



Physician-reported Clinical Unmet Needs, Burden and Treatment Patterns of Paediatric Psoriasis Patients: A US and EU Real-world Evidence Study

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This study is a retrospective analysis using data collected from the Adelphi Paediatric Psoriasis Disease-Specific Programme cross-sectional survey. Despite being treated for their psoriasis, a substantial proportion of paediatric patients presented with moderate (18.3%) or severe (1.3%) disease at sampling; 42.9% and 92.0% had a body surface area (BSA) of >10%, and 38.8% and 100.0% had a Psoriasis Area Severity Index (PASI) score >10, respectively. Overall, 69.9% of patients had only ever been treated with a topical therapy for their psoriasis. For patients with moderate or severe disease at sampling, 16.3% and 14.4% were currently receiving conventional systemics or biologic therapy, respectively. There is a clinical unmet need in this paediatric population; a considerable percentage of patients still experienced moderate or severe disease and persistent psoriasis symptoms, with numerous body areas affected. A significant proportion of patients were undertreated, which may explain the high burden of disease observed.

Key words: psoriasis; paediatric psoriasis; point-in-time survey; real-world; clinical characteristics; unmet needs.

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One-third of patients with psoriasis (PsO) experience disease onset before the age of 20 years (1), and the median onset age of paediatric PsO (<18 years) is 7–10 years (1). Paediatric PsO has a significant effect on the quality of life (QoL) of children, who often experience stigmatization due to PsO manifestations (2).

European Union (EU) and United States (US) guidelines have recently been developed and published, providing evidence-based recommendations for the management and treatment of paediatric PsO (3, 4). In adult patients with PsO, disease severity is defined using standard scores, such as body surface area (BSA), Psoriasis Area and Severity Index (PASI), and Dermatology Life

SIGNIFICANCE

Real-world data on paediatric psoriasis are limited. Treatment patterns vary depending on geographical location, reimbursement issues and type of treating physician. This study describes clinical unmet needs and treatment patterns of >2,000 paediatric psoriasis patients across the USA, UK, France, Germany, Spain and Italy. Despite being treated for their psoriasis, patients exhibited persistent disease burden, even in patients with mild severity. Paediatric patients are mostly managed using topical therapies; less than 20% moderate or severe patients (for whom a systemic treatment is indicated) had ever received biologic therapy.

Quality Index (DLQI) scores. According to the EU/US guidelines, BSA should not be used as the only measure of disease severity, and additional tools, such as Physician's Global Assessment (PGA), PASI and Children's DLQI (CDLQI), should also be considered (3, 4).

The majority of paediatric patients with PsO with mild disease severity are adequately managed with topical therapies; however, phototherapy and systemic medications are often necessary to treat moderate to severe disease. Currently, all conventional non-biologic systemic treatments are used off-label in the EU and US for paediatric PsO; topical calcineurin inhibitors are also unapproved (5). However, methotrexate is the most common non-biologic systemic agent used to treat moderate to severe paediatric PsO worldwide (6); cyclosporine (7–9), fumaric acid esters (10) and systemic retinoids (6, 11) are also used for this indication. Etanercept was the first biologic agent approved, and is the most extensively studied agent in paediatric PsO (12). There are currently 5 biologic agents approved for moderate to severe paediatric PsO: etanercept, adalimumab (EU only), ustekinumab, secukinumab and ixekizumab (12–15). Notably, both secukinumab and ixekizumab have only recently been approved for this indication.

Considering the evolving treatment landscape, recent treatment guidelines, and approval of newer biologic agents, current data on unmet clinical needs and treatment patterns in paediatric patients with PsO are needed.

The aim of this study was to identify physician-reported burden of disease (including disease severity, disease characteristics, current PsO symptoms and affected areas) and current treatment patterns in a large real-world paediatric PsO patient cohort. This manuscript reports the primary objective results of a cross-sectional survey conducted by Adelphi Real World in the US and 5 EU countries (EU5; UK, France, Germany, Spain, Italy).

MATERIALS AND METHODS

Study design

This study was a retrospective analysis of a cross-sectional survey to assess the clinical unmet needs and treatment patterns in the paediatric PsO population, using data collected as part of the Adelphi Paediatric PsO Disease-Specific Program (DSP™) across the US and EU5 countries. Data collection occurred between February 2020 and October 2020. This was a market research survey conducted by Adelphi Real World independently of Novartis. This manuscript details physician-reported outcomes only.

Inclusion and exclusion criteria

Dermatologists, general practitioners or primary care practitioners (GP/PCP), and paediatricians actively managing paediatric PsO patients were included in the study. To be included in this survey, physicians had to consult with ≥ 10 paediatric PsO patients in a typical month. There were no exclusion criteria for physicians. To be included in the study, patients had to be 4–17 years old (inclusive) with a diagnosis of PsO, visiting a participating dermatologist, paediatrician or GP/PCP, and receiving treatment for PsO.

Patients could have been receiving multiple treatment classes together (e.g. topical and conventional systemic therapy, or conventional systemic and biologic therapy).

Data sources and questionnaires employed

Data presented in this manuscript are based on physician-provided survey information. The Paediatric DSP physician survey was completed by all physicians included in the analysis. This survey provided information on physician experience and physician-attitudinal data related to disease severity and classification, PsO-related comorbidities, classification of PsO and treatment use.

All physicians completed the Paediatric PsO DSP physician-completed Patient Record Form (PRF). Each physician included a PRF for the subsequent 10 paediatric PsO patients attending their practice. Dermatologists, however, must have included 2 biologic-treated paediatric PsO patients, in addition to 8 random patients attending their practice as per the physician-related inclusion criteria. The biologic oversample data, however, were not included in the analysis used for this study.

The PRF consisted of 13 sections (Sections A–M) with each section covering the following topics: patient demographics (A), clinical profile (B), disease pattern (C), concomitant conditions (D), hospitalizations (E), current PsO treatment (F), treatment history (G), satisfaction with treatment (H), reasons for choice of drug therapy (I), patient compliance, knowledge and impact (J), consultation history (K), funding/authorization for the patient's current PsO treatment (L), and formulary and protocols for use of the current biologic originator/biosimilar (M).

Study objectives

The primary objective of this study was to describe physician-reported clinical unmet needs among the paediatric PsO population. The key secondary objective of this study was to describe current treatment patterns among the paediatric PsO population. Outcomes related to primary and secondary objectives are listed in Appendix S1.

Disease severity

Disease severity was categorized based on the physician's individual judgement, with no clinical definition already applied. The physicians may therefore have considered multiple factors when subjectively defining a patient's severity (e.g. BSA, PASI, current symptoms and areas affected). Although this study was a cross-sectional survey and data are related to the time of sampling (or "currently"), retrospective physician-judged severity classifications were also collected. Data are presented with severity categorized at the following points in the course of PsO (**Fig. 1A**):

1. At time of sampling (currently; termed Analysis 1): physician-judged severity at time of survey completion and data capture, based on most recent consultations. Of note, all patients were being treated for their PsO at the time of data capture.
2. At time of first PsO diagnosis (termed Analysis 2): to gain insight into the course of patients' disease, some data were

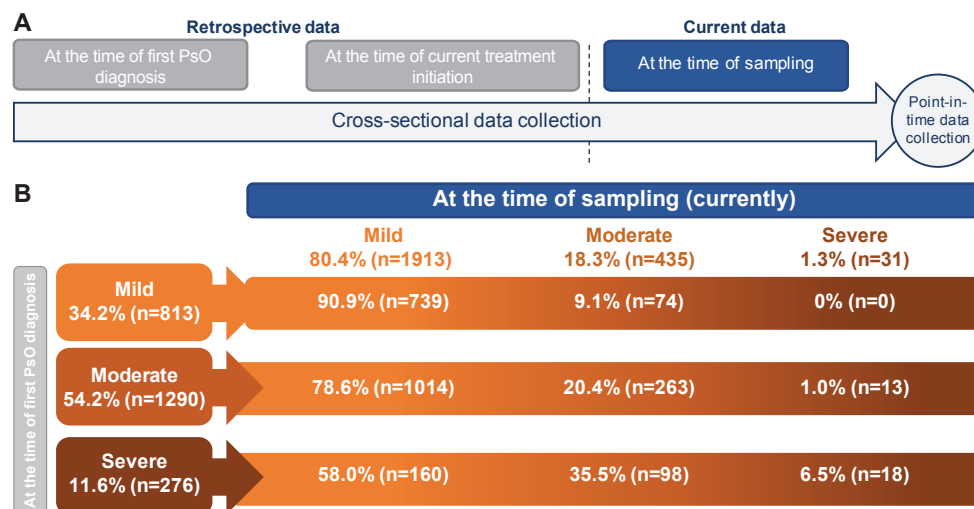


Fig. 1. Patient disease severity collection and outcomes. (a) Schematic describing collection of severity data both retrospectively (at the time of diagnosis and at the time of current treatment initiation) and at the time of sampling (currently). (b) Schematic demonstrating the frequency of mild, moderate and severe patients based on categorization at the time of first psoriasis diagnosis (retrospective) vs at the time of sampling (currently).

interpreted based on patient's initial severity classification. The retrospective rating of severity at diagnosis may have already been provided by a physician other than the survey-completing one; answers may therefore have been provided based on the patient's case notes and not their own personal assessment of the patient.

3. At time of current treatment initiation (termed Analysis 3): severity classification prior to beginning the current treatment regimen was used to interpret treatment patterns in paediatric PsO patients.

BSA, PASI and physician-judged severity outcomes were also recorded both retrospectively (Analyses 2/3) and currently (Analysis 1); all other outcomes were only recorded at sampling.

For certain analyses regarding treatment patterns, patients with either a moderate or severe disease were grouped and presented together (termed "moderate or severe disease"), since both of these categories are eligible for treatment escalation with systemic agents.

Subgroup analysis

In addition to sub-analysis by physician-judged disease severity, data were also filtered as follows:

- To adequately assess clinical unmet needs in the overall patient population, allowing sufficient time to respond to treatments, data were filtered to exclude paediatric patients with a treatment time <4 weeks for topical therapy and/or <12 weeks for conventional systemic and/or biologic therapy.
- To further delineate the clinical unmet needs in this patient population, a more in-depth analysis was carried out on the sub-set of patients who were currently not experiencing a flare in their PsO.

Data analysis

Basic descriptive statistics were derived using the software package StataCorp. 2019. Stata Statistical Software: Release 16.1 (StataCorp LLC, College Station, TX, USA).

Regulatory and ethics considerations

The survey was performed in compliance with the European Pharmaceutical Market Research Association (EphMRA) and in full accordance with the US Health Insurance Portability and Accountability Act (HIPAA) 1996. Ethical approval was granted by the Western Copernicus Group Institutional Review Board (WCG-IRB).

RESULTS

Population

In total, data from 324 treating physicians were included in the study (58%, $n=187$, dermatologists; 22%, $n=71$, GPs/PCPs; and 20%, $n=66$ paediatricians). In total, physicians completed 2,877 Patient Record Forms (PRFs; US, $n=690$; UK, $n=260$; France, $n=469$; Germany, $n=490$; Spain, $n=477$; Italy, $n=491$), each representing 1 paediatric PsO patient. To ensure adequate time to respond to treatments, paediatric patients with a treatment time <4 weeks for topical therapy and/or <12 weeks for conventional systemic and/or biologic therapy were removed from the overall population for all subsequent analyses, resulting in a total population of $n=2,379$ (Table I).

Table I. Disease characteristics, overall and by physician-judged disease severity at sampling (Analysis 1)

Characteristics	Total ($n=2,379$)	Physician-judged severity (Analysis 1)		
		Mild ($n=1,913$)	Moderate ($n=435$)	Severe ($n=31$)
Age, years, mean \pm SD	12.9 \pm 3.4	12.8 \pm 3.4	13.2 \pm 3.5	13.8 \pm 3.3
Sex, male, n (%)	1,258 (52.9)	995 (52.0)	248 (57.0)	15 (48.4)
Time since 1 st psoriasis diagnosis, months, mean \pm SD	25.8 \pm 27.4	24.2 \pm 25.8	32.2 \pm 31.8	32.3 \pm 39.1
Body surface area ($n=1,983$)		($n=1,578$)	($n=380$)	($n=25$)
% at sampling mean \pm SD	6.7 \pm 9.8	4.5 \pm 7.5	14.1 \pm 12.0	31.3 \pm 14.0
Body surface area \leq 10 at sampling, n (%)	1,681 (84.8)	1,462 (92.6)	217 (57.1)	2 (8.0)
Body surface area >10 at sampling, n (%)	302 (15.2)	116 (7.4)	163 (42.9)	23 (92.0)
% at time of initiation of current treatment, mean \pm SD	15.3 \pm 15.1 ($n=1,740$)	13.7 \pm 13.8 ($n=1,391$)	21.3 \pm 17.9 ($n=328$)	30.4 \pm 19.3 ($n=21$)
Psoriasis Area and Severity Index ($n=1,219$)		($n=1,006$)	($n=201$)	($n=12$)
At sampling mean \pm SD	4.9 \pm 8.6	3.3 \pm 6.1	11.7 \pm 12.3	28.4 \pm 17.3
Psoriasis Area and Severity Index \leq 10 at sampling, n (%)	1085 (89.0)	962 (95.6)	123 (61.2)	0 (0)
Psoriasis Area and Severity Index >10 at sampling, n (%)	134 (11.0)	44 (4.4)	78 (38.8)	12 (100.0)
At time of initiation of current treatment, mean \pm SD	11.9 \pm 12.5 ($n=1,118$)	10.4 \pm 10.6 ($n=920$)	18.4 \pm 16.3 ($n=188$)	31.5 \pm 26.4 ($n=10$)
Physician's Global Assessment at sampling, n (%)	($n=2,379$)	($n=1,913$)	($n=435$)	($n=31$)
0	512 (21.5)	501 (26.2)	11 (2.5)	0 (0.0)
1	654 (27.5)	641 (33.5)	12 (2.8)	1 (3.2)
2	784 (33.0)	687 (35.9)	95 (21.8)	2 (6.5)
3	380 (16.0)	79 (4.1)	293 (67.4)	8 (25.8)
4	47 (2.0)	4 (0.2)	24 (5.5)	19 (61.3)
5	2 (0.1)	1 (0.1)	0 (0.0)	1 (3.2)
Flaring, n (%)	166 (24.0) ($n=693$)	73 (15.3) ($n=477$)	74 (38.5) ($n=192$)	19 (79.2) ($n=24$)
Flare in the past 12 months, n (%)	693 (29.1)	477 (24.9)	192 (44.1)	24 (77.4)
In remission* n (%): No	1,071 (45.0)	675 (35.3)	366 (84.1)	30 (96.8)
Psoriatic arthritis present, n (%)	89 (3.7)	52 (2.7)	33 (7.6)	4 (12.9)
Biologic** experienced, n (%)	302 (12.7) ($n=2,378$)	229 (12.0) ($n=1,912$)	66 (15.2) ($n=435$)	7 (22.6) ($n=31$)

*Remission status is physician-judged. **Also includes biosimilar therapy. Where the full number of patients is not available, number of patients per group is indicated within the table (n). SD: standard deviation.

Psoriasis disease severity

The overall clinical characteristics of the paediatric PsO patients, based on physician-judged severity at time of sampling (Analysis 1) are shown in Table I. At sampling, 80.4% (1,913/2,379) of patients had mild disease, 18.3% (435/2,379) had moderate disease and 1.3% (31/2,379) had severe disease despite currently being treated. In contrast, retrospectively reported physician-judged severity at time of PsO diagnosis (Analysis 2) described 34.2% (813/2,379) of patients with mild disease, 54.2% (1,290/2,379) had moderate, and 11.6% (276/2,379) had severe disease.

Using severity data between time of diagnosis and time of sampling (Fig. 1A), the remaining unmet needs in paediatric PsO patients could be ascertained, as illustrated in Fig. 1B (Analysis 2 vs Analysis 1). Of those patients with mild disease at diagnosis, 90.9% (739/813) were still reported as having mild disease at sampling; however, 9.1% (74/813) progressed to moderate disease at sampling. Despite successful treatment in a large proportion of patients, 20.4% (263/1,290) with moderate disease at diagnosis still had moderate disease and 1.0% (13/1,290) progressed to severe disease at sampling. Similarly, of those patients with severe disease at diagnosis, 35.5% (98/276) and 6.5% (18/276) still had moderate or severe disease at sampling, respectively.

Psoriasis disease characteristics, symptoms and affected areas

The mean \pm standard deviation (SD) BSA% and PASI scores overall at sampling were $6.7 \pm 9.8\%$ (1,983/2,379) and 4.9 ± 8.6 (1,219/2,379), respectively. Overall, 51.0% (1,213/2,379) of patients had a PGA score ≥ 2 , indicating an absence of clear or almost clear skin (i.e. no PGA 0/1 response; Table I), 24.0% (166/693) of patients were currently experiencing a flare of their PsO, 29.1% (693/2,379) had reported a flare in the previous 12 months and 45% (1,071/2,379) were not in remission based on physician-judgement.

The high disease burden was particularly evident in patients with moderate and severe disease at sampling (Analysis 1). Of the patients with moderate and severe disease, 42.9% (163/380) and 92.0% (23/25) had a BSA of $> 10\%$, and 38.8% (78/201) and 100.0% (12/12) had a PASI > 10 , respectively. At sampling, 38.5% (74/192) of patients with moderate PsO and 79.2% (19/24) of patients with severe PsO were experiencing a flare. Table SI further details physician-reported symptoms and areas affected by PsO at sampling.

To further delineate the clinical unmet needs, a more in-depth analysis was carried out on the sub-set of patients not currently experiencing a flare (Table SII). Even in those patients treated for a minimal period of time in this study (< 4 weeks for topical therapy and/or < 12 weeks for conventional systemic and/or biologic therapy)

and not experiencing a flare, a remaining clinical unmet need was identified; 38.8% (714/1,840) of patients with mild disease did not have clear or almost clear skin (PGA 2–5), still reported a mean of 2.5 ± 2.2 PsO symptoms and 1.5 ± 1.5 areas currently affected by their PsO (Table SII). Of patients with moderate or severe disease not currently experiencing a flare at sampling, unmet clinical need was particularly evident; these patients reported a mean BSA of $13.7 \pm 11.6\%$ and $27.5 \pm 8.7\%$ and a mean PASI score of 11.6 ± 12.3 and 18.0 ± 4.3 , respectively. Moderate and severe patients experienced 4.6 ± 2.9 and 4.7 ± 2.3 current PsO symptoms, with 3.5 ± 2.3 and 5 ± 2.5 affected areas, respectively.

Severity by type of treating physician

Physician-judged disease severity frequencies at sampling (Analysis 1) were similar among dermatologists, paediatricians and GP/PCPs. Table SIII describes clinical characteristics by type of treating physician. To ensure these clinical characteristics were not influenced by flare, PsO patients flaring during time of sampling were excluded from this analysis. Despite similar proportions of mild, moderate and severe patients per groups, treating physicians do not assess severity in the same way. Dermatologists reported a lower mean BSA% and PASI score in moderate or severe patients compared with GP/PCPs and paediatricians (Table SIII).

Treatment patterns

Treatment history. Overall, 96.3% (2,291/2,378) of patients had ever received topical PsO therapies. Conversely, only 15.4% (367/2,378), 12.0% (285/2,378) and 12.7% (302/2,378) of patients had ever received phototherapy, conventional systemic and biologic therapy, respectively (Fig. 2A).

Treatment class ever received was also analysed by disease severity at diagnosis (Analysis 2). Of patients categorized with mild, moderate and severe disease at diagnosis, 5.7% (46/813), 12.6% (162/1,290) and 28.0% (77/275) had ever received conventional systemics, and 4.1% (33/813), 11.2% (144/1,290) and 45.5% (125/275) had ever received biologic therapy for their PsO, respectively (Fig. 2A). Specifically, for those patients with a disease severity of moderate or severe at diagnosis, only 15.3% (239/1,565) and 17.2% (269/1,565) had ever received conventional systemics or biologic therapy, respectively.

Overall, 69.9% (1,662/2,378) of patients had only ever been treated with a topical therapy for their PsO. Categorized by physician-judged severity at current treatment initiation (Analysis 3), 69.2% (886/1,281) and 22.3% (75/336) of moderate and severe patients had only ever been treated with a topical therapy for their PsO (Fig. 3A). Of note, only 9.6% (123/1,281) and 50.0% (168/336) of moderate and severe patients were biologic experienced, respectively (Fig. 3B).

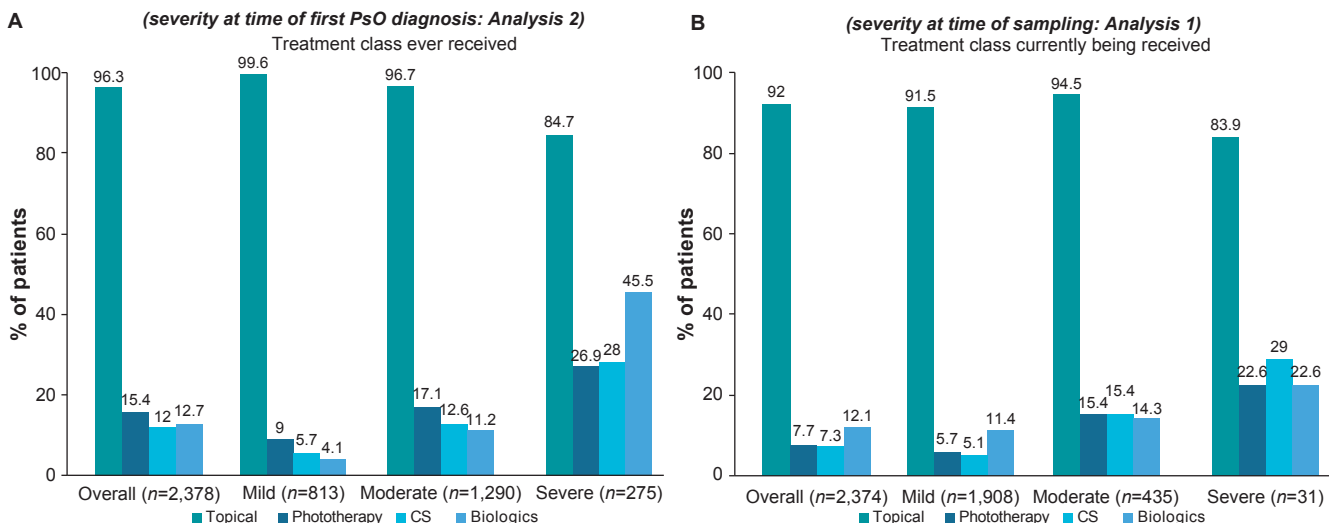


Fig. 2. Treatment classes ever received by severity at diagnosis (Analysis 2) and treatment classes currently being received by severity at time of sampling (Analysis 1). (a) Bar graph demonstrating percentage of patients ever receiving topical, phototherapy, conventional systemics (CS) and biologic therapy (including biosimilars) overall and in patients with physician-judged mild, moderate or severe disease at the time of diagnosis (Analysis 2). (b) Bar graph demonstrating percentage of patients currently receiving topical, phototherapy, CS and biologic therapy (including biosimilars) overall and in patients with physician-judged mild, moderate or severe disease at the time of sampling (Analysis 1). PsO: psoriasis.

Current treatments. Overall, 92.0% (2,183/2,374) of patients were currently receiving topical PsO therapy. This is compared with 7.7% (182/2,374), 7.3% (173/2,374) and 12.1% (286/2,374) of patients who were currently receiving phototherapy, conventional systemic and bio-

logic therapy, respectively (Fig. 2B). Specifically, for those patients with either a moderate or severe disease at sampling, only 16.3% (76/466) received conventional systemics and 14.4% (16/466) were on biologic therapy.

A more detailed description of current treatment types, overall and categorized by severity at current treatment initiation is shown in **Table II**. Adalimumab was the most commonly prescribed biologic therapy (overall 6.0%, 143/2,374; mild 0.4%, 3/761; moderate 4.1%, 52/1,279; severe 26.4%, 88/334).

Of those patients not receiving a biologic at sampling, physicians were asked if the patients' current condition may warrant the use of one; physicians answered yes

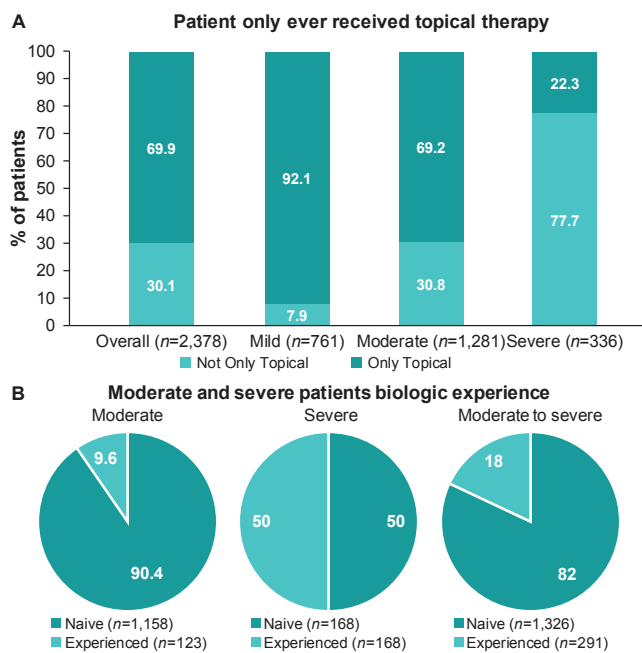


Fig. 3. Patients who received only topical therapy and biologic experience, overall and by severity at the time of current treatment initiation (Analysis 3). (a) Bar graph demonstrating percentage of patients who only ever received topical therapy to treat their psoriasis (PsO), overall and in patients with physician-judged mild, moderate or severe disease at the time of current treatment initiation (Analysis 3) (b) Pie charts demonstrating the frequency of biologic-naïve and experienced patients with physician-judged moderate, severe and moderate or severe disease at the time of current treatment initiation (Analysis 3).

Table II. Current treatment types, overall and by severity at time of current treatment initiation (Analysis 3)

Treatment, n (%)	Physician-judged severity (Analysis 3)			
	Overall (n=2,374)	Mild (n=761)	Moderate (n=1,279)	Severe (n=334)
Class: Topicals				
Topical steroid ^a	1,104 (46.5)	357 (46.9)	634 (49.6)	113 (33.8)
Topical non-steroid ^a	826 (34.8)	321 (42.2)	445 (34.8)	60 (18.0)
Topical combination products	664 (28.0)	178 (23.4)	392 (30.7)	94 (28.1)
Class: Phototherapy				
Phototherapy (PUVA, UVB)	182 (7.7)	28 (3.7)	115 (9.0)	39 (11.7)
Class: Conventional systemics				
Methotrexate	106 (4.5)	2 (0.3)	74 (5.8)	30 (9.0)
Cyclosporine	20 (0.8)	0 (0)	13 (1.0)	7 (2.1)
Acitretin	42 (1.8)	0 (0)	17 (1.3)	25 (7.5)
Fumarate	6 (0.3)	0 (0)	3 (0.2)	3 (0.9)
Class: Biologics				
Etanercept ^b	80 (3.4)	1 (0.1)	45 (3.5)	34 (10.2)
Adalimumab ^b	143 (6.0)	3 (0.4)	52 (4.1)	88 (26.4)
Ustekinumab	63 (2.7)	5 (0.7)	17 (1.3)	41 (12.3)
Class: Other	2 (0.1)	0 (0)	0 (0)	2 (0.6)

^aExcluding combination products. ^bIncluding both originator and biosimilar molecules. PUVA: psoralen and ultraviolet A; UVB: ultraviolet B.

for 12.6% (261/2,069) of patients (Analysis 1; Fig. S1A [overall] and S1B–D [by type of treating physician]).

Among patients not receiving a biologic, but whose PsO condition warranted the use of one ($n=261$ above), the most frequent reasons reported by physicians were: "patients/guardian does not want the patient to take a biologic" (23.0%, 60/261), "concerns regarding safety/side-effects" (19.2%, 50/261), "patient/guardian does not want to administer" (16.5%, 43/261) and "formulary/insurance restrictions" (16.1%, 42/261).

Treatments by type of physician. Patients consulting with a dermatologist were more likely to be currently receiving a conventional systemic (10.1%, 126/1,247) and biologic therapy (17.4%, 217/1,247), followed by patients treated by paediatricians (conventional systemics 5.4%, 29/537; biologics 9.1%, 49/537). Patients currently treated by GP/PCPs were least likely to receive conventional systemics (3.0%, 18/594) or biologics (3.4%, 20/594) (Table SIV).

In particular, 12.0% and 55.3% of patients with moderate and severe disease at current treatment initiation (Analysis 3) and being treated by a dermatologist were currently receiving a biologic, respectively. This was compared with 7.2% and 47.6% of moderate and severe patients treated by a paediatrician, and 3.6% and 17.8% of patients treated by a GP/PCP, respectively.

In addition, 59.3% (740/1,247), 79.3% (426/537) and 83.5% (496/594) of all patients treated by dermatologists, paediatricians and GP/PCPs, respectively, had only ever received topical therapies to treat their PsO.

DISCUSSION

Management of paediatric PsO is challenging and has historically been based on expert opinions and review of sparse evidence available in paediatric PsO (16, 17). EU and US guidelines were recently published to reflect the best available evidence for the management and treatment of paediatric PsO and associated comorbidities (3, 4). In addition, targeted treatment options for this indication have improved considerably in recent times. Hence, paediatric PsO registries and real-world data are crucial to understand the current disease burden and treatment needs of this patient population. These analyses describe the clinical unmet needs, burden of disease and treatment patterns of a large real-world population of paediatric PsO patients within the US and 5 EU countries.

The data presented in these analyses describe a robust multi-national population of paediatric patients currently undergoing treatment for PsO. Within the current study population, 65.8% had a moderate or severe disease when they were first diagnosed with PsO and were presumably untreated. This is compared with 19.6% of moderate to severe patients at sampling, who were receiving treatment for their PsO. Although the proportion

of moderate to severe disease in the paediatric psoriasis population is not well established, previous studies have reported frequencies of 27.5% (Italy (18)), 12.5–13.4% (US (19, 20)), and 32.2% (France [severe only] (21)). Discrepancies are probably due to the inconsistencies in grading disease severity. In the US and French studies, a classification of moderate to severe disease was based on prescription of systemic agents, whereas the Italian study categorized moderate to severe patients as those have a PASI >10. A recent Delphi consensus rejected the mild, moderate and severe categories in favour of those who were either candidates for topical therapies or candidates for systemic therapy (22). Further real-world analyses are needed to accurately identify and report on the frequency of moderate to severe disease in the general paediatric psoriasis population.

These data suggest that, although many paediatric PsO patients are currently well managed, there are still a proportion of patients with a high remaining disease burden, with a physician-judged moderate or severe disease, reporting high BSA, PASI and PGA scores, and a large number of current symptoms and affected areas, despite being treated for a pre-defined minimal period of time. Patients with a mild PsO also exhibited persistent disease burden (based on number and frequency of PsO symptoms and areas affected by PsO), despite the fact that these patients were undergoing treatment for their PsO at the time of inclusion in this survey, further emphasizing the clinical unmet needs in these patients. These data support previous reports of increased CDLQI scores, indicating an impairment in quality of life, even in paediatric patients with only mild PsO (23).

This study demonstrated that subjective severity ratings of mild, moderate and severe disease differ by treating physician specialty, suggesting that treating physicians do not assess severity in the same way. These data also indicate that dermatologists are most successful in managing their patient's disease severity, particularly in patients with moderate or severe disease. Dermatologists showed more congruence between their subjective ratings of disease severity and the more objective scores, which could be due to their disease-specific training and experience with BSA, PASI and PGA assessment tools. Similarly, a recent physician questionnaire reporting that less than half of paediatricians surveyed were certain in their diagnosis of paediatric PsO, and 80% would refer a paediatric PsO patient to a dermatologist (to confirm diagnosis, initiate therapy or continue treatment with a specialist) (24). Previously published studies have also emphasized the need for specialized care for paediatric PsO patients, citing a lack of knowledge and expertise in the management of PsO from GP/PCPs, who often fail in managing PsO as a long-term condition (25–27).

This analysis demonstrates that paediatric patients are mostly managed with topical therapies, with 69.9%

of all paediatric patients only ever receiving topical therapy to treat their PsO. These data support a recent publication, in which 62.3% of paediatric patients from the Child-CAPTURE registry were treated only with topical therapy and the median time from PsO onset to therapy escalation was 7.3 years, and 10.8 years for a switch to systemics (28). Here, we highlight 2 aspects of under-treatment in paediatric PsO patients; for patients with moderate or severe PsO at diagnosis (i.e. with underlying moderate to severe disease), 15.3% and 17.2% had ever received either conventional systemics or biologic therapies, despite being eligible for treatment escalation. Furthermore, a small proportion of moderate or severe patients at sampling were currently receiving systemic treatment (16.3% on conventional systemics; 14.4% on biologics), indicating a possible under-treatment of these patients.

Of particular interest, despite the fact that different treating physician specialities consult with similar proportions of patients with mild, moderate and severe disease, only 3.4% of patients treated by a GP/PCP were receiving a biologic (compared with 9.1% of patients treated by a paediatrician and 17.4% of patients treated by a dermatologist). This suggests that GP/PCPs are less likely to escalate therapy compared with dermatologists, which may be due to both a lack of awareness of treatment guidelines and national regulatory differences related to prescription of systemic treatments. A recent French survey mirrored these data, with only 4% of GPs and paediatricians using systemic treatments compared with 32% of dermatologists. Of note, dermatologists in support of using systemic treatments in paediatric PsO tended to be younger, work in hospitals and consult frequently with severe patients (29). Biologic therapies have been used to treat paediatric PsO for over a decade; data on the use of biologic therapy is quickly expanding and numerous studies have reported the safety of systemic therapy in this patient population (6, 30, 31). Nevertheless, the most common reasons for patients not receiving a biologic were patient/guardian decision and concerns regarding the safety/side-effect profile of biologic therapy, suggesting the need for better education surrounding the use of biologics for paediatric PsO patients and their parents/guardians.

Limitations of these data include the subjective, physician-judged severity assessments and the fact that patients may have been treated by different physicians at different time-points (i.e. the treating physician at the time of surveying may not have been the physician to diagnose the patient's PsO). Possible misclassification or over/understating of patients' condition may result in areas of discordance between similar variables (e.g. physician-judged severity categorization and BSA). Furthermore, this survey was cross-sectional, and therefore cannot provide insight into the natural course of paediatric PsO (i.e. whether paediatric PsO patients

remain in their disease severity category from diagnosis). Accuracy and completeness of data collection is subject to the integrity and discretion of participating physicians. However, to ensure appropriate qualification of participating physicians and accuracy of data collected, physicians included in the DSP were recruited via professional market researchers. Rigorous data checks were performed, which included monitoring the physicians' patient record data completion.

In conclusion, despite receiving PsO treatment, a high disease burden remains amongst paediatric PsO patients, with patients reporting high BSA, PASI and PGA scores, and high numbers of current symptoms and affected areas. This was particularly pronounced for patients with moderate or severe disease; however, patients with mild disease also exhibit persistent disease burden while being treated. Paediatric PsO patients are predominantly managed by topical therapies. A proportion of moderate or severe patients are undertreated, which may explain the persistent burden of disease observed.

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Novartis Pharma AG did not influence the original survey either through contribution to the design of questionnaires or data collection. All data that support the findings of this study are the intellectual property of Adelphi Real World. All requests for access should be addressed directly to James Lucas at james.lucas@adelphigroup.com.

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