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Evaluation of a Case Series of Patients With Palmoplantar Pustulosis in the United States

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IMPORTANCE Palmoplantar pustulosis (PPP) is a is a chronic, orphan disease with limited epidemiological data.

OBJECTIVE To describe the clinical characteristics, treatments, longitudinal disease course, and health care utilization in adults with PPP across the US.

DESIGN, SETTING, AND PARTICIPANTS This retrospective, longitudinal case series from 20 academic dermatology practices in the US included a consecutive sample of 197 adults who met the European Rare and Severe Psoriasis Expert Network consensus definition for PPP between January 1, 2007, and December 31, 2018. Data analysis was performed June 2020 to December 2020.

MAIN OUTCOMES AND MEASURES The primary outcome was to describe the patient characteristics, associated medical comorbidities, treatment patterns, complications, and PPP-specific health care utilization.

RESULTS Of 197 patients, 145 (73.6%) were female, and the mean (SD) age at presentation was 53.0 (12.6) years, with a mean (SD) follow-up time of 22.1 (28.0) months. On initial presentation, 95 (48.2%) patients reported skin pain, and 39 (19.8%) reported difficulty using hands and/or feet. Seventy patients (35.5%) were treated with systemic treatments, and use of more than 20 different systemic therapies was reported. In patients with at least 6 months of follow-up (n = 128), a median (IQR) of 3.7 (4-10) dermatology visits per year were reported; 24 (18.8%) patients had 5 or more visits during the study period.

CONCLUSIONS AND RELEVANCE In this case series, PPP was associated with persistent symptoms, continued health care utilization, and a lack of consensus regarding effective treatments, emphasizing the unmet medical need in this population. Additional research is necessary to understand treatment response in these patients.

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Editorial page 13
Related article page 73
Supplemental content

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Palmoplantar pustulosis (PPP) is a limited form of pustular psoriasis characterized by persistent, sterile macroscopic pustules on the palms and/or soles and presents both in isolation and in patients with a history of plaque psoriasis. Previous research suggests there is a genetic overlap between PPP and plaque psoriasis,[1-4] but despite any similarities, there are also key differences. Palmoplantar pustulosis predominantly presents in women, while psoriasis occurs in men and women equally. Despite the limited body surface area associated with PPP compared with psoriasis, patients with palmoplantar psoriasis have been shown to experience greater health-related quality-of-life impairment than those with moderate to severe plaque psoriasis.[5,6] Finally, treatments for PPP and palmoplantar psoriasis are similar, but much less is known about the response to treatment in patients with PPP. The objective of this study is to describe the clinical characteristics, longitudinal disease course, treatments, and health care utilization in patients with PPP across the US.

Methods

Study Design and Population

This is a retrospective case series of adults (age ≥18 years) with a diagnosis of PPP made by a dermatologist between January 1, 2007, and December 31, 2018. Up to 10 potential cases were identified from each of 20 sites using electronic health records and/or site-specific databases, starting with cases seen most recently. All diagnoses were confirmed by the principal investigator at each site at the time of data entry, and only patients who met the European Rare and Severe Psoriasis Expert Network consensus definition for PPP—documentation of primary, persistent (<3 months), sterile, macroscopic pustules on the palms and/or soles, not occurring within psoriatic plaques[7]—and had a dermatology encounter with active pustular disease during the study period were included. This study was granted exempt status by the University of Penn-

sylvania Institutional Review Board because the research met eligibility criteria for review exemption authorized by 45 CFR §46.104, category 4. A waiver of documentation of consent was granted as authorized by 45 CFR §164.512.

Data Collection

The index date or "initial encounter" was the first date of active disease within the reporting institution. Information about demographics, medical history, disease course, and treatments, including initial encounter and all subsequent encounters during the study period, were abstracted from the medical record into a standardized data collection form.

Sample Size

A target sample size of 200 patients was calculated to allow for the prevalence of associated covariates to be estimated with a 95% CI and maximum margin of error of 10%. The final sample size (n = 197) reflects that not all sites had enough patients who met inclusion criteria within the study period.

Statistical Analysis

Descriptive statistics were used to summarize the baseline patient characteristics, medical history, and information regarding clinical encounters and treatments. Median duration of therapy was calculated for each patient and each systemic therapy for all patients/drugs combinations with at least 1 subsequent visit after initiation of therapy. For patients without an identified stop date, the last visit in the study period where the therapy was "continued" was used as the end date. In patients with at least 6 months of follow-up, PPP-specific health care utilization was also descriptively examined. Logistic regression was used to examine the association of age and sex with the likelihood of a patient reporting high outpatient dermatology utilization in follow-up, defined as median of 5 or more visits per year. Data analysis was performed using Stata, version 16.1 (StataCorp LLC). This study was reported in adherence with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guidelines.

Results

There were 197 patients (mean [SD] age at presentation, 53.0 [12.6] years; 145 [73.6%] were women) who met the inclusion criteria, with a mean (SD) follow-up time of 22.1 (28.0) months (**Table 1**). Skin pain was the most common symptom reported (95 [48.2%]), with many patients reporting difficulty using hands and/or feet (39 [19.8%]), arthralgias (25 [12.7%]), and myalgias (4 [2.0%]). On skin examination, 158 patients (80.2%) had pustules on the palms, 151 (76.7%) had pustules on the soles, 118 patients (59.9%) had pustules on the palms and soles, and 21 (10.2%) had involvement of the nail unit.

A range of treatments were used, including topical therapies, systemic steroids, systemic anti-infectives and systemic psoriatic therapies (**Table 2**). During the initial encounter, 127 (64.5%) patients were treated with topical therapies only. Systemic antibiotics were given to 9 (4.6%), and 10 (5.1%) received systemic steroids. Of systemic therapies, acitretin was most commonly prescribed (n = 27), followed by methotrexate (n = 22) and phototherapy (n = 21). Biologic therapy was less frequently used as an initial therapy (n = 18). Additional details regarding the clinical course and duration of therapy are available in the eResults and eTables 1-4 in the Supplement.

Health care utilization was examined in patients with at least 6 months of follow-up time (n = 128). Of those patients, 4 required an emergency department visit for flaring PPP symptoms (**Table 3**). Follow-up dermatology office visits were common; 105 (82.0%) had at least 1 follow-up visit, 40 (31.3%) had 2 to 3 visits, and 24 (18.8%) had 5 or more total visits during the follow-up period (data not shown). The median (IQR) number of dermatology visits was 3.7 (4-10) per year. In age- and sex-adjusted models, female sex was associated with a decreased risk of high outpatient dermatology utilization in follow-up, defined as 5 or more visits per year (odds ratio, 0.49; 95% CI, 0.25-0.95) (data not shown).

Key Points

Question What are the patient characteristics and disease course of adults with palmoplantar pustulosis in the US?

Findings In this case series of 197 adults with palmoplantar pustulosis, 35.5% of patients were treated with systemic therapies, and more than 20 different systemic therapies were used. In 128 patients with at least 6 months of follow-up, a median of 3.7 dermatology visits per year were reported; 18.8% of patients had 5 or more visits during the study period.

Meaning Palmoplantar pustulosis was associated with persistent symptoms, continued health care utilization, and a lack of consensus regarding effective treatments, emphasizing the unmet medical need in this population.

Discussion

This multi-institutional case series of patients with PPP from across the US demonstrates that PPP is associated with continued disease activity over time and that treatment requires multiple therapies, with a lack of consensus regarding optimal therapy. As seen in previous cohorts, there was a strong female predominance, and a history of smoking was more common than in the general population (38.1% vs 14.0%).[4,8-10]

Currently, there are no US Food & Drug Administration–approved treatments specifically for PPP. A Cochrane review that included 37 studies (1663 participants; mean [range] age, 50 [34-63] years; 24% were men) concluded that evidence is lacking for all major long-term PPP treatments (superpotent corticosteroids, phototherapy, acitretin, methotrexate, and cyclosporine), and only low- and moderate-quality evidence is available for the efficacy of biologic agents.[11] In this cohort, older systemic treatments, including acitretin, methotrexate, and phototherapy, were the most commonly used initial therapies. This mirrors what has been reported from other PPP cohorts.[4,9,12] Biologic agents, which are highly efficacious, first-line therapies for

Table 1. Baseline Characteristics of Patients With Palmoplantar Pustulosis (PPP) (n = 197)

Characteristic	No. (%)
Sex	
Female	145 (73.6)
Male	52 (26.4)
Age at presentation, y	
Mean (SD) [range]	53.0 (12.6) [18-81]
Median (IQR)	54 (46-62)
Follow-up time, mo	
Mean (SD) [range]	22.1 (28.0) [0-129.4]
Median (IQR)	10.4 (3.0-30.6)
Year of first visit	
2007-2010	10 (5.1)
2011-2014	50 (25.4)
2015-2018	137 (69.5)
BMI	
Mean (SD)	29.6 (6.5)
Missing	96 (48.7)
Race	
American Indian/Alaska Native	2 (1.0)
Asian	3 (1.5)
Black or African American	30 (15.2)
White	120 (60.9)
Multiracial	2 (1.0)
Unknown/not reported	40 (20.3)
Smoking history	
Current	75 (38.1)
Former	54 (27.4)
Never	49 (24.9)
Unknown/not reported	19 (9.6)
Alcohol use	
Current	78 (39.6)
Former	13 (6.6)
Never	34 (17.3)
Unknown/not reported	72 (36.6)
Prior history of psoriasis and pustular psoriasis	
Psoriasis	32 (16.2)
Duration prior to presentation, median (IQR) [range], y	3.5 (1-11) [0-25][a]
Psoriatic arthritis	18 (9.1)
Duration prior to presentation, median (IQR) [range], y	6 (2.5-9) [0-12][a]
PPP	91 (46.2)
Duration prior to presentation, median (IQR) [range], y	3.0 (1-9) [0-40][a]

Abbreviation: BMI, body mass index, calculated as weight in kilograms divided by height in meters squared.

[a] Information available for 12 patients with psoriasis, 8 with psoriatic arthritis, and 57 with PPP.

Table 2. Initial Treatments in Patients With Palmoplantar Pustulosis (n = 197)[a]

Treatment	No. (%)
Topical therapy only	127 (64.5)
Topical steroid[b]	167 (84.8)
Low potency	5
Mid potency	16
High potency	153
Other topical medications[c]	34 (17.3)
Topical antibiotics	3
Topical antifungals	3
Topical retinoid	4
Vitamin D analog	27
Systemic antibiotics[d]	9 (4.6)
Cephalosporin	2
Penicillin	2
Tetracycline	4
Vancomycin	1
Class not reported	1
Systemic antiviral	0
Systemic antifungal	1 (0.5)
Systemic steroids	10 (5.1)
Phototherapy	
Narrowband UV-B	15 (7.7)
Oral PUVA	2 (1.0)
Topical PUVA	4 (2.0)
Oral systemic treatments	
Acitretin	27 (13.7)
Apremilast	2 (1.0)
Cyclosporine	9 (4.6)
Dapsone	1 (0.5)
Methotrexate	22 (11.2)
Biologic agents	
Abatacept	1 (0.5)
Adalimumab	6 (3.1)
Etanercept	3 (1.5)
Infliximab	4 (2.0)
Secukinumab	1 (0.5)
Ustekinumab	3 (1.5)

Abbreviation: PUVA, psoralen–UV-A.

[a] All treatments recorded for each patient were included.

[b] A total of 167 patients received at least 1 topical steroid. The sum of patients in each steroid class is greater than 167 because some patients received more than 1 topical steroid, so percentages are not reported for individual treatments.

[c] A total of 34 patients received at least 1 other topical medication. The sum of patients in each type of topical treatment is greater than 34 because some patients received more than 1 treatment, so percentages are not reported for individual treatments.

[d] One patient received 3 days of penicillin antibiotic therapy followed by 5 days of vancomycin therapy. The sum of patients is greater than 9 because some patients received more than 1 antibiotic treatment, so percentages are not reported for individual treatments.

plaque psoriasis, were used less frequently in PPP.[4,9,12] The reason for this may be the paucity of efficacy data outside of case reports and case series. Two small randomized, placebo-controlled trials of secukinumab and guselkumab showed modest efficacy results.[13,14] Additional prospective studies focused specifically on patients with PPP are necessary to better understand the efficacy of biologic therapies.

Owing to the chronic nature of PPP, it is important to understand PPP-specific health care utilization over time. In this study, patients with at least 6 months of follow-up time had a median (IQR) of 3.7 (2.0-5.6) dermatology visits per year with a range of 0.7 to 13.5 visits. In total, 18.8% of patients had 5 or more follow-up visits, demonstrating a high volume of PPP-specific encounters over time. While health care utilization in PPP has not been studied extensively, a previous Japanese

study found that 36% of patients with PPP use health care services each month, with highest utilization during the hottest season, though this health care utilization is not specific to PPP.[15]

Limitations

There are inherent limitations to retrospective research, including nonstandardized or missing information. Patients were all identified from academic medical centers with inclusion criteria favoring patients seen most recently, and therefore findings may not be generalizable to all patients with PPP in the US. Additionally, the medical record does not contain objective measurements of disease severity.

Table 3. Health Care Utilization in Patients With Palmoplantar Pustulosis With at Least 6 Months of Follow-up Time (n = 128)

Health care utilization	Median (IQR) [range]
Follow-up time, mo	23.9 (10.7-44.8) [6-129.4]
No. of patients requiring hospitalization in follow-up	0
No. of patients with an ED visit in follow-up[a]	4
No. of dermatology visits	6 (4-10) [2-24]
Visits/y of follow-up	3.7 (2.0-5.6) [0.7-13.5]
No. of visits for flares[b]	2 (1-4) [0-12]
No. of visits for flares/y of follow-up[b]	0.9 (0.3-1.8) [0-7.9]

Abbreviation: ED, emergency department.

[a] Four unique patients each had 1 ED visit.

[b] All visits were included where patients reported worsening symptoms/disease activity or an escalation of therapy occurred.

Conclusions

In this multicenter case series of 197 patients, PPP was associated with persistent symptoms, continued health care utilization, and lack of consensus regarding effective treatments, emphasizing the unmet medical need in this population. Future prospective research is necessary to determine the efficacy of therapies in patients with pustular disease, distinct from plaque psoriasis, and develop new therapies specifically for PPP.

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