

## Efficacy and Safety of 1% Clotrimazole Cream Occlusion with the Mechanical Reduction as an Adjuvant Therapy for the Treatment of Onychomycosis

Sir,

According to the article “Treatment of Dermatophytosis in Elderly, Children, and Pregnant Women” published in the Indian Dermatology Online Journal, Volume 8; September-October 2017, dermatophytic infection is challenging in some population groups such as pregnant women, children, and elderly.<sup>[1]</sup> Elderly individuals have been reported to be highly infected with onychomycosis, with occurrences of almost 20% and 50% in those aged over 60 and 70 years, respectively.<sup>[2]</sup> In this review, authors have cited that treatment of onychomycosis in the elderly should be topical antifungals with or without chemical (40% urea) or mechanical nail avulsion.<sup>[3]</sup> In our opinion, mechanical nail avulsion is a cheap and effective adjuvant therapy for onychomycosis, especially in resource-limited regions.

Approved by the Institutional Review Board (Si135/2008), a randomized control trial regarding the efficacy and safety of 1% clotrimazole cream occlusion along with mechanical reduction for the treatment of onychomycosis was conducted at Siriraj Hospital, Thailand. Thirty patients with 49 nails were included in the study and divided into two groups. The control group received oral antifungal drugs alone, which were either oral pulse itraconazole or daily oral terbinafine, whereas the experimental group received oral antifungal drugs and topical antifungal with mechanical nail avulsion by nail filing [Figure 1].

Each nail was evaluated by clinical and laboratory investigations. Laboratory investigations include potassium hydroxide (KOH) examination under microscopy and culture for dermatophytes or nondermatophytes. All participants were interviewed in terms of personal history and risk factors of onychomycosis. The severity of fungal nail infection was evaluated by The Scoring Clinical Index for Onychomycosis (SCIO) and Baran–Hay nail severity index.

Among 49 nails, 34 (69.4%) were toenails and 15 (30.6%) were fingernails. Distal and lateral subungual onychomycosis were the main clinical presentations (91.8%). The rest



Figure 1: Mechanical nail reduction by nail filing and applying 1% clotrimazole cream occlusion on the infected nail overnight

included superficial white onychomycosis (4.1%) and total dystrophic onychomycosis (4.1%). Eighty-six percent of causative fungal organisms were dermatophytes and 14% were nondermatophytes [Table 1].

At the end of the 16-month follow-up study, 88% (22 out of 25 nails) in the experimental group and 72.2% (19 out of 24 nails) in the control group achieved complete cure. The criteria of complete cure is negative mycological laboratory results of both KOH and fungal culture together with lesser than 10% of affected nail plate area involvement which according to “Onychomycosis: Current Trends in Diagnosis and Treatment” is defined as normal appearance in 80–100% of the nail.<sup>[4]</sup> Furthermore, the median time to cure and mean nail thickness in the group receiving oral antifungals together with topical antifungals with mechanical nail avulsion decreased significantly ( $P$  value = 0.006 and  $<0.001$ , respectively) [Figure 2]. Moreover, it has shown that nail filing is an effective adjuvant therapy to standard oral antifungal drugs in treating onychomycosis.

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### Conflicts of Interest

There are no conflicts of interest.

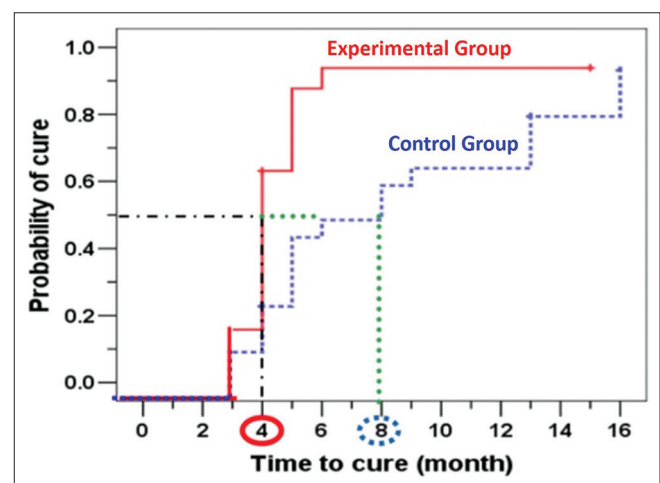


Figure 2: Kaplan–Meier analysis illustrated the median time to cure of both groups including the control and experimental groups

**Table 1: Demographic data, severity score, clinical presentation, and causative organisms in the experimental group and control group**

	Experimental group	Control group	P*
Sex			
Male (n) (%)	9 (60.6)	10 (66.7)	1.00
Female (n) (%)	6 (40.0)	5 (33.3)	
Age (years) (mean±SD)	54.0±16.7	62.7±16.6	0.17
Body mass index (mean±SD)	24.8±4.6	24.7±3.2	0.91
Nail severity score			
The scoring clinical index for onychomycosis (mean±SD)	12.3±6.1	10.06±5.3	0.31
Baran-Hay score index (mean±SD)	7.6±2.0	8.5±2.2	0.15
Causative fungal organisms			
Dermatophyte (n) (%)	22 (88.8)	20 (83.3)	0.95
Nondermatophyte (n) (%)	3 (12)	4 (16.7)	
Types of onychomycosis			
Distal lateral subungual (n) (%)	23 (92.0)	22 (91.7)	
Total dystrophic (n) (%)	2 (8.0)	0 (0)	
Superficial white (n) (%)	0 (0)	2 (8.3)	

SD: Standard deviation; n: number of cases. \*P<0.05: Statistical significance

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