

Real-World Use of Biologics and Prescription Topical Medications in Pediatric Psoriasis in a Large Dermatology Network in the U.S.



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Background

One-third of psoriasis (PsO) patients report disease onset during childhood, but few treatments are FDA-approved for use in pediatric patients with persistent disease who do not respond to conventional non-biologic treatments and/or phototherapy. There is a paucity of real-world data on the use of approved and off-label biologics in this population.

Objective

To describe the use of prescription topical and biologic treatments, and maximum percent body surface area (%BSA), in a real-world pediatric PsO population

Methods

- The OM1 PsO Registry (OM1, Inc; Boston, MA) follows more than 110,000 PsO patients in the U.S. managed by dermatologists longitudinally with deep clinical data, including laboratory, treatment, and disease activity information, and linked administrative claims starting from 2013.
- All patients aged 4 to <18 years of age at the first observed PsO diagnosis code (index date) were included. Follow-up was censored at 18 years of age
- PsO subtype, maximum %BSA, and select medication use during the follow-up period were reported
- Patient use of biologics with FDA-approval for adult or pediatric or PsO were identified by prescriptions, administrations and/or fills.
- Use of prescription topicals was also evaluated, including corticosteroids, vitamin D analogs, and calcineurin inhibitors

Results

- A total of 3,484 pediatric PsO patients were identified (60% female; mean (SD) age at index 13(4) years (**Table 1**)
- Mean (SD) duration of follow-up was 30 (24) months
- 64% of patients were treated only with prescription topicals, 2% were treated only with biologics, and 17% were treated with both. 17% of patients had no record of either
- The most frequently occurring PsO subtype was plaque
- Comorbid inflammatory arthritic/bowel diseases were present in 13% of biologic-treated and 2% of non-biologic-treated patients
- Mean maximum %BSA differed significantly among treatment groups ($p < 0.0001$) (**Figure 1**)

Figure 1. Maximum %BSA among treatment groups

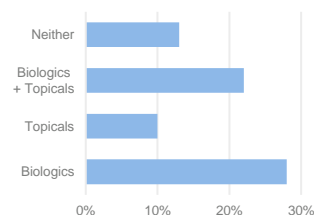


Table 1. Characteristics of treatment groups (N=3,484)

	Biologics	Topicals	Biologics + Topicals	Neither
N (%)	78 (2%)	2228 (64%)	594 (17%)	584 (17%)
Mean age at index (SD)	14.2 (2.5)	12.3 (3.6)	12.4 (3.1)	13.6 (3.5)
% Female	59%	61%	56%	61%
% with plaque PsO	79%	73%	89%	42%
Mean duration of follow-up (months)	25.2 (19.7)	29.6 (23.2)	39.0 (24.6)	20.6 (20.1)
Maximum %BSA mean (SD); median (Q1, Q3)	28% (30) 12 (4, 45)	10% (15) 5 (2,11)	22% (24) 11 (5.5, 30)	13% (19) 5 (2,12)

Table 2. First Record of Biologic Treatment (N=672)

Biologic	N (%)
TNF inhibitors	
Etanercept*	329 (49.0)
Adalimumab	147 (21.9)
Certolizumab	0
Infliximab	23 (3.4)
IL-17 inhibitors	
Ixekizumab*	6 (0.9)
Secukinumab*	1 (0.1)
Brodalumab	0
IL-23 inhibitors	
Guselkumab	1 (0.1)
Risankizumab	0
Tildrakizumab	0
IL-12/23 inhibitor	
Ustekinumab*	165 (24.6)
JAK inhibitor	
Tofacitinib	0

*FDA-approved for <18 years (age range varies)

- TNF inhibitors were the most commonly used biologic treatments for pediatric PsO patients; among those who received treatment with biologics, 49% were prescribed etanercept. 22% were prescribed adalimumab despite not being FDA-approved for pediatric patients (**Table 2**)
- Ustekinumab, an IL-12/23 inhibitor, was also frequently used (25%). IL-17 inhibitors were rarely used despite FDA approval for ixekizumab and secukinumab in this population (<1% each)
- Among patients who received any prescription topicals before age 18 (N=2822), corticosteroids were almost always used (97%), and a substantial proportion of patients (37%) also used vitamin D analog and calcineurin inhibitors (19%)
- Of patients with no evidence of treatment with biologics or prescription topicals, documented use of other systemics (e.g., methotrexate, cyclosporin) was uncommon (data not shown) and patients were less likely to have documented plaque PsO subtype

Conclusions

- In a large, real-world cohort of dermatologist-managed pediatric PsO patients, nearly 1 in 5 patients were prescribed biologics before age 18
- Young PsO patients who received treatments with biologic therapies had significantly higher disease burden (by %BSA) than those treated with other (or no) evaluated therapies
- Further research is needed to describe the comparative effectiveness of on- and off-label treatments and optimal treatment pathways in this population