University Medical Center Hamburg-Eppendorf
Institute for Health Services Research in Dermatology and Nursing

Institute for Health Services Research in Dermatology and Nursing

Disease burden and patient-defined treatment needs and benefits in patients with psoriasis with and without anogenital involvements

Neuza da Silva[1], Matthias Augustin[1], Dagmar Wilsmann-Theis[2], Athanasios Tsianakas[3], Petra Staubach[4], Rachel Sommer[1]

CVderm
German Center for Health Services Research in Dermatology

INTRODUCTION & OBJECTIVES

Clinical decisions are routinely based on the Psoriasis Area and Severity Index (PASI) and the Dermatology Life Quality Index (DLQI). However, these instruments do not capture the additional burden of anogenital psoriasis and the specific needs of these patients, particularly in terms of their interpersonal and sexual relationships.

Study objectives:

- to compare patient-reported outcomes (PROs) of disease burden between patients with psoriasis with and without anogenital involvement;
- to identify the specific treatment needs of patients with anogenital psoriasis;
- to examine which clinical and psychosocial variables contribute to more patient-defined treatment benefits.

MATERIALS & METHODS

Study design and patient cohort

The study had a multicentre cross-sectional observational case-control design. Patients were consecutively recruited in 4 dermatological centers in Germany (Hamburg, Bonn, Bad Bentheim and Mainz) between April 2020 and October 2022.

Inclusion criteria:

- Male or female aged at least 18 years
- Diagnosis of any type of moderate to severe psoriasis
- Ability to complete the questionnaires in German language
- Signed Informed Consent Form (ICF)

Exclusion criteria:

- Any comorbid condition which would place the subject at unacceptable risk participating in the study or confound the interpretability of study results

Measures

The study included two sets of standardized questionnaires, one that was completed by the physician and one that was completed by the patient.

Clinician-reported outcomes (ClinROs):

- Psoriasis Area and Severity Index (PASI; range 0 – 72 [max. severity])
- Static Physician's Global Assessment of Genitalia (sPGA-G; range 0 [clear] – 5 [very severe])

Patient-reported outcomes (PROs):

- Dermatology Life Quality Index (DLQI; range 0 [not at all] – 30 [very])
- Perceived Stigmatization Questionnaire (PSQ; range 0 [never] – 4 [always])
- Relationship and Sexuality Scale (RSS; range 0 – 36 [max. sexual impairment])
- Patient Benefit Index (PBI): Patient Needs Questionnaire (PNQ) + Patient Benefit Questionnaire (PBQ; range 0-4)

RESULTS

Comparative analyses between groups with vs. without anogenital psoriasis

Participants were 320 patients with psoriasis (age = 42.6±14.0 years; 67.2% male): 161 had anogenital lesions and 159 had no anogenital involvement (sPGA-G ≤1).

Patients with anogenital involvement had higher disease burden, both in terms of clinical indicators (Table1), but also in terms of QoL and sexual impairments (Table 2). However, they were less often treated with biologics (Table 1), and reported less patient-defined treatment benefits (Table 2).

Table 1 | Comparison of clinical characteristics between patients with vs. without anogenital involvement.

		No anogenital involvement	Anogenital psoriasis	χ^2/ t
Disease severity [PASI], M ± SD		2.55 ± 4.60	7.57 ± 6.88	-7.66***
Severity of anogenital lesions [sPGA-G], M ± SD		0.11 ± 0.31	2.30 ± 0.95	-27.63***
Disease duration (years), M ± SD		19.70 ± 14.00	18.73 ± 13.78	0.62
Treatment, n (%)	Biologic	119 (74.8%)	72 (44.7%)	30.17***
	Conventional systemic	19 (11.9%)	41 (25.5%)	9.59**
	Topical	67 (42.1%)	106 (65.8%)	18.09***
	Phototherapy	5 (3.1%)	31 (19.3%)	20.79***
	Other	6 (3.8%)	6 (3.7%)	0.00
Comorbidities (yes), n (%)		73 (45.9%)	100 (62.1%)	8.45**

Chi-square tests for categorical variables/ independent samples t-tests for continuous variables; *p < 0.05; **p < 0.01; ***p < 0.001.

Table 2 | Comparison of disease burden and patient needs between patients with vs. without anogenital involvement.

	No anogenital involvement	Anogenital psoriasis	F
QoL impairments [DLQI], M ± SD	4.09 ± 5.65	10.79 ± 7.28	23.38***
Perceived stigmatization [PSQ], M ± SD	0.90 ± 0.59	1.14 ± 0.62	2.50
Sexual impairments [RSS], M ± SD	14.57 ± 5.36	18.94 ± 6.47	16.50***
PNQ: Reducing physical impairments, M ± SD	2.80 ± 1.15	3.12 ± 0.88	2.45
PNQ: Reducing psychological impairments, M ± SD	2.33 ± 1.37	2.59 ± 1.24	0.19
PNQ: Reducing social impairments, M ± SD	2.04 ± 1.41	2.36 ± 1.25	1.12
PNQ: Reducing impairments due to therapy, M ± SD	2.36 ± 1.31	2.69 ± 1.04	1.79
PNQ: Having confidence in healing, M ± SD	3.17 ± 1.16	3.24 ± 1.05	0.03
Patient benefits [PBI], M ± SD	3.10 ± 1.05	2.01 ± 1.24	19.90***

Multivariate analysis of covariance for PNQ: Wilks' Lambda = 0.98, F(5, 298) = 1.06, p = 0.382.
F: Univariate analysis of covariance, controlling for disease severity, treatment and comorbidities; *p < 0.05; **p < 0.01; ***p < 0.001.

Although there were no significant differences on the PNQ subscales, the individual item analyses revealed that patients with anogenital psoriasis rated the needs to "be free of itching", "sleep better", "be less burdened in your partnership", "be able to have a normal sex life", and "need less time for daily treatment" as more important.

Associations between clinical and psychosocial variables and patient benefits

Regression analysis (Table 3) explained 55% of the variance in patient benefits (PBI). Specifically, more patient benefits were associated with lower severity of psoriasis and of anogenital lesions, being treated with biologic agents and not with conventional systemic drugs, less DLQI impairments, higher perceived stigmatization, and no anogenital involvement.

Table 3 | Regression analyses explaining the variance in patient-defined treatment benefits (PBI).

	Step 1: Covariates		Step 2: Disease burden		Step 3: Anogenital involvement		Step 4: Interaction effects	
	ß	t	ß	t	ß	t	ß	t
Age	0.08	1.13	0.08	1.28	0.08	1.29	0.08	1.29
Gender [a]	-0.01	-0.20	0.01	0.16	0.00	0.00	-0.01	-0.15
Disease severity [PASI]	-0.21	-2.94**	-0.10	-1.55	-0.15	-2.19*	-0.16	-2.35*
Severity of anogenital lesions [sPGA-G]	-0.15	-2.07*	-0.06	-0.89	0.17	1.61	0.17	1.53
Disease duration	0.13	1.96	0.10	1.57	0.09	1.56	0.11	1.78
Biologic treatment [b]	0.27	4.11***	0.24	3.85***	0.23	3.76***	0.21	3.54***
Conv. systemic treatment [b]	-0.16	-2.75**	-0.10	-1.96	-0.10	-1.94	-0.11	-2.08*
Topical treatment [b]	-0.06	-0.99	-0.03	-0.58	-0.05	-0.88	-0.05	-0.84
Phototherapy [b]	0.01	0.16	0.03	0.59	0.05	0.83	0.02	0.44
Comorbidities [b]	-0.09	-1.65	-0.03	-0.63	-0.03	-0.51	-0.04	-0.73
QoL impairments [DLQI]			-0.45	-6.47***	-0.44	-6.41***	-0.48	-4.78***
Stigmatization [PSQ]			0.15	2.55*	0.16	2.76**	0.09	1.24
Sexual impairments [RSS]			-0.05	-0.89	-0.03	-0.54	-0.08	-0.95
Anogenital involvement [b]					-0.26	-2.76**	-0.24	-2.39*
DLQI * Anogenital							0.02	0.24
PSQ * Anogenital							0.13	1.75
RSS * Anogenital							0.05	0.67
Model summary	$\Delta R^2 = 0.40$ $\Delta F_{10, 211} = 14.01^{***}$		$\Delta R^2 = 0.12$ $\Delta F_{3, 208} = 17.29^{***}$		$\Delta R^2 = 0.02$ $\Delta F_{1, 207} = 7.64^{**}$		$\Delta R^2 = 0.01$ $\Delta F_{3, 204} = 1.99$	
Total model summary	$R^2 = 0.55$; $F_{17, 204} = 14.63^{***}$							

[a] 0 = male, 1 = female; [b] 0 = no, 1 = yes. * p < 0.05; ** p < 0.01; *** p < 0.001, two-tailed.

DISCUSSION

The higher disease burden and the lower treatment benefits in patients with anogenital psoriasis highlight the utmost importance of considering the specific patient needs in clinical decisions, sideways with disease severity and functional impairments.

Several biologic systemic drugs, namely IL-17 and IL-23 inhibitors, have demonstrated efficacy, not only regarding the clearance of the genital lesions, but also in reducing sexual limitations.

[1] Institute for Health Services Research in Dermatology and Nursing (IVDP), University Medical Center Hamburg-Eppendorf (UKE), Germany.
[2] Department for Dermatology and Allergy, University Bonn, Germany.
[3] Department of Dermatology, Fachklinik Bad Bentheim, Germany.
[4] Department of Dermatology, University Medical Center Mainz, Germany.

Contact: Dr. Neuza da Silva, Ph.D., n.dasilva@uke.de
Funding: This investigator-initiated study was supported by Lilly Deutschland GmbH.

PEOPLE CENTERED HEALTH CARE
www.pchc.eu