

A financial perspective on the topical treatment of onychomycosis



To the Editor: A recent article from the July 2015 issue of the JAAD described the results of phase-III studies of a novel topical treatment for onychomycosis, tavaborole solution (Kerydin, Sandoz Inc, Princeton, NJ)¹. The randomized trials compared treatment with the boron-based solution to the vehicle control. Exclusion criteria were myriad, including involvement of more than 60% of the nail plate, a nail plate thicker than 3 mm, “severe disease,” concurrent tinea pedis, a history of chronic tinea pedis, known immunosuppression, peripheral vascular disease, and diabetes mellitus with A1C >8%. Despite these generous exclusion criteria, after 48 weeks of daily therapy, the primary end-point of complete cure was achieved in only 6.5% of patients versus 0.5% treated with the placebo (study 1) and 9.1% versus 1.5% for the placebo group (study 2). A similar study published in the April 2013 issue of the JAAD reported the results of phase-III trials of topical efinaconazole solution (Jublia) for onychomycosis.² Daily treatment for 48 weeks with efinaconazole achieved a complete cure rate of 17.8% versus 3.3% for placebo (study 1) and 15.2% versus 5.5% for placebo (study 2).

I found it enlightening to consider these efficacy statistics from the perspective of number needed to treat (NNT) and associated cost. Averaging the 2 tavaborole trials results in a combined efficacy of 7.8% or, expressed as NNT, 12.8 individuals would have to complete 48 weeks of daily tavaborole therapy for every expected cure. A 10 mL monthly supply of tavaborole costs \$1253.40 (or \$13,787.40 for the 11-month treatment course).³ Multiplying these two values ($12.8 \times \$13,787.40$) reveals that, when using tavaborole, each successfully treated case of onychomycosis costs a predicted \$176,478.72. The combined cure rate for efinaconazole is 16.5%, or 6 when expressed in terms of NNT. An 8 mL monthly supply of efinaconazole costs \$1,098.49 (or \$12,083.39 for the 48-week treatment

course).³ The product of these values reveals an expected cost of \$72,500.34 for each patient successfully treated with efinaconazole.

Admittedly, this “back of the napkin” analysis is not without shortcomings; it lacks sensitivity analyses as well as confidence intervals around the NNT, and there are well-documented concerns regarding “averaging” the results of clinical trials.⁴ Nevertheless, in this era of cost-conscious medicine, the prospect of spending 3-7 times the American median annual personal income to cure a single case of onychomycosis does not seem to represent an appropriate use of resources.

James Prewitt Lagrew, MD

Department of Dermatology and Dermatologic Surgery, Medical University of South Carolina, Charleston, SC

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Correspondence to: James Prewitt Lagrew, MD, Department of Dermatology and Dermatologic Surgery, Medical University of South Carolina, 135 Rutledge Ave, Charleston, SC 29425

E-mail: lagrew@musc.edu

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