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Emergency department use by patients with prurigo nodularis in the United States

To the Editor: Prurigo nodularis is a debilitating condition characterized by intensely pruritic nodules. Although it is often managed in the outpatient setting, patients may experience acute flares that result in presentation to the emergency department.[1] Despite prurigo nodularis's toll on patients' physical and emotional well-being, limited information exists on its economic burden.[2,3] The goal of the present study was to quantify the use and cost of emergency care for prurigo nodularis.

We used data from the 2016 National Emergency Department Sample from the Healthcare Cost and Utilization Project. The National Emergency Department Sample is a cross-sectional sample of 20% of hospital-owned emergency departments in the United States, with greater than 32 million visits captured. The prurigo nodularis cohort was identified according to *International Classification of Diseases, 10th Revision, Clinical Modification* code

Table I. Demographic information of prurigo nodularis patients compared with general patient population presenting to the emergency department

	General population		Prurigo nodularis		
Variable	Weighted freq	Percentage (95% confidence interval)	Weighted freq	Percentage (95% confidence interval)	*P* value
Age, y					
0—19	32,721,926	22.6 (21.1-24.2)	<50	0.7 (0.2-2.4)	<.001
20—39	42,784,061	29.6 (28.9-30.3)	207	12.1 (8.3-17.4)	<.001
40—59	34,783,167	24.0 (23.5-24.6)	860	50.3 (42.9-57.7)	<.001
60—79	24,360,292	16.8 (16.4-17.2)	532	31.1 (25.6-37.3)	<.001
>80	10,051,363	6.9 (6.7-7.2)	98	5.7 (3.6-8.9)	.048
Discharge month					
Jan—Mar	36,677,219	25.4 (25.3-25.5)	383	23.0 (18.8-27.8)	.005
Apr—Jun	36,174,747	25.0 (24.9-25.1)	266	28.0 (23.5-33.0)	<.001
Jul—Sep	36,405,047	25.2 (25.1-25.3)	383	23.0 (18.9-27.8)	.009
Oct—Dec	35,348,144	24.4 (24.3-24.6)	433	26.0 (21.2-31.5)	.39
Male sex	64,380,409	44.5 (44.2-44.8)	793	46.4 (39.5-53.5)	.12
Female sex	80,298,693	55.5 (55.2-55.8)	916	53.6 (46.5-60.5)	.12
Income quartile					
First	50,267,605	35.4 (33.4-37.3)	594	36.4 (29.2-44.2)	>.99
Second	38,744,510	27.3 (25.7-28.8)	324	19.8 (15.0-25.7)	<.001
Third	29,776,303	20.9 (19.8-22.2)	392	24.0 (17.8-31.6)	.02
Fourth	23,361,705	16.4 (14.9-18.1)	323	19.7 (14.5-26.4)	.002
Insurance					
Medicare	33,339,465	23.1 (22.4-23.7)	760	44.9 (38.7-51.2)	<.001
Medicaid	46,702,902	32.3 (31.2-33.5)	503	29.7 (23.4-36.8)	.011
Private	41,340,631	28.6 (27.7-29.5)	251	14.8 (10.7-20.2)	<.001
Self-pay	16,478,447	11.4 (10.8-12.0)	131	7.7 (5.0-11.8)	<.001
No charge	587,299	0.4 (0.3-0.6)	<50	1.1 (0.3-4.1)	<.001
Other	6,082,695	4.3 (4.0-4.6)	<50	1.9 (0.8-4.1)	<.001
Region					
Northeast	26,446,888	18.3 (16.4-20.4)	348	20.4 (13.3-29.8)	.03
Midwest	32,902,943	22.7 (20.8-24.8)	519	30.4 (21.6-40.8)	<.001
South	58,050,749	40.1 (37.5-42.8)	572	33.4 (25.2-42.9)	<.001
West	27,300,230	18.9 (17.3-20.5)	271	15.8 (10.1-23.9)	.001
Teaching status					
Metropolitan nonteaching	41,566,281	28.7 (26.7-30.9)	256	15.0 (9.9-22.1)	<.001
Metropolitan teaching	80,813,216	55.8 (53.4-58.3)	1353	79.2 (71.6-85.2)	<.001
Nonmetropolitan	22,321,313	15.4 (14.2-16.7)	99	5.8 (3.3-10.0)	<.001

Apr, April; *Dec*, December; *Freq*, frequency; *Jan*, January; *Jul*, July; *Jun*, June; *Mar*, March; *Oct*, October; *Sept*, September.

L28.1. Weighted survey analysis was performed in Stata 15 (StataCorp, College Station, TX) to determine national estimates, using published sample weights, clusters, and strata.

Overall, there were 390 visits with a diagnosis of prurigo nodularis (weighted frequency 1,709). Table I provides demographic information of patients with prurigo nodularis compared with the general emergency department patient population. Patients presenting to the emergency department with prurigo nodularis were 53.6% women, with a mean age of 55.0 ± 1.0 years. The most common primary diagnoses for patients with a secondary diagnosis of prurigo nodularis were sepsis (8.3%; 95% confidence interval [CI] 5.7%-11.9%), cellulitis (6.3%; 95% CI 3.9%-10.1%), heart failure (5.8%; 95% CI 3.9%-8.7%), and HIV (2.5%; 95% CI 1.4%-4.5%).

Patients with prurigo nodularis were significantly more likely to be admitted as inpatients to the hospital compared with the general patient population (67% vs 13%; odds ratio [OR] 67.4; 95% CI 61.5-72.7; $P < .001$). Factors associated with inpatient admission with prurigo nodularis included older age (multivariate regression 20-39 years: reference 40-59 years, adjusted OR 4.6, 95% CI 2.5-8.4, $P < .001$; 60-79 years: adjusted OR 3.6, 95% CI 1.8-7.4, $P < .001$) and Medicare insurance status (adjusted OR 2.5; 95% CI 1.4-4.5; $P = .002$; private insurance as reference). The average cost for emergency department services for prurigo nodularis patients was $3206 ± $397, and the total cost of emergency department services in 2016 nationally was $4,377,553 ± $740,743.

The present study demonstrates the financial burden of prurigo nodularis in the emergency department setting. The average cost for emergency department services for prurigo nodularis patients was substantially higher than that reported for atopic dermatitis patients ($3,206 vs $643).[4] The cost discrepancy may reflect higher proportions of prurigo nodularis patients with serious systemic illness and the higher rates of inpatient hospital admission compared with that for atopic dermatitis patients. Previous work has demonstrated the increased rate of infection in prurigo nodularis patients, consistent with our results that show that a large proportion of prurigo nodularis patients receive a diagnosis of sepsis and cellulitis.[2] The scratching behavior and skin breakdown associated with prurigo nodularis may enhance pathogen host penetration and cause greater infection risk, as we observed here.[5]

Strengths of this study include use of a nationally representative data set. Limitations include small sample size and lack of treatment information. Furthermore, prurigo nodularis is underrecognized by nondermatologic specialties, which may conservatively bias results. Emergency care use for prurigo nodularis patients seems to be driven by the high prevalence of serious infection in this cohort. Because novel agents such as nemolizumab are currently in clinical development for prurigo nodularis, the introduction of these therapies may decrease emergency department use. Further work is needed to improve treatment options to optimize prurigo nodularis management in the outpatient setting.

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Reprints not available from the authors.

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Efinaconazole 10% topical solution for the treatment of onychomycosis in pediatric patients: Open-label phase 4 study

To the Editor: Onychomycosis is a chronic fungal nail infection affecting an estimated 0.35% to 5.5% of children worldwide,[1] although parents and health care practitioners are hesitant to use long-term systemic treatments in children.[2] Efinaconazole 10% topical solution is an azole antifungal approved by the US Food and Drug Administration to treat onychomycosis in patients 6 years of age and older.[3,4] We report here a phase 4, open-label, multicenter study (NCT02812771) of efinaconazole in patients 6 to 16 years old with distal lateral subungual onychomycosis.

Efinaconazole was administered once daily for 48 weeks, with 4-week posttreatment follow-up at week 52. Participants had culture-positive mild to severe onychomycosis affecting 20% or more of at least 1 great toenail. The study was approved by institutional review boards and was conducted according to international scientific/ethical standards. All participants and/or legal guardians provided informed consent. The primary study objective was evaluation of tolerability and pharmacokinetics (PK).

Of 62 enrolled participants, 12 (19.4%) discontinued the study (withdrawal by parent/guardian, n = 6; lost to follow-up, n = 5; participant request, n = 1). For those who received the study drug (n = 60; safety population), the mean age was 13.4 years, 66.7% were male, and 88.3% were White. None of the treatment-emergent adverse events (TEAEs) led to study discontinuation (Table I). The only treatment-related TEAE was ingrown nail. No safety signals or trends associated with local skin reactions were observed. Adverse event findings and TEAE rates from this study were similar to those from two 52-week, phase 3 pivotal studies of efinaconazole 10% in adults.[3]

The PK population included 17 participants (12-16 years) with moderate to severe onychomycosis affecting 50% or more of each great toenail and onychomycosis in at least 4 additional toenails. The mean age was 14.1 years, 64.7% of patients were male, and 100% were White. In 15 participants with evaluable PK data at week 4, the concentration-time profile for efinaconazole was relatively stable during the 24-hour dosing interval. Systemic exposure to efinaconazole was low, with a mean area under the concentration-time curve (AUC_{0-24}) of 11.4 ng*h/mL and maximum plasma concentration (C_{max}) of 0.549 ng/mL. The median time to C_{max} was 12 hours. These results are comparable to those previously reported in adults (AUC_{0-24}, 12.15 ng*h/mL; C_{max}, 0.67 ng/mL).[4]

Beyond the favorable safety results and expected PK profile, this study showed that a substantial proportion of participants had positive treatment responses to efinaconazole (Fig 1). Rates for complete cure (40.0%) and mycologic cure (65.0%) were considerably higher in this pediatric study than those observed previously in two 1-year adult studies (complete cure: 15.2%-17.8%; mycologic cure: 53.4%-55.2%).[3,4] Higher cure rates in children may be due to faster nail growth, shorter nail length, and/or shorter duration of infection (potentially

Table I. Treatment-emergent adverse event summary in pediatric participants treated with efinaconazole (safety population)

TEAEs	Efinaconazole 10% topical solution (n = 60)
Number of TEAEs	99
Participants with ≥1 TEAE, n (%)	38 (63.3)
Participants with ≥1 treatment-emergent SAE, n (%)	1 (1.7)*
TEAEs by maximum severity, n (%)	
Mild	31 (51.7)
Moderate	7 (11.7)
Severe	0
Most common TEAEs (≥5% in safety population), n (%)	
Nasopharyngitis	18 (30.0)
Headache	6 (10.0)
Influenza	5 (8.3)
Tinea pedis†	4 (6.7)
Contusion	4 (6.7)
Nail injury	4 (6.7)
Ingrown nail	4 (6.7)
Food poisoning	3 (5.0)
Treatment-related TEAE, n (%)	
Ingrown nail	2 (3.3)‡

SAE, Serious adverse event; *TEAE,* treatment-emergent adverse event.
*The SAE of pneumonia was deemed unrelated to treatment; the moderate event resolved with hospitalization and did not require a change in study drug application.
†At screening or baseline, tinea pedis was not exclusionary (severe moccasin tinea pedis was exclusionary); a total of 8 participants (13.3%) had tinea pedis at baseline.
‡Eight total events in 2 participants.