

Anxiety and Depression in Patients with Prurigo Nodularis: Results from the PN – paTient Reported burden of sickNess (PN-TREK) Study

Shawn G Kwatra¹, Bruno Martins², Min Yang², Abigail Zion², Joseph Zahn³, Bengisu Ozarslan⁴, Donia Bahloul⁵, Ryan B Thomas³

¹Johns Hopkins University School of Medicine, Baltimore, MD, USA; ²Analysis Group, Boston, MA, USA; ³Regeneron Pharmaceuticals, Inc., Tarrytown, NY, USA; ⁴Sanofi, Istanbul, Turkey; ⁵Sanofi Genzyme, Gentilly, France



Copies of this poster obtain through Quick Response (QR) Code are for personal use only

SYNOPSIS

- Prurigo nodularis (PN) is a chronic skin disease characterized by severely itchy nodules typically on the trunk and extremities.¹
- The intense itch, often accompanied by skin pain, stinging, and burning, experienced by patients with PN along with the associated comorbidities affects their quality of life and mental health.²
- Patients with PN may have comorbid anxiety and depression that could be exacerbated by their disease; however, there have been limited data regarding the impact of PN on patients' mental health.

OBJECTIVE

- To assess depression and anxiety symptoms in patients with PN stratified according to different categories of itch.

METHODS

Study design and population

- In this cross-sectional online survey, adult patients with a self-reported diagnosis of PN for ≥3 months with active disease (≥6 nodules, itch of any level, and history/signs of repeated scratching, picking, or rubbing) were recruited from the United States.

Data collection and assessments

- Data were collected on patient demographics, clinical characteristics, comorbidities, itch severity, and mental health.
- Itch severity during the past week was measured using Worst Itch Numeric Rating Scale (WI-NRS; 0–10, a higher score indicating more severe itch).³
- Patients were stratified into WI-NRS itch score categories of 0–2, 3–6, and ≥7.
- Patients were asked to self-report diagnosis of anxiety and depression as part of the survey; quantitative assessments of anxiety and depression were done based on the Hospital Anxiety and Depression Scale for anxiety (HADS-A) and depression (HADS-D), respectively.
- A HADS cut-off of ≥8 on either domain was considered suggestive of the presence of anxiety/depression.⁴

Statistical analysis

- Comparisons across different WI-NRS score categories were performed using T-tests, Chi-square tests, and Fisher's exact tests, using "WI NRS 0–2" subgroup as the reference group.
- Results were also represented as odds ratio (OR) and 95% confidence interval (CI) using the Fisher's exact test.
- Continuous variables were summarized with mean and standard deviation (SD), whereas categorical variables were summarized with frequency count and percentage.

RESULTS

- Overall, 132 patients with PN participated in the survey.
- The mean age (SD) of patients was 51.0 (9.6) years; 59.1% were female. Mean (SD) time since diagnosis was 4.1 (5.1) years.
- The mean (SD) WI-NRS score was 6.0 (3.1); 46.2% ($n = 61$) had WI-NRS scores ≥7, 34.1% ($n = 45$) had WI-NRS scores 3–6, and 19.7% ($n = 26$) had WI-NRS scores 0–2.
- The demographic and clinical characteristics of patients are shown in **Table 1**.

Table 1. Demographic and clinical characteristics of patients

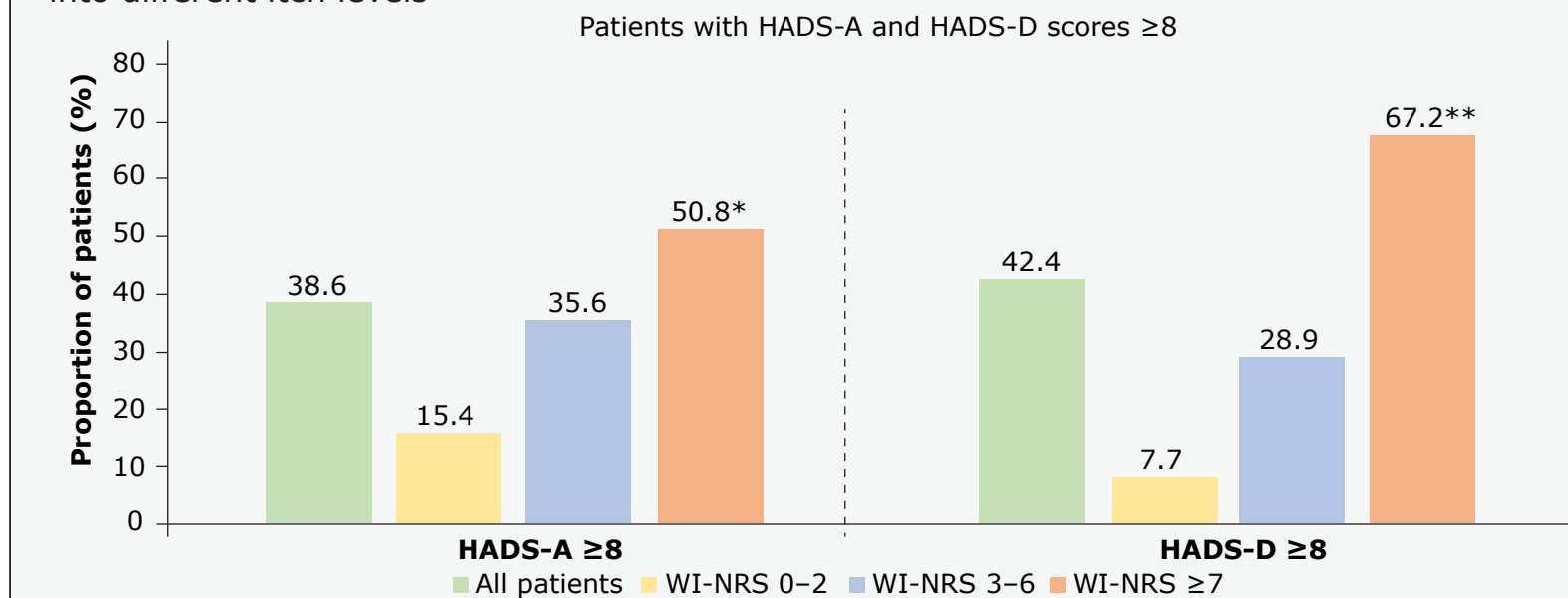
Characteristics	All patients (N = 132)	Itch level categories based on WI-NRS score				
		WI-NRS 0–2 (n = 26)	WI-NRS 3–6 (n = 45)	P-value ^a	WI-NRS ≥7 (n = 61)	P-value ^b
Age, years, mean (SD)	51.0 (9.6)	48.6 (9.9)	49.6 (8.9)	0.67	53.1 (9.5)	0.06
Time since diagnosis, years, mean (SD)	4.1 (5.1)	2.6 (2.3)	2.4 (2.1)	0.72	6.0 (6.7)	0.00
Female, n (%)	78 (59.1)	15 (57.7)	24 (53.3)	0.91	39 (63.9)	0.83
Race, n (%)						
White or Caucasian	65 (49.2)	11 (42.3)	19 (42.2)	0.77	35 (57.4)	0.59
Black or African American	14 (10.6)	3 (11.5)	5 (11.1)		6 (9.8)	
Native American/American Indian or Alaska Native	10 (7.6)	1 (3.8)	6 (13.3)		3 (4.9)	
Asian or Pacific Islander	4 (3.0)	2 (7.7)	1 (2.2)		1 (1.6)	
Multiple races or others	16 (12.1)	4 (15.4)	6 (13.3)		6 (9.8)	
Current number of nodules, n (%)						
~6–19 nodules	38 (28.8)	12 (46.2)	17 (37.8)	0.84	9 (14.8)	0.01
~20–49 nodules	53 (40.2)	10 (38.5)	17 (37.8)		26 (42.6)	
~50–100 nodules	30 (22.7)	3 (11.5)	7 (15.6)		20 (32.8)	
>100 nodules	11 (8.3)	1 (3.8)	4 (8.9)		6 (9.8)	
Patient-reported atopic comorbidities ^c , n (%)						
Asthma	23 (17.4)	1 (3.8)	11 (24.4)	0.04	11 (18.0)	0.10
Atopic dermatitis	20 (15.2)	4 (15.4)	7 (15.6)	1.00	9 (14.8)	1.00
Patient-reported non-atopic comorbidities ^c , n (%)						
Anxiety	34 (25.8)	6 (23.1)	11 (24.4)	1.00	17 (27.9)	0.84
Cardiovascular diseases ^d	30 (22.7)	4 (15.4)	8 (17.8)	1.00	18 (29.5)	0.26
Depression	23 (17.4)	4 (15.4)	8 (17.8)	1.00	11 (18.0)	1.00
Insomnia/sleep disorder	23 (17.4)	2 (7.7)	5 (11.1)	1.00	16 (26.2)	0.10
Overweight/obesity	23 (17.4)	3 (11.5)	3 (6.7)	0.66	17 (27.9)	0.17
T2DM	21 (15.9)	3 (11.5)	7 (15.6)	0.74	11 (18.0)	0.54
Autoimmune diseases ^e	20 (15.2)	3 (11.5)	6 (13.3)	1.00	11 (18.0)	0.54
IBD ^f	19 (14.4)	7 (26.9)	5 (11.1)	0.11	7 (11.5)	0.11

^aWI-NRS 3–6 vs. WI-NRS 0–2. ^bWI-NRS ≥7 vs. WI-NRS 0–2. ^cComorbidities with prevalence of at least 10% across all patients were included. ^dExamples include coronary heart disease, cardiac arrhythmias, heart failure, aneurysms, and hypertension. ^eExamples include ankylosing spondylitis, psoriatic arthritis, rheumatoid arthritis, lupus, and Sjogren's. ^fExamples include Crohn's disease, and ulcerative colitis. IBD, inflammatory bowel disease; SD, standard deviation; T2DM, type 2 diabetes mellitus; WI-NRS, Worst Itch – Numeric Rating Scale.

Mental health

- Approximately, 25.8% ($n = 34$) and 17.4% ($n = 23$) of patients self-reported having a diagnosis of comorbid anxiety and depression, respectively (**Table 1**); 38.6% ($n = 51$) and 42.4% ($n = 56$) of patients had HADS-A and HADS-D scores ≥8, respectively, suggesting the presence of anxiety and depression (**Figure 1**).
- A higher proportion of patients with WI-NRS ≥7 (vs. WI-NRS 0–2) had anxiety (50.8% vs. 15.4%; $P = 0.002$) and depression (67.2% vs. 7.7%; $P < 0.0001$) as suggested by the HADS score (≥8) (**Figure 1**).

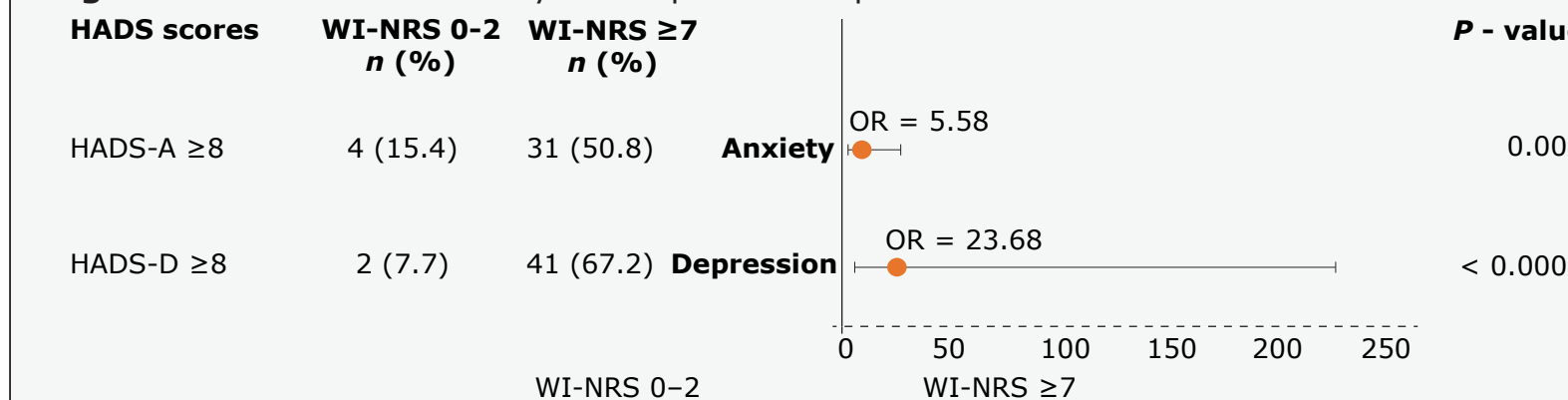
Figure 1. Anxiety and depression as per HADS-A and HADS-D scores in PN patients categorized into different itch levels



* $P = 0.002$ vs. WI-NRS 0–2. ** $P < 0.0001$ vs. WI-NRS 0–2. HADS, 0: least anxious/depressed, 21: most anxious/depressed; HADS scores ≥8 suggestive of the presence of anxiety and depression. HADS, Hospital Anxiety and Depression Scale; HADS-A, HADS – anxiety; HADS-D, HADS – depression; PN, prurigo nodularis; WI-NRS, Worst Itch – Numeric Rating Scale.

- The odds of anxiety (HADS-A ≥8) and depression (HADS-D ≥8) in patients with WI-NRS ≥7 was significantly higher than those with WI-NRS 0–2 (HADS-A: OR, 5.58 [95% CI: 1.63–24.91]; $P = 0.002$; HADS-D: OR, 23.68 [95% CI: 5.08–225.59]; $P < 0.0001$) (**Figure 2**).

Figure 2. Odds ratio of anxiety and depression in patients with WI-NRS 0–2 vs. WI-NRS ≥7



HADS, Hospital Anxiety and Depression Scale; HADS-A, HADS – anxiety; HADS-D, HADS – depression; OR, odds ratio; WI-NRS, Worst Itch – Numeric Rating Scale.

CONCLUSION

- The disparity between comorbid anxiety and depression self-reported by patients and those evaluated by patient-reported outcomes, HADS-A and HADS-D, may suggest that mental health burden in PN is higher than suspected.
- Moreover, the results suggest that patients with high itch severity are more likely to suffer from anxiety and depression. It is therefore important to consider both anxiety and depression when treating patients with PN.

REFERENCES

- Huang, A.H., et al. *J Invest Dermatol.* 2020; 140(2): 480–483.e4.
- Wongvibulsin, S., et al. *J Invest Dermatol.* 2021; 141(10): 2530–2533.e1.
- Numerical rating scale (NRS). <http://www.pruritussymposium.de/numericalratingscale.html>. Accessed August 7, 2023.
- Bjelland, I., et al. *J Psychosom Res.* 2002; 52(2): 69–77.

ACKNOWLEDGMENTS

Medical writing/editorial assistance was provided by Ali Nasir Siddiqui, PhD and Kaushik Subramanian, PhD of Sanofi.

CONFLICTS OF INTEREST

SGK has been advisory board member/consultant for AbbVie, Celldex Therapeutics, Galderma, Incyte Corporation, Pfizer, Regeneron Pharmaceuticals, and Kiniksa Pharmaceuticals and investigator for Galderma, Kiniksa Pharmaceuticals, Pfizer, and Sanofi. BM, MY, and AZ are employees of Analysis Group and received research funding from Sanofi to perform this study. JZ and RBT are employees of Regeneron Pharmaceuticals and may hold stocks and/or stock options in the company. BO and DB are employees of Sanofi and may hold stocks and/or stock options in the company.

FUNDING

The study was sponsored by Sanofi and Regeneron Pharmaceuticals, Inc.