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Patient Satisfaction with Oral *versus* Nonoral Therapeutic Approaches in Onychomycosis

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The follow-up results of a 9-month observational study of 150 onychomycosis patients treated with a variety of mechanical, topical, and oral therapies by podiatric physicians and dermatologists are presented. Changes from baseline in toenail condition and patient satisfaction were assessed at 4- and 9-month follow-up. At 9 months, patients who had received oral therapy reported significantly fewer onychomycosis-related problems in social situations, including embarrassment or self-consciousness about the appearance of nails, avoidance of contact by others, being perceived as unclean or untidy, and the desire to keep their nails concealed. Patient-reported satisfaction with the treatment program was significantly higher for those receiving oral therapy than for those receiving nonoral therapy. (J Am Podiatr Med Assoc 91(10): 521-527, 2001)

Onychomycosis of the nail is a common condition, and clinicians often fail to appreciate the seriousness with which many patients regard it. This unsightly and uncomfortable fungal infection can impair physical functioning, limit choice of footwear, negatively affect self-esteem, and give rise to self-consciousness, anxiety, depression, and the fear of contagion to others.[1, 2] Studies indicate that these factors can detract from a patient's overall quality of life.[3]

Traditional podiatric treatments, such as debridement and topical medications, may improve a patient's comfort and appearance, but they do not cure onychomycosis. New oral antifungal agents, such as terbinafine and itraconazole, have been shown to be effective in treating onychomycosis.[4, 5] Since these drugs have the potential to clear the infecting organisms and produce a clinical cure, they are likely to require a shorter duration of therapy and significantly fewer office visits than palliative treatments, such as debridement or topical therapy. Overall, this makes oral agents cost-effective.[6, 7] Recent analysis has shown that potential cost-effectiveness is driven by significantly higher clinical improvement rates in patients treated with oral antifungal agents.[8] However,

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when physicians make treatment choices they must also consider patient satisfaction and potential effects on quality of life.

This study evaluated changes in toenail condition and in satisfaction with treatment in patients with onychomycosis who received a variety of mechanical, topical, and oral therapies during a 9-month observation period. Patient and clinician assessment of symptoms, quality of life, and patient satisfaction at baseline were reported previously.[9] Patient outcomes were assessed according to the various treatment options. The resulting observations illustrate important differences in the ways that clinicians approach treatment for different age groups and how the type of treatment (oral antifungal therapy or other therapies) relates to self-reported clinical improvement and patient satisfaction.

Methods

This longitudinal study collected comprehensive observational data from patients with onychomycosis for a 9-month period. Treatment for onychomycosis consisted of mechanical therapy (nail debridement), topical medication (clotrimazole, Fungi-Nail [Kramer Laboratories, Inc, Miami, Florida], terbinafine, ciclopirox olamine, clotrimazole and betamethasone, econazole, tolnaftate [none of which were approved by the US Food and Drug Administration for onychomycosis at the time of study]), oral medication (terbinafine, itraconazole, fluconazole), or surgery, as deemed necessary by the clinicians. Investigators in the study were instructed to treat patients as they would normally to avoid influencing the choice of products or approaches to therapy. Data collected at entry and at two follow-up visits were compared to assess changes in nail condition, patient satisfaction, and quality of life.

Data Collection, Entry, and Retrieval

Patients at eight sites in the US were invited to participate in the study during routine office visits to their dermatologist or podiatric physician. Study sites were comprised of three podiatric medical centers and five dermatology centers. Enrollment was offered to patients 18 years or older who were literate in English and who had a clinical diagnosis of onychomycosis as confirmed by the appearance of onycholysis and subungual hyperkeratosis. Patients on oral antifungal drug therapy at the time of enrollment were excluded.

At enrollment (baseline visit), patients completed an informed-consent form and received a physical examination by their physician to document the degree of nail involvement. Any existing conditions known to affect immune function were noted. The study coordinator or health-care provider completed a baseline information form for each patient, which provided data on the patient's clinical history, nail assessment, current manifestations, treatment, and any laboratory tests that were performed at the time of the visit. Such tests included fungal diagnostic tests, chemistry panels, pregnancy tests, urinalysis, and hematology tests.

At enrollment, patients also were asked to complete a questionnaire on demographics, medical history, and baseline health-related quality of life. Questions addressed areas of general concern, including physical functioning, social functioning, pain, health distress, and stigma. The questionnaire also included disease-specific items concerning onychomycosis, such as the ability to perform physical activities (for example, standing, playing tennis, or dancing) and the burden associated with caring for nail discoloration, thickening, soreness, or redness. These questions were derived from previous studies and have been researched extensively and validated in patients with onychomycosis and other conditions.[3, 10-12] The quality-of-life questionnaire was administered again at 4 and 9 months after enrollment.

A second clinical evaluation was performed 4 months after enrollment. Patients at six of the eight study sites also participated in a final clinical examination at 9 months. Patients were asked to use a 5-item scale to rate their satisfaction with the nail treatment program. This scale was administered at baseline, 4 months, and 9 months.

Uniform questionnaires and procedural manuals were used to ensure the consistency and quality of data collected across sites. All data were collected and maintained in a confidential database at a centralized patient-tracking facility. To ensure patient confidentiality, project team members were required to sign confidentiality agreements before receiving access to patient questionnaires. In addition, all patient identifiers were removed when the data were merged into the database.

This article analyzes the demographic and clinical characteristics of the full sample, as reported by the physician, the patient, or both. Longitudinal comparisons are presented for the 4- and 9-month visits, including physician global assessment of changes in nails compared with baseline, changes in therapy as a function of initial therapy, physician and patient assessments of nail improvement, and changes in patients' self-reported satisfaction with their treatment. Data comparisons were also made on the basis of

oral *versus* nonoral treatment. Patients in the oral therapy group were defined as those treated by any form of oral medication or any combination of oral plus topical medication. Patients grouped under nonoral therapy were those treated with topical nail therapy, such as debridement, topical medication, or any combination of topical treatments. When appropriate, comparisons for significant differences were calculated by means of either a chi-square test or a Student's *t*-test.

Results

Patients

A total of 160 patients were invited to participate. Nine (5.6%) declined and one was excluded for having fingernail rather than toenail onychomycosis. Thus, a total of 150 patients were enrolled in the study. Three of these patients, however, were found to be taking oral antifungal drug therapy at the time of enrollment and were excluded from all analyses. The final full sample at baseline was 147 patients (mean age, 59.9 ± 16.2 years), with 54% younger than age 65. The study enrolled slightly more men than women. Approximately half of the patients visited a dermatologist (51%), while the remainder (49%) visited a podiatric physician (Table 1).

Of the 147 patients included in the analysis, 50% had onychomycosis for 4 years or more, and 47% had received previous treatment for onychomycosis. At baseline, patients had a mean of 5.3 ± 3.2 toenails affected by onychomycosis (range: 1 to 10 toenails).

Table 1 compares patient demographics and data for oral *versus* nonoral therapies. At the baseline visit, 58 patients (39%) received a prescription for an oral antifungal medication. Of these 58 patients, 53 received oral therapy only. Of the 53 patients, 39 patients (74%) received terbinafine, 13 (24%) received itraconazole, and 1 (2%) received fluconazole. Nine patients (6%) received no treatment for their onychomycosis at the initial visit. One of these patients started oral therapy 4 weeks later and for analytic purposes was included in the oral therapy group. One patient started nail debridement 4 weeks after the baseline visit and was included in the nonoral therapy group. The remaining 7 patients received debridements at the 4-month visit and also were included in the nonoral group.

Patients who received oral therapy had a mean of 5.6 ± 3.4 toenails involved at baseline while patients receiving nonoral therapy had a mean of 5.0 ± 3.0 toenails involved. Patients receiving oral antifungal therapy were significantly more likely to be under the care of a dermatologist than a podiatric physician ($P = .001$). On average, the 58 patients receiving oral medication were younger (52.5 ± 15.7 years) than the 89 patients not receiving oral medication (64.7 ± 14.8 years) ($P = .001$).

Clinical Tests and Procedures

Fewer than half of the patients underwent onychomycosis-related laboratory tests at baseline or at either follow-up visit. The majority of laboratory tests were performed at baseline. The most common tests were potassium hydroxide (KOH) preparation and fungal culture. The likelihood of the patient having had a KOH test to confirm the diagnosis at baseline was significantly greater if the patient was receiving oral therapy (43% on oral therapy received a KOH test *versus* 4% on nonoral therapy; $P = .001$). The difference at baseline was not significant for fungal culture tests, although it was more common in patients receiving oral therapy (26% oral *versus* 16% nonoral). Of the seven patients on whom fungal cultures were performed at the 9-month visit, all appeared to be treatment failures.

Podiatric physicians performed significantly more nail debridements than did dermatologists. Of those patients who visited a podiatric physician, 85% underwent debridement, while 5% of patients treated by a dermatologist underwent this procedure ($P < .001$).

Patient Improvement and Satisfaction

At the 4- and 9-month follow-up visits, physicians noted improvement in 81% and 83%, respectively, of patients on oral therapy but in only 39% and 35% (at 4 and 9 months, respectively) of patients on nonoral therapy (Fig. 1). This difference in improvement for oral *versus* nonoral therapy was significant ($P = .001$). For patients on oral therapy, the mean number of affected toenails reported by physicians declined from 5.6 at baseline to 4.5 at 4 months and to 3.8 at 9 months.

Patients who were treated with debridement or topical agents had longer courses of treatment than those who received oral medication. Of the patients whose initial therapy included oral antifungal medication, only 7 patients (12%) were still taking oral antifungal medication at the 4-month follow-up, and only 1 (2%) at the 9-month follow-up was still taking the medication. In contrast, of the 64 patients treated with debridement at baseline, 52 (81%) were still receiving this treatment at the 4-month follow-up, and 36 (56%) at the 9-month follow-up. Also, 31 (62%) of the 50 patients who were started on topical antifungal

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