SHORT COMMUNICATION

Patient-reported Outcomes and Burden of Disease in Paediatric Patients with Psoriasis: Real-world Data from EU5 and US

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Psoriasis (PsO) is a chronic, systemic, inflammatory skin disorder, characterized by red, scaly plaques (1). PsO affects approximately 2–4% of individuals in western countries (2). Approximately one-quarter of patients with PsO experience disease onset before adulthood (3). Paediatric PsO (onset < 18 years) is associated with a substantial negative effect on quality of life (QoL) and patients have a greater risk of developing psychosocial disorders compared with those without PsO (4–6). Furthermore, due to the visibility of psoriatic plaques, paediatric patients with PsO experience social discomfort, bullying and stigma (6–9). Previously we have described physician-reported clinical unmet needs and treatment patterns in a real-world population of >2,000 paediatric patients with PsO (10).

The aim of the current study was to describe patient-reported outcomes (PROs) and disease burden among a paediatric PsO population across the United States, and EU5 (UK, France, Germany, Spain, and Italy).

METHODS AND RESULTS

Methods of this retrospective analysis of a cross-sectional survey have been reported previously (10). In brief, dermatologists, general practitioners or primary care practitioners (GP/PCP), and paediatricians actively managing paediatric patients with PsO were included. All physicians completed a patient record form (PRF) for the subsequent 10 paediatric patients with PsO attending their practice (PRF details published previously (10)). Each patient was invited by their physician to complete a voluntary self-completion questionnaire. Patient self-completion questionnaires (PSC) were completed by patients aged 12–17 years; carer self-completion questionnaires (CSC) were completed by carers of patients < 12 years on their behalf. Matched physician-reported outcomes (via PRFs) were included.

Data are based on disease severity categorization at survey sampling. Disease severity categories (mild, moderate, severe) were based on physician judgement; no clinical definition was applied. Further methodological information is shown in Appendix S1.

Data were collected from 324 treating-physicians (58% (187/324) dermatologists; 22% (71/324) GPs/PCPs; 20% (66/324) paediatricians). Overall, physicians completed 2,877 PRFs, each representing 1 paediatric patient with PsO. To ensure adequate time with treatment response, patients with a treatment time < 4 weeks for topical therapy and/or < 12 weeks for conventional systemic and/or biologic therapy were excluded, leaving a total analysable population of 2,379. The mean ± standard deviation (SD) age was 12.9 ± 3.4 years and 53% (1258/2379) were male. Demographics and disease characteristics were published previously (10).

Patient-reported data were collected for 42.7% (1017/2379) of the analysed population, 666/1017 (65.5%) via the PSC and 351/1017 (34.5%) via the CSC. For the present analysis, physician-reported data (via PRFs) were included only for those patients with corresponding patient-reported data (i.e. a matched dataset, $n = 1{,}017$). Within the matched dataset, physicians reported that 79.8% of all patients had mild disease, 18.2% had moderate disease, and 2.0% had severe disease (Fig. S1).

At sampling, patients reported the impact of disease on QoL, with a mean Children's Dermatology Life Quality Index (CDLQI) of 4.7 ± 5.1 (PSC) and 5.2 ± 5.1 (CSC) (**Fig. 1**); the impact on QoL was greater in patients with more severe disease (Fig. 1A). The effect of paediatric PsO on daily activities, itch severity and skin pain severity are illustrated in Fig. 1B–D, respectively. Patients with a moderate to severe disease experienced the greatest impact on QoL.

When asked about the frequency of PsO-related itching, overall, 27.4% and 34.6% of patients and carers, respectively, reported patients being affected "sometimes, usually, or all of the time" in the previous week (Table SI). The proportion of patients affected by itch "sometimes, usually, or all of the time" was substantially greater in patients with a moderate (63.6% PSC; 64.1% CSC) or severe (75.0% PSC; 57.1% CSC) disease. Itch had an impact on school/work, sleep, physical activities, and social activities. A large proportion of patients with moderate or severe PsO reported that itch impacted their sleep "quite a bit, a lot, or a huge amount" (moderate: 29.6% PSC, 35.0% CSC; severe: 72.7% CSC, 66.7% CSC) (Table SI).

The mean CDLQI in patients with an itch severity score ≤ 5 was 4.3 ± 4.5, compared with 10.9 ± 6.5 in patients with an itch severity score of 6–10 ($p < 0.0001$, Student's *t*-test). A strong positive correlation was observed between itch severity and CDLQI, overall (Fig. S2A; Spearman's rho [ρ] = 0.67), and split by PSC (Fig. S2B; ρ = 0.68) and CSC (Fig. S2C; ρ = 0.65).

PsO also had an effect on the QoL of family members (Fig. S3). Furthermore, the effect of PsO on QoL of patients was generally greater in patients from the EU5 compared with those from the US (Fig. S4) (see Appendix S2 for additional details).

Overall, levels of treatment dissatisfaction were moderate and similarly reported between physicians, patients, and carers (22.6%, 25.5%, and 33.6%, respectively) (Fig. S5A). Patients with mild disease displayed the highest level of treatment satisfaction. Of interest, 11.9%, 18.1%, and 24.8% of physician-, patient- and carer-reported patients with mild disease were dissatisfied with their current treatment, respectively (Fig. S5B). Furthermore, greater proportions of patients with either moderate or severe disease were dissatisfied with their treatment and believed that better disease control could be achieved (Fig. S5C–D). Patients/carers of patients receiving biologic therapy at sampling reported higher levels of treatment satisfaction vs those not currently receiving a biologic (Fig. S5E–F).

The most frequently reported reason for treatment dissatisfaction across physicians, patients, and carers was "complete skin clea-

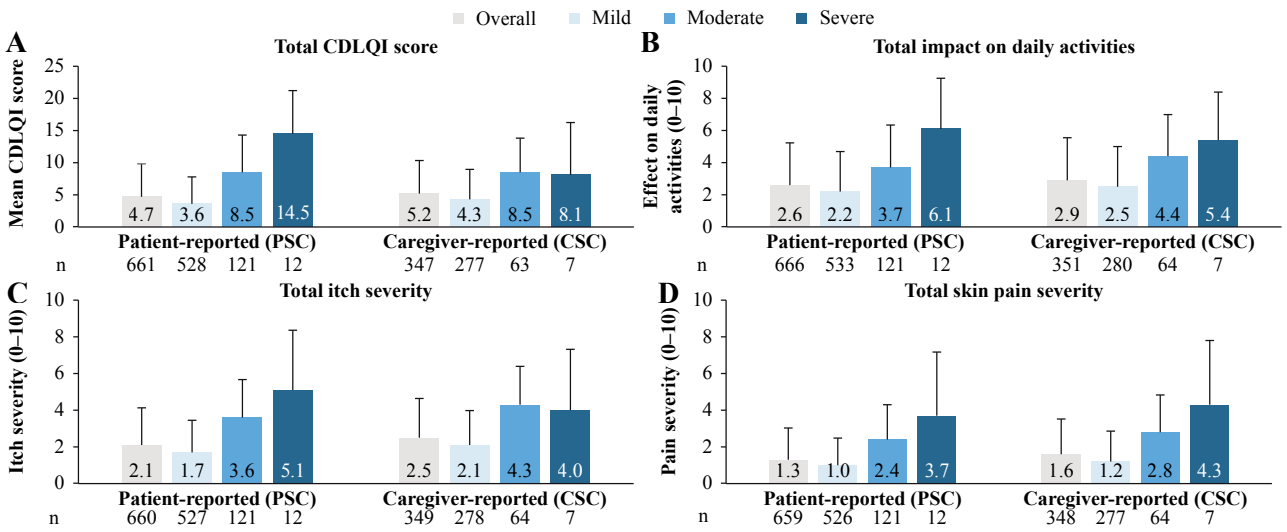

Fig. 1. Effect of paediatric psoriasis (PsO) on quality of life overall and by physician-judged disease severity at the time of sampling. Bar charts demonstrating: (A) mean Children's Dermatology Life Quality Index (CDLQI) scores; (B) impact of disease on daily activities; (C) itch severity; and (D) skin pain severity, in the EU5 (UK, France, Germany, Spain, and Italy) and USA combined. Parts (B–D) are based on a numerical scale of 0–10, where 0 represents no impact/itch/pain and 10 represents worst impact/itch/pain. CSC: carer self-completion questionnaire; *n*: number of patients with available data; PSC: patient self-completion questionnaire. Numbers within each bar are data labels and correspond to the mean number of each score per group. Error bars represent the standard deviation.

rance was not achieved"; the reported frequency was substantially higher as reported by patients/carers vs physicians (Table SII). Patients/carers expressed that "people can still see my/my child's psoriasis" as a key reason for dissatisfaction. The most commonly recorded treatment goal was "'relieves itching", which was answered most frequently by carers of patients (Table SIII). Of interest, "clears 100% of skin" was reported as an important treatment goal by 61.4% and 60.1% of patients and carers, respectively, compared with only 35.4% of physicians.

Treatment dissatisfaction was relatively similar between the EU5 and US populations (see Appendix S2 for more details).

DISCUSSION

PROs and patient perspectives, such as impact of disease on QoL, treatment satisfaction, and treatment goals, provide essential information that can be used to inform holistic management of paediatric PsO. This study included matched physician- and patient-/carer-reported data for >1,000 paediatric patients with PsO in 6 countries across 2 continents. Overall, PsO had a substantial impact on patients' lives. Mean CDLQI scores were ~5, despite ~80% of patients reporting mild disease. Scores were substantially higher in patients with moderate or severe disease. The current study showed that patients frequently experienced itch, with greater severity of itching in patients with more severe PsO. Furthermore, itch impacted school, sleep, and physical and social activities, and itch severity correlated with CDLQI. The most frequently answered treatment goal amongst patients and carers was "relieves itch". This supports a Dutch study in which "'no itch" was an important treatment goal among paediatric and adolescent patients (11).

In the current study, satisfaction with treatment was relatively high in the overall population; this is in contrast with studies in adult PsO which report lower treatment satisfaction (12–14). This is probably due to the predominance of patients with mild PsO, since patients with moderate and severe PsO report dissatisfaction levels in agreement with adult studies. The main reason for dissatisfaction was aligned between physicians, patients, and carers (lack of clear skin) and patients and carers more frequently reported "clears 100% of skin" and "works quickly" as key treatment goals. This is consistent with a recent paediatric PsO study in which preventing or reducing new psoriatic lesions were listed as the most important treatment goals (11).

Potential limitations of this study include the subjective, physician-judged severity assessment applied and the use of self-reported data. Recall bias may have affected the responses of physicians to the questionnaires, and completion of the CSC by carers may also have influenced outcomes.

In conclusion, management of paediatric PsO should consider the impact of disease on health-related QoL, patient perceptions on treatment satisfaction, and treatment goals.

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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. Ethics approval was granted by the Western Copernicus Group Institutional Review Board (WCG-IRB).

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