



BRIEF REPORT

Management of Pediatric Psoriasis: A U.S. Survey Based on Visits from the National Ambulatory Medical Care Survey (NAMCS)

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Received: August 8, 2023 / Accepted: September 26, 2023 / Published online: October 13, 2023
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ABSTRACT

Introduction: Approximately one-third of psoriasis cases present in the first two decades of life. Many psoriasis treatments are approved by the U.S. Food and Drug Administration (FDA) for adults, including topical agents, systemic non-biologic agents, and systemic biologic agents. Only a handful of psoriasis treatments are FDA approved for children. Given the constantly evolving landscape of pediatric psoriasis

management, our aim is to characterize how children with psoriasis are treated in the U.S.

Methods: Data from the 2003–2016 and 2018 National Ambulatory Medical Care Survey (NAMCS) were used to evaluate patient demographics and treatment patterns for visits of children with psoriasis. Visits were stratified by those with a diagnosis of psoriasis and those for children with a diagnosis of psoriasis. Separate analyses for visits of children with a diagnosis of psoriasis were performed, including for sex, race, ethnicity, age, specialty of provider seen, and medications prescribed.

Results: Pediatric psoriasis visits accounted for 3.3% of visits with psoriasis from 2003 to 2016 and in 2018; about one-third of those visits were to primary care providers. Children with psoriasis were prescribed a variety of topical and systemic medications, of which the most frequently prescribed treatments were topical tacrolimus, followed by topical clobetasol and topical betamethasone dipropionate or betamethasone valerate. Etanercept was the only biologic prescribed to children. At least 59% of the visits for children with a diagnosis of psoriasis included a topical prescription while at least 5.3% of the visits included a systemic prescription.

Conclusion: Use of off-label treatments was common for pediatric psoriasis. Most children with psoriasis were treated with topicals, of which tacrolimus, an unapproved treatment, was the most common. The frequent use of

Prior Presentation: This manuscript is based on work that was presented as a poster at the 2022 Pediatric Dermatology Research Alliance Annual Conference on November 4, 2022 in Bethesda, Maryland.

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tacrolimus could indicate an avoidance of corticosteroids in children.

Keywords: Office visits; Pediatric dermatology; Practice management; Primary care; Psoriasis

Key Summary Points

Our aim is to characterize how children with psoriasis are treated in the U.S. We hypothesized that many off-label treatments are prescribed because only a handful of psoriasis treatments have been approved for children by the U.S. Food and Drug Administration.

Pediatric patients accounted for 3.3% of visits for psoriasis during the years 2003–2016 and 2018, and one-third of these were with primary care providers.

The treatments prescribed most frequently were topical tacrolimus, followed by topical clobetasol and topical betamethasone dipropionate or betamethasone valerate, while topical hydrocortisone and isotretinoin were the least frequently prescribed medications. Etanercept was the only prescribed biologic.

The majority of treatments in pediatric psoriasis patients were used off label.

INTRODUCTION

Psoriasis is a chronic, immune-mediated, inflammatory skin condition [1]. While the condition is most common in adults, approximately one-third of psoriasis cases present in the first two decades of life [2]. Psoriasis affects approximately 1% of children [3]. Many psoriasis treatments have been approved by the U.S. Food and Drug Administration (FDA) for adults, including topical agents such as corticosteroids, vitamin D analogues, and tazarotene; systemic non-biologics; and systemic biologics [4].

Approved systemic non-biologic agents include methotrexate, apremilast, cyclosporine, and acitretin [5]. Approved systemic biologic agents include tumor necrosis factor (TNF)-alpha inhibitors, interleukin (IL)-17 inhibitors, an IL-12/23 inhibitor, and IL-23 inhibitors [6]. However, only a handful of psoriasis treatments have been FDA approved for children. Topical corticosteroids are not approved by the FDA for the treatment of psoriasis in children, although combination products containing calcipotriol and betamethasone dipropionate are FDA approved in children aged > 12 years. Other FDA approved agents for children include etanercept, ixekizumab, secukinumab, and ustekinumab in patients with psoriasis aged > 4, 6, 6, and 12 years, respectively [3, 7]. Many treatments approved for adult psoriasis can be used in children, but an off-label prescription may be needed [3]. Efficacy and safety studies and outcome data from long-term follow-ups are often insufficient in pediatric patients [3]. Given the constantly evolving landscape of pediatric psoriasis management, our aim is to characterize how children with psoriasis are treated in the U.S. We hypothesized that many off-label treatments are prescribed due to the lack of FDA-approved treatment options.

METHODS

The National Ambulatory Medical Care Survey (NAMCS) is an annual survey conducted by the National Center for Health Statistics (NCHS) at the U.S. Centers for Disease Control and Prevention that collects objective information about the use of ambulatory medical services in the U.S. [8]. The NAMCS surveys a large, generalizable sample of physicians, nurse practitioners, and physician assistants who provide outpatient care, and samples visits. A three-stage, random selection process is used that involves first sampling 112 geographic areas in the U.S. From these geographic areas, physicians and non-physician providers are selected using American Medical Association (AMA) and American Osteopathic Association (AOA) master files. For each randomly selected provider, a 1-week period of visits is sampled, and a

proportion of visits to analyze are chosen based on the number of patients in each practice, which ranges from 20% to 100%. For each visit sampled, information is collected on patient demographics, diagnoses, medications prescribed, and services and procedures performed [9].

To estimate nationally representative values, each sampled visit is assigned a weighting factor to adjust for the time and region in which the visit took place, the probability of clinic and physician selection, nonresponse, and different physician specialties. The process of weighting the data allows for the estimation of nationally representative values and involves a multistage estimation process of inflation by reciprocals of the probabilities of selection, nonresponse adjustment, a ratio adjustment to fixed totals and, finally, weight smoothing [9].

NAMCS data were used to identify and characterize trends in outpatient dermatology visits from 2003 to 2016 and 2018; the NAMCS did not collect data in 2017. Due to publication delays in the NAMCS, data past 2018 were not available. Visits were stratified by those with a diagnosis of psoriasis and those for children with a diagnosis of psoriasis. Separate subanalyses for visits with children with a diagnosis of psoriasis were performed, including for sex, race, ethnicity, age, specialty of provider seen, and medications prescribed. Although “psoriasis” was a diagnosis at the visit, it cannot be determined whether the visit was for a new diagnosis of psoriasis or for a follow-up appointment. The indication for the prescription is not stated in the NAMCS; therefore, we only included medications prescribed that can be used to treat psoriasis according to the joint American Academy of Dermatology-National Psoriasis Foundation (AAD-NPF) pediatric guidelines [3]. While one of the NAMCS drug codes for triamcinolone did not specify if it was administered as a topical or an injection, it was included with the topical corticosteroids. The frequency of visits at which topical treatments and systemic treatments were prescribed was obtained by summing the respective medication classes that were in the first medication category. Therefore, these values provide an underestimation. Descriptive statistics were

conducted using the survey procedures of SAS version 9.4 (SAS Institute Inc., Cary, NC, USA). It is required that only one Institutional Review Board (IRB) must review the NAMCS; in this context, the NCHS Ethics Review Board (ERB) provided approval.

RESULTS

An estimated 1.2 million visits (3.3% of total psoriasis visits) for children with a diagnosis of psoriasis were evaluated. This estimate was based on 56 pediatric visits that were associated with a diagnosis of psoriasis. The distribution of male and female children with a diagnosis of psoriasis was similar (48% of patients were males while 52% were females; Table 1). Children with a diagnosis of psoriasis were predominantly White (91% of patients), and the predominant ethnicity was non-Hispanic or Latino (87% of patients). The mean age of children with a diagnosis of psoriasis was 11 (range 1–17) years. Most children with a diagnosis of psoriasis were seen by dermatologists (62% of patients); 30% of visits for children with a diagnosis of psoriasis were with primary care providers; and 7.7% of visits were with non-dermatology or primary care providers.

Children with a diagnosis of psoriasis were prescribed a variety of medications that can be used to treat psoriasis according to the AAD-NPF pediatric guidelines. The treatments prescribed most frequently were topical tacrolimus (prescribed at 15% of visits), followed by topical clobetasol (prescribed at 14% of visits) and topical betamethasone dipropionate or betamethasone valerate (prescribed at 13% of visits) (Fig. 1). The medications least frequently prescribed were topical hydrocortisone (prescribed at 0.84% of visits) and isotretinoin (prescribed at 1.1% of visits). Etanercept was the only prescribed biologic to children (prescribed at 3.7% of visits).

At least 59% of the visits for children with a diagnosis of psoriasis included a topical prescription while at least 5.3% of the visits included a systemic prescription. Of the total number of prescriptions of topical and systemic medications that could be used to treat

Table 1 Demographics of study participants

Patient demographics	Percentage of children with a diagnosis of psoriasis
Sex	
Male	48%
Female	52%
Race	
White	91%
African American	6.2%
Other race	3.0%
Ethnicity	
Hispanic or Latino	13%
Non-Hispanic or Latino	87%
Age (years)	
Minimum age	1
Median age	11
Maximum age	17

psoriasis, topical agents accounted for 91% and systemic agents for 9.2%.

DISCUSSION

Children with psoriasis are at a two-to-four-fold increased risk of hyperlipidemia, hypertension, diabetes mellitus, psoriatic arthritis, Crohn's disease, anxiety, and depression [10–12]. Early diagnosis and initiation of the appropriate treatment for psoriasis in childhood may delay and prevent serious impacts on a child's quality of life and comorbidities [10]. Our results are consistent with previous reports that the number of affected females with childhood psoriasis is slightly higher than the number of males [13, 14]. In our study, visits with primary care accounted for 30% of visits of children with psoriasis.

The majority of treatments in pediatric psoriasis were used off label, and included topical corticosteroids, topical calcineurin inhibitors, anthralin, topical retinoids, systemic non-

biologics, oral retinoids, and systemic biologics. This finding is consistent with our hypothesis. The most frequently prescribed medication to children with a diagnosis of psoriasis was topical tacrolimus, an unapproved agent. While the use of topical tacrolimus to treat psoriasis is off label, there is evidence that topical tacrolimus is effective for psoriasis when applied to intertriginous and facial areas and for corporal plaques [15]. The frequent use of nonsteroidal topical medications, including tacrolimus and calcipotriene, may indicate the desire to avoid excessive corticosteroid exposure in children and the lack of FDA approval for most topical corticosteroids for pediatric psoriasis.

Etanercept was the only biologic prescribed to children. In the years this survey data were collected, ixekizumab, secukinumab, and ustekinumab had not yet received the approval of the FDA for pediatric psoriasis [7, 16, 17]. Based on the joint AAD-NPF guidelines [3] which recommend etanercept for children aged > 6 years and methotrexate and cyclosporine for the treatment of moderate to severe psoriasis in children, at least 5.3% of children with psoriasis had moderate to severe psoriasis. However, since ixekizumab, secukinumab, and ustekinumab, as well as other systemic non-biologics and biologics that may have off-label use in pediatric patients, were not prescribed in any of the visits sampled, this is likely an underestimate.

Limitations to using the NAMCS data include that the data was based on a sample of visits rather than a sample of patients and survey participation not being mandatory, which limits the ability to make nationwide estimates using these data [8]. In addition, the NAMCS does not sample visits to outpatient departments of hospitals and thus only outpatient visits to physician offices were included. Publication delays in the NAMCS limit our ability to characterize treatments over the most recent years as more medications have been FDA approved for children. In addition, visits are included based on an associated diagnosis code for psoriasis, and it is not specified whether the patient was diagnosed clinically or from a biopsy. Finally, the indications for prescribed medications were unclear, the estimates in our

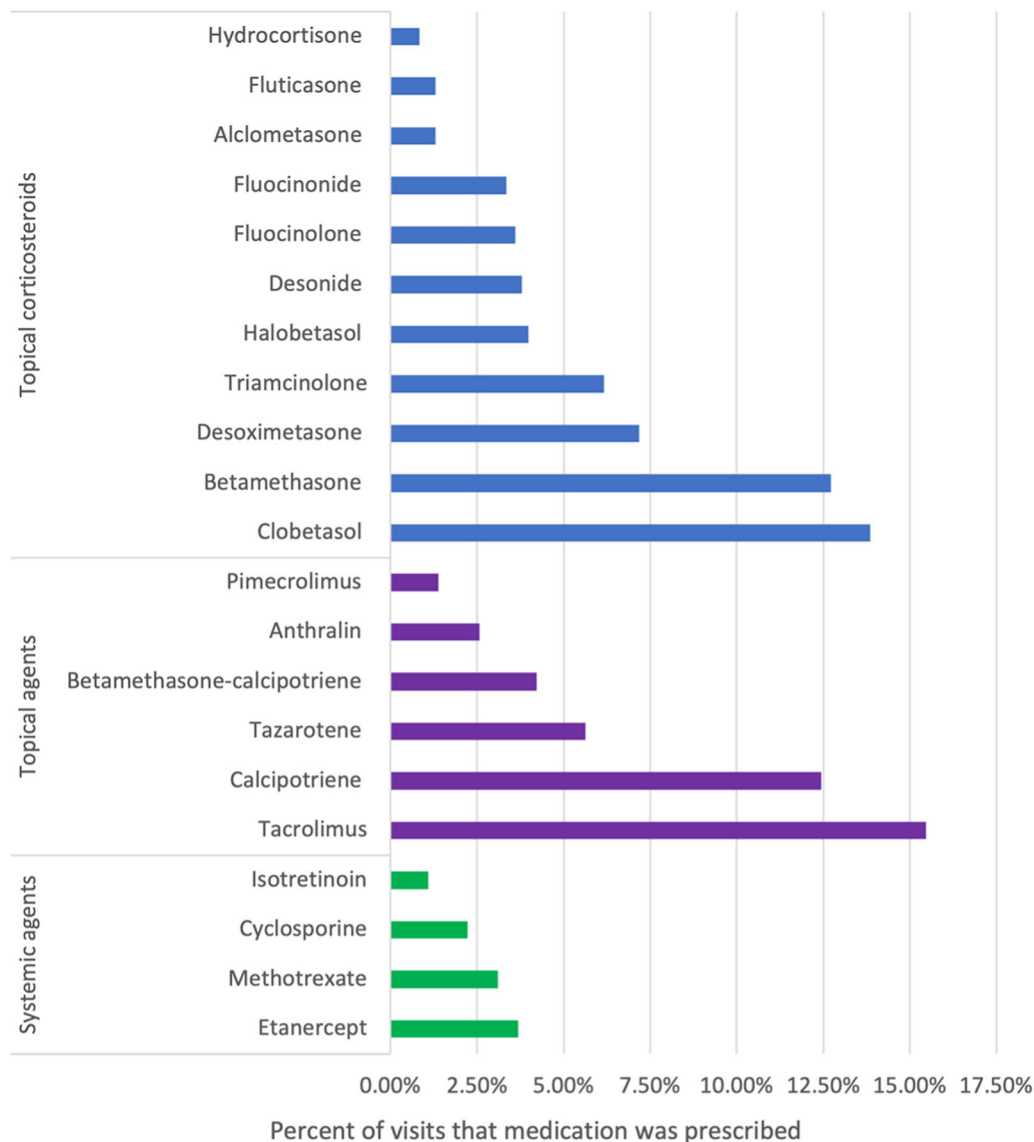


Fig. 1 Medications prescribed for children with a diagnosis of psoriasis evaluated during the years 2003–2016 and 2018

study were based on only 56 pediatric office visits, and whether patients received phototherapy was not included.

CONCLUSION

Children with psoriasis were frequently treated by dermatologists. Use of off-label treatments was common for pediatric psoriasis. Most children with psoriasis were treated with topicals, of which tacrolimus, an unapproved treatment,

was most common. The frequent use of tacrolimus could indicate an avoidance of corticosteroids in children. In the years this survey data were collected, etanercept was the only biologic prescribed to children with psoriasis. Moderate to severe psoriasis requiring a biologic was uncommon. Studying the use of off-label treatments to treat pediatric psoriasis is worth exploring.

Prior Presentation This manuscript is based on work that was presented as a poster at the 2022 Pediatric Dermatology Research Alliance

Annual Conference on November 4, 2022 in Bethesda, Maryland (USA).

Author Contributions. Conceptualization: Jessica N. Pixley and Steven R. Feldman. Methodology: Rachel E. Tao, Jessica N. Pixley, and Phillip G. Holovach. Formal analysis and investigation: Rachel E. Tao, Jessica N. Pixley, and Phillip G. Holovach. Writing-original draft preparation: Rachel E. Tao. Writing-review and editing: Rachel E. Tao, Jessica N. Pixley, Phillip G. Holovach, Alan B. Fleischer Jr., and Steven R. Feldman. Supervision: Steven R. Feldman. All authors have read and approved the final manuscript.

Funding. No funding or sponsorship was received for this study or publication of this article.

Data Availability. The datasets generated during and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Declarations

Conflict of interest. Steven R. Feldman has received research, speaking, and/or consulting support from AbbVie, Accordant, Almirall, Alvotech, Amgen, Arcutis, Arena, Argenx, Bioccon, Boehringer Ingelheim, Bristol-Myers Squibb, Dermavant, Eli Lilly and Company, Eurofins, Forte, Galderma, Helsinn, Janssen, Leo Pharma, Microcos, Mylan, Novartis, Ono, Ortho Dermatology, Pfizer, Regeneron, Samsung, Sanofi, Sun Pharma, UCB, Verrica, Voluntis, and vTv Therapeutics. He is founder and part owner of Causa Research and holds stock in Sensal Health. Alan B. Fleischer Jr. is a consultant for Almirall, Incyte, Galderma, and SCM Lifescience (fees). He is an investigator for Cara, Galderma and Trevi (research support). Rachel E. Tao, Jessica N. Pixley, and Phillip G. Holovach have no conflicts to disclose.

Ethical Approval. Only one Institutional Review Board (IRB) must review the NAMCS, and the NCHS Ethics Review Board (ERB) has done so.

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