Concise report

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Psoriasis of the external auditory canal: prevalence, clinical features and impact on quality of life

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Abstract

Psoriasis of the external auditory canal (PsEAC) is often under-recognized. The aims of this study were to assess the prevalence of PsEAC, its association with a particular psoriasis subtype and its impact on quality of life (QoL). A prospective study was carried out in two Spanish university hospitals, enrolling consecutive patients who attended a consultation for psoriasis. The clinical features of psoriasis and PsEAC were recorded and the Dermatology Life Quality Index (DLQI) and Itch Numerical Rating Scale (Itch-NRS) were distributed to patients. Overall, 188 of 1000 patients (18.8%) included in the study had PsEAC, which was associated with severity of psoriasis, presence of inverse psoriasis and involvement of the scalp, nails and genitals, but not with obesity or psoriatic arthritis. PsEAC was the main reason for consultation in 27 patients, with itching being the main symptom. In this study, PsEAC had a prevalence of 18.8%. The occurrence of PsEAC was associated with poorer QoL, as measured by DLQI and Itch-NRS.

Psoriasis is a chronic inflammatory disease of the skin.[1] The most common type is chronic plaque psoriasis. It may involve all body sites, including the external auditory canal.[2] Psoriasis of the ear has not been well studied but may affect up to 37% of patients with psoriasis.[3–6] The main objective of this study was to determine the prevalence of psoriasis of the external auditory canal (PsEAC) in patients attending consultations for cutaneous psoriasis. The secondary objective was to determine whether PsEAC was associated with a psoriasis phenotype.

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Report

This observational, prospective, cross-sectional, multicentre study was conducted in northern Spain between June 2019 and October 2019 by six investigators in two tertiary referral university hospitals, the Hospital Universitario Central de Asturias and Hospital Universitario Marqués de Valdecilla.

The study was proposed to all consecutive patients aged ≥ 18 years who consulted about psoriasis, regardless of previous lines of treatment. PsEAC was defined as the presence of erythematous–squamous lesions or scaly lesions in the EAC.[3] Otoscopy was not performed.

Patient demographics and psoriasis characteristics were obtained from each patient's medical record. The clinical severity of psoriasis was recorded using the maximum score on the Psoriasis Area and Severity Index (PASI) in the patient's medical history. Psoriasis was classified as mild, moderate (PASI ≤ 10) or severe

Table 1 Demographic and clinical characteristics of the study population, and characteristics associated with psoriasis of the external auditory canal univariate analysis.

Characteristic[a]	Total	PsEAC present		*P*
		Yes (*n* = 188)	No (*n* = 812)	
Sex ratio, M : F or *n* (%)	530 : 470 (53 : 47)	96 (51.1)	434 (53)	0.55
Age, years; mean ± SD	48.1 ± 14.88	48.8 ± 17.26	47.9 ± 15.21	0.66
BMI > 30	279 (27.9)	52 (27.6)	227 (28.0)	0.93
Psoriasis family history	492 (49.2)	91 (48.4)	401 (49.3)	0.80
Age of psoriasis onset < 40 years	700 (70.0)	131 (69.7)	569 (70.0)	0.91
Psoriasis type				
Plaque	929 (92.9)	174 (92.0)	755 (93.5)	0.83
Inverse	39 (3.9)	15 (7.97)	24 (2.95)	0.001
Guttate	99 (9.9)	19 (10.1)	80 (9.85)	0.91
Erythrodermic	12 (1.2)	2 (1.06)	10 (1.23)	0.84
Specific location				
Scalp	800 (80.0)	171 (90.9)	629 (77.5)	< 0.001
Palms and soles	120 (12.0)	14 (7.4)	106 (13.0)	0.03
Nails	508 (50.8)	111 (59)	397(49.0)	0.012
Genitals	81 (8.1)	25 (13.2)	56 (6.8)	< 0.01
Psoriatic arthritis	319 (31.9)	75 (39.9)	244 (30.0)	< 0.01
PASI > 10	409 (40.9)	98 (52.1)	311 (38.3)	0.001
On systemic therapy	497(49.7)	108 (57.4)	389 (47.9)	0.02

BMI, body mass index; PASI, Psoriasis Area and Severity Index; PsEAC, psoriasis of the external auditory canal. [a]Data are *n* (%) unless otherwise specified.

Table 2 Comparison of quality-of-life measurements in psoriasis patients with and without canal auricular involvement.

Score	Received, *n*	EAC involvement, *n* (median) [range]		*P*[c]
		Yes[a]	No[b]	
DLQI	423	152 (4.8) [0–16]	271 (2.2) [0–22]	< 0.001
Itch-NRS	457	152 (5.6) [0–10]	305 (4.2) [0–8]	< 0.001

DLQI, Dermatology Life Quality Index; EAC, external auditory canal; Itch-NRS, Itch Numerical Rating Scale. [a]80 patients (52.6%) were receiving systemic treatment; [b]271 (64%) and 181 (59.3%) patients were receiving systemic treatment; [c]Mann–Whitney *U*-test.

Table 3 Characteristics associated with psoriasis of the external auditory canal in multivariate analysis.

Characteristic	OR (95% CI)	*P*
Inverse psoriasis	1.23 (0.49–3.08)	0.64
Scalp involvement	2.76 (1.61–4.75)	< 0.001
Palm and sole involvement	0.41 (0.22–0.77)	< 0.01
Nail involvement	1.58 (1.07–2.31)	0.02
Genital psoriasis	3.63 (1.94–6.78)	< 0.001
Arthritis	0.93 (0.66–1.45)	0.93
PASI > 10	1.72 (1.23–2.42)	< 0.01

PASI, Psoriasis Area and Severity Index.

(PASI > 10). All patients were also asked to complete two self-report questionnaires on quality of life (QoL), the Dermatology Life Quality Index (DLQI)[7] and the Itch Numerical Rating Scale (Itch-NRS).[8]

Statistical analyses were performed using SPSS software (V24.0; IBM SPSS, Armonk, NY, USA). Assuming an estimated prevalence of PsEAC of 18% as recently stated[4] and a precision of 0.025, the minimum required number of patients to be included was 908. Data were summarized as mean ± SD or median and interquartile range (25th–75th percentiles) for continuous data, and as frequency (*n*) and percentage (%) of groups for categorical data. The prevalence of PsEAC was estimated, including the 95% CI. To study the differences between patients with and those without PsEAC, unadjusted comparisons were performed using Student unpaired samples *t*-test or the Mann–Whitney *U*-test for quantitative data, and the χ^2 test or Fisher exact test for categorical data, as appropriate. Factors associated with genital psoriasis were determined by logistic regression. Variables with values of $P < 0.05$ in the univariate analyses were included in the selection process for the final multinomial, logistic regression model, and two-tailed values of $P < 0.05$ were considered significant.

In total, 1000 patients were enrolled during the 4-month study period (Table 1). The study participation

rate was 100%. The demographic and clinical characteristics of the patients are shown in Table 1. Of the 1000 total patients, 188 (18.8%; 95% CI = 16.4–21.2) had a clinical history of PsEAC confirmed by a dermatologist or had PsEAC at the time of the study. PsEAC was the reason for the consultation in 27 cases [11 males (40.7%), 16 females (59.3%)]. The prevalence was similar in the two hospitals. The psoriasis was severe in 409 patients (40.9%).

Overall, 319 patients had psoriatic arthritis (31.9%). Additionally, 168 patients of the 188 patients with PsEAC (88.2%) had at least one of the following symptoms: itching, stinging or pain. All 27 patients who sought consultation for PsEAC reported severe itching.

Of the 1000 patients, 457 of returned questionnaires before starting treatment (response rate 45.7%). DLQI results are summarized in Table 2. DLQI was impaired in patients with PsEAC. There was also a difference between the groups in the Itch-NRS scale, which evaluated pruritus (itching).

The risk factors associated with the presence of PsEAC in the univariate analyses are summarized in Table 1. In the multivariate analysis (Table 3) scalp involvement (OR = 2.76, 95% CI 1.61–4.75), nail psoriasis (OR = 1.58, 95% CI 1.07–2.31), genital psoriasis (OR 3.63, 95% CI 1.94–6.78) and severe psoriasis (OR = 1.72, 95% CI 1.23–2.42) were all significantly associated with PsEAC.

Very few studies reported in the literature include descriptions of ear psoriasis, and even fewer consider EAC involvement. From an historical point of view, in 1809, Willan included the external ear as one of the body surfaces affected in psoriasis.[9]

Based on a series of 1000 patients with psoriasis, our study showed a frequency of PsEAC of 18.8%. This rate was lower than that reported by Farber[3] (34%) and Molin[6] (37%). However, it was similar to the PsEAC involvement frequency observed in a study designed to evaluate genital psoriasis (17.5%).[4]

In our series, the presence of PsEAC was associated with the severity of psoriasis and the presence of psoriasis of the genitals, scalp and nails. As reported in another study,[5] the scalp was the most common concurrent extra-auricular site in our patients with PsEAC. However, we did not find an association between PsEAC and body mass index (BMI), psoriatic arthritis, family history of psoriasis, or age of onset of psoriasis.

Our study revealed that patients with PsEAC have a worse QoL in general, as measured by the DLQI and Itch-NRS scores. Picking and scratching lesions increased patient morbidity, and should be avoided to prevent the appearance of the Koebner phenomenon, which increases the frequency of psoriasis plaques.[3] The differences in the Itch-NRS scale between patients with and without PsEAC in our series can be attributed to the high percentage of patients reporting pruritus (itching) in the PsEAC group or to the fact that these patients have more severe disease.

Our study has several limitations. The PASI values used were the highest recorded in the patient's history. Our study included patients with psoriasis regardless of whether they attended general dermatology or specialized psoriasis consultations. Moreover, many of our patients did not return the questionnaires. Despite these limitations, we believe this study provides useful information about PsEAC.

In conclusion, our study highlights a high prevalence of PsEAC in patients with psoriasis. The occurrence of PsEAC was associated with more severe disease and had a negative impact on QoL as measured by DLQI score.

Learning points

- PsEAC affects 18.8% of patients with psoriasis vulgaris.
- PsEAC was associated with severity of psoriasis and impaired QoL.
- PsEAC had an impact on prevalence, clinical features and QoL.

Conflict of interest

The authors declare that they have no conflicts of interest.

Funding

None.

Ethics statement

The study was approved by the Research Ethics Committee of the Principality of Asturias (113/2018). Informed consent not applicable.

Data availability

Data are available on request from the corresponding author.

References

1 Wi D, Wilson A, Satgé F, Murrell DF. Psoriasis and osteoporosis: a literature review. *Clin Exp Dermatol* 2022; **47**: 1438–45.

2 Griffiths CE, Barker JN. Pathogenesis and clinical features of psoriasis. *Lancet* 2007; **370**: 263–71.
3 Farber EM. Ear psoriasis. *Cutis* 1992; **50**: 105–7.
4 Larsabal M, Ly S, Sbidian E *et al*. GENIPSO: a French prospective study assessing instantaneous prevalence, clinical features and impact on quality of life of genital psoriasis among patients consulting for psoriasis. *Br J Dermatol* 2019; **180**: 647–56.
5 Blake A, Enos C, Armstrong AW *et al*. Results of a survey of the National Psoriasis Foundation Medical Board on the management of ear psoriasis. *J Psoriasis Psoriatic Arthritis* 2020; **5**: 28–31.
6 Molin L. Psoriasis. A study of the course and degree of severity, joint involvement, socio-medical conditions, general morbidity and influences of selection factors among previously hospitalized psoriatics. *Acta Derm Venereol Suppl (Stockh)* 1973; **53**: 1–125.
7 Finlay AY, Khan GK. Dermatology Life Quality Index (DLQI) – a simple practical measure for routine clinical use. *Clin Exp Dermatol* 1994; **19**: 210–16.
8 Phan NQ, Blome C, Fritz F *et al*. Assessment of pruritus intensity: prospective study on validity and reliability of the visual analogue scale, numerical rating scale and verbal rating scale in 471 patients with chronic pruritus. *Acta Derm Venereol* 2012; **92**: 502–7.
9 Willan R. *On Cutaneous Diseases*. Vol. 1. Philadelphia: Kimber and Conrad, 1809; 114–43.

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*SOTYKTU was studied in two global, Phase 3, randomised, multi-arm clinical studies: POETYK PSO-1 and PSO-2. **PASI 75 and sPGA 0/1 vs. placebo at Week 16 were co-primary endpoints**. PASI 75 was defined as ≥75% reduction from baseline in the Psoriasis Area and Severity Index. sPGA was defined as sPGA score of 0 or 1 with ≥2-point improvement from baseline. N numbers: PSO-1: SOTYKTU (n=332); apremilast (n=168), placebo (n=166); PSO-2: SOTYKTU (n=511); apremilast (n=254), placebo (n=255). SOTYKTU delivered superior PASI 75 response rates vs placebo (PSO-1: 58.4% vs. 12.7%, p<0.0001; PSO-2: 53.0% vs. 9.4%, p<0.0001) at Week 16, and superior results achieving clear or almost clear skin (sPGA 0/1) vs. placebo (PSO-1: 53.6% vs. 7.2%, p<0.0001; PSO-2: 49.5% vs. 8.6%, p<0.0001) at Week 16 (co-primary endpoints).[2,3]

†Via enzyme inhibition, enzyme induction, or transporter inhibition.[1]

Abbreviations: AE, adverse event; DDI, drug–drug interaction; PASI, Psoriasis Area and Severity Index; sPGA, static Physician's Global Assessment; TYK2, tyrosine kinase 2.

References:
1. SOTYKTU. Summary of Product Characteristics.
2. Armstrong A *et al. J Am Acad Dermatol*. 2023;88(1):29–39.
3. Strober B *et al. J Am Acad Dermatol*. 2023;88(1):40–51.
4. SOTYKTU. European Product Assessment Report (EPAR). 26 January 2023. Available at https://www.ema.europa.eu/en/documents/assessment-report/sotyktu-epar-public-assessment-report_en.pdf (Accessed September 2023).

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ADDITIONAL INFORMATION AVAILABLE ON REQUEST

Approval code: 1787-IE-2300001

Adverse events should be reported. Reporting forms and information can be found at: Northern Ireland – www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store; Ireland – via HPRA Pharmacovigilance at www.hpra.ie Adverse events should also be reported to Bristol-Myers Squibb via medical.information@bms.com or 0800 731 1736 (Northern Ireland); 1 800 749 749 (Ireland).