT PULSE-DOSED TERBINAFINE IN THE TREATMENT OF TINEA CORPORIS AND/OR TINEA CRURIS

V Shivakumar, Rajendra Okade, V Rajkumar, K Sajitha[1], S R Prasad[1]

Departments of Dermatology and [1]Microbiology, Sri Devaraj Urs Medical College, Tamaka, Kolar, India. ***Address for correspondence:*** *Dr. V Shivakumar, No. 66, 11th Cross, Indiranagar 1st Stage, Bangalore, Karnataka, India. E-mail: dermashiva@rediffmail.com*

Indian J Dermatol 2011:56(1):121-2

Sir,

Dermatophyte infections are amongst the most common dermatologic conditions.[1] Systemic therapy is indicated when the lesions are widespread, recurrent, chronic, or fail to respond to topical therapy.[2] The conventional oral antifungal regimens are of long duration and are associated with toxicity and poor compliance. Hence, a newer cost-effective regimen with a well-tolerated oral antifungal agent is desirable. Terbinafine's fungicidal action, combined with its improved pharmacokinetic properties, makes it an ideal drug for the purpose.[3,4]

Here we report the results of an open trial on the efficacy of intermittent (once in 3 days) pulse-dosed oral terbinafine therapy (total of 7 doses) in patients with tinea corporis and/or cruris, as there are no previous studies on this topic in literature.

A total of 100 patients (above 16 years of age) clinically diagnosed to have extensive (>100 cm^2) tinea corporis and/or cruris and who were not on systemic or topical antifungal therapy were recruited for this open-label study. The study was undertaken over a period of 1 year from May 2007 to April 2008. Pregnant and lactating women; patients on immunosuppressive therapy; and those with liver disorders, HIV infection, or with known hypersensitivity to drugs were excluded. Mycological investigations included microscopy using 10% KOH mount and fungal culture on Sabouraud's dextrose agar.

Of the 100 patients initially recruited, dermatophytes were isolated from 46 patients who met the study criteria. These patients received one 250-mg tablet of terbinafine once in 3 days, with a total of seven tablets completing the therapy. After a period of 3 weeks, the clinical condition in all the patients was assessed and mycological investigations as above were repeated. Patients were followed-up every 3 weeks till the end of the 12th week.

The primary efficacy measure was mycological cure (negative KOH mount and/or culture). The secondary measures of efficacy were clinical changes from baseline

at weeks 3 and 12. Patients were categorized as 'healed' (absence of signs and symptoms), 'markedly improved' (>50% clinical improvement), 'partial response' (<50% clinical improvement), 'no change,' or 'worsened.' Clinical cure was defined as complete absence of symptoms and signs or marked improvement.

In this study, the average age of patients was 36 years with male predominance (67%). The majority of patients had both tinea corporis and cruris (45%), while 37% had tinea corporis alone. At the end of 3 weeks of treatment with terbinafine, 43 (93.4%) of the 46 patients had responded completely as evidenced by the disappearance of symptoms, resolution of skin lesions, and negative fungal cultures. None of the patients reported any adverse effect to the drug.

There were three (6.5%) treatment failures. One of these, who showed no clinical response at all, had persistent lesions due to *T. tonsurans*. The other two patients responded only partially as evidenced by persistence of clinical lesions. One of these patients had long-standing extensive skin involvement, while the other was a diabetic. Fungal cultures showed persistence of *T. rubrum* and *T. mentagrophytes* infections respectively in them.

Thus 93.4% of patients who were administered intermittent pulse-dosed oral terbinafine were cured of infection at the end of 3 weeks. However, one patient relapsed during the 2nd month of follow-up and skin scrapings from his lesion grew *T. rubrum*, as it had earlier.

Thus, at the end of the total follow-up period (81.6 ± 4.1 days), 42 of 46 patients enrolled at the beginning of the study were clinically and mycologically cured, giving an overall cure rate of 91.3%.

The elimination of terbinafine from several body compartments is biphasic, with a rapid initial elimination followed by a slower secondary elimination.[5]

The fungicidal property of the drug, its ability to rapidly penetrate the stratum corneum and the nail plate, and its relatively longer post-antibiotic effect (PAE)[6] suggest that an intermittent pulse-dosed treatment regimen may provide better therapeutic outcome with a low relapse rate.[3,4]

In this study, intermittent pulsed terbinafine (once in 3 days) for a period of 3 weeks achieved a cure rate of 91.3% with a very low relapse rate in the treatment of tinea corporis/ cruris confirming the above favourable pharmacokinetic properties of terbinafine.

Therefore, pulsed intermittent terbinafine therapy can be considered as a good therapeutic option in the management of tinea corporis and/or cruris. This reduces the cost of treatment and the risk of cumulative toxicity and increases patient compliance, thereby making the treatment cost effective.

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Quick Response Code:	Website: www.e-ijd.org
	DOI: 10.4103/0019-5154.77579