Topical Antifungals for Treatment of Onychomycosis

REBECCA KRASAEATH, MD, JD, and JOSE ELIZONDO, MD, *Advocate Illinois Masonic Medical Center, Department of Family Medicine, Chicago, Illinois*

Clinical Question

What is the rate of resolution of onychomycosis treated with topical antifungal agents?

Evidence-Based Answer

Topical antifungal agents are effective in treating onychomycosis, with a number needed to treat (NNT) of 7 to 17. (Strength of Recommendation: A, based on consistent findings from good-quality randomized controlled trials.) Efinaconazole 10% topical solution achieved complete cure rates of 15% to 18% vs. 3.3% to 5.5% for vehicle (NNT = 7 to 10). Tavaborole 5% topical solution achieved complete cure rates of 6.5% to 9.1% vs. 0.5% to 1.5% for vehicle (NNT = 13 to 17). Ciclopirox 8% nail lacquer achieved a complete cure rate of 7% compared with 1% for vehicle (NNT = 17). Each medication must be used daily for 48 weeks.

A 2013 review of two randomized, double-blind, vehicle-controlled, parallel-group, multicenter trials (n = 870 and 785) evaluated efinaconazole 10% topical solution vs. vehicle with no efinaconazole for complete cure of distal subungual onychomycosis.[1] Patients 18 to 70 years of age received efinaconazole or vehicle, which they applied once daily for 48 weeks followed by four weeks of treatment-free follow-up. Effectiveness and safety were assessed at 12-week intervals and at a final visit at 52 weeks. At the 52-week visit, complete cure was significantly greater for patients who used efinaconazole (study 1: 18% vs. 3.3%; study 2: 15% vs. 5.5%; $P < .001$). Adverse events included local site reactions (2%) and were clinically similar to those associated with vehicle.

A 2015 review of two randomized, double-blind, vehicle-controlled, parallel-group, multicenter trials (n = 594 and 604) evaluated tavaborole 5% topical solution vs. vehicle with no tavaborole for complete cure of distal subungual onychomycosis.[2] Patients 18 years and older were randomized (2:1) to receive tavaborole or vehicle once daily for 48 weeks. Effectiveness and safety were assessed at baseline, week 2, week 6, and every six weeks thereafter until week 48, with final evaluation at week 52. Tavaborole was significantly more effective than vehicle alone when applied daily for 48 weeks (complete cure in 6.5% and 9.1% vs. 0.5% and 1.5% of patients; $P < .001$). Rates of completely clear or almost clear nails with negative mycology were also significantly greater in the treatment group (15% and 18% vs. 1.5% and 3.9%; $P < .001$). Adverse effects were limited to local site reactions, such as exfoliation (2.7%), erythema (1.6%), and dermatitis (1.3%).

A 2000 pooled study of two double-blind, vehicle-controlled, parallel-group, multicenter trials (n = 185 and 173) evaluated ciclopirox 8% nail lacquer in the treatment of distal subungual onychomycosis.[3] Rates of complete cure were greater with ciclopirox compared with vehicle (7% vs. 1%; $P = .001$). Mild transient irritation at the application site was the most common adverse effect.

Address correspondence to Jose Elizondo, MD, at jose.elizondo-md@advocatehealth.com. Reprints are not available from the authors.

Author disclosure: No relevant financial affiliations.

REFERENCES

1. Elewski BE, et al. Efinaconazole 10% solution in the treatment of toenail onychomycosis. *J Am Acad Dermatol.* 2013;68(4):600-608.
2. Elewski BE, et al. Efficacy and safety of tavaborole topical solution, 5%, a novel boron-based antifungal agent, for the treatment of toenail onychomycosis. *J Am Acad Dermatol.* 2015;73(1):62-69.
3. Gupta AK, et al. Ciclopirox 8% nail lacquer in the treatment of onychomycosis of the toenails in the United States. *J Am Podiatr Med Assoc.* 2000;90(10):495-501. ■