SHORT COMMUNICATION

Real-world Clinical Efficacy and Patient-reported Treatment Satisfaction of Nemolizumab Treatment in Prurigo Nodularis

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Prurigo nodularis (PN) is a chronic inflammatory skin disease caused by immune and neuroregulatory dysregulation (1). Severe and persistent pruritus in PN imposes a substantial disease burden (1, 2). Many patients consider itch relief their primary goal (1). Racial differences in PN have been reported, with a high prevalence among women in Western populations, whereas PN is more common in men in Asian populations (3, 4). In Japan, patient surveys have indicated low satisfaction with conventional therapies, highlighting considerable unmet needs (5, 6). Treatment satisfaction is closely associated with pruritus severity and quality-of-life measures (5, 6). The primary goals are to reduce pruritus and promote lesion healing. However, despite guideline-recommended stepwise approaches, many patients remain inadequately controlled (1, 2).

Currently, nemolizumab is approved for PN in addition to dupilumab (7). Nemolizumab inhibits interleukin-31-mediated fibrosis and neuroinflammation and has demonstrated improvements in pruritus and lesions within 16 weeks (8–10). Surveys have evaluated the disease burden and treatment satisfaction in the prebiologic era; however, questionnaire-based studies focusing on patients with PN treated with nemolizumab remain limited (5, 6). Although the Peak Pruritus Numerical Rating Scale (PP-NRS) and Prurigo Nodularis-Investigator's Global Assessment (PN-IGA) provide objective measures of disease activity, they may not fully capture treatment satisfaction. Evaluating subjective burden across daily life, work and psychological well-being may provide a more comprehensive patient-centred perspective (5, 6, 10–13). Such assessments can identify unmet needs not reflected in conventional clinical indices and help clarify the extent to which nemolizumab addresses these needs. Therefore, we conducted a questionnaire-based survey of patients with PN treated with nemolizumab (5, 6, 10, 11).

MATERIALS, METHODS, AND RESULTS

Study design and patients

We conducted a single-centre retrospective study to evaluate the clinical effectiveness and patient-reported outcomes (PROs) of nemolizumab in PN. This study was conducted at the Tokyo Metropolitan Police Hospital between 2024 and 2026. The study included 20 patients with PN who received nemolizumab (initially 60 mg, followed by 30 mg monthly). Patients with concomitant atopic dermatitis (AD) were included only if their AD was controllable with topical treatment. Patients who continued treatment for at least 12 weeks were included in the analysis, whereas those who discontinued treatment because of adverse events were excluded. Previously reported cases from our institution were included (14, 15).

Clinical assessments and results

The baseline clinical characteristics are summarized in **Table I**. The median age was 77.5 years; 55% of the patients were men. The higher proportion of men was consistent with previous Japanese data (3) Three patients had concomitant AD; 4 had previously received dupilumab. PP-NRS and PN-IGA are validated clinical outcome measures and were assessed at baseline and week 16, consistent with previous trials (10–13). The baseline median PP-NRS and PN-IGA scores were 8 and 3, respectively, and improved significantly to 1 and 2 at week 16 (both $p<0.001$). As unvalidated clinical outcome measures, daily time spent on topical treatment and daily preoccupation time with PN were recorded as PROs, with patients retrospectively recalling their status before and after treatment within 1 month after completion of week 16. These measurements were recorded at 30 min intervals. Many patients had already started nemolizumab treatment at the time of study planning, precluding the collection of these data at treatment initiation. To maximize the sample size, assessments were uniformly conducted after the completion of week 16. Daily topical treatment time ($n=10$) decreased from 1 to 0 h ($p<0.05$); daily preoccupation time with PN ($n=14$) decreased from 7 to 0.5 h ($p<0.01$).

Statistical analysis

As all clinical data were non-normally distributed, they are presented as medians with interquartile ranges. Changes in PP-NRS, PN-IGA, daily topical treatment time and daily preoccupation time with PN were compared between weeks 0 and 16 using the Wilcoxon signed-rank test. Statistical significance was set at $p<0.05$. The assessments were based on post-week

Table I. Baseline characteristics and 16 Week efficacy of nemolizumab in patients with prurigo nodularis (*n*=20)

Characteristics	
Age, years	77.5 [65.25–83.25]
Sex	Male, 11; Female, 9
Comorbidities; the number of patients (percentages)	
Atopic dermatitis	3 (15%)
Cardiovascular disease	5 (25%)
Hypertension	8 (40%)
Diabetes mellitus	4 (20%)
Hyperlipidaemia	4 (20%)
Renal dysfunction	4 (20%)
Prior treatment; the number of patients (percentages)	
Topical corticosteroids	20 (100%)
Antihistamines	20 (100%)
Phototherapy	1 (5.0%)
Oral corticosteroid	1 (5.0%)
Oral cyclosporine	2 (10%)
Nalfurafine hydrochloride	1(5.0%)
Difelikefalin acetate	1 (5.0%)
Dupilumab	4 (20%)
Baseline disease severity and 16 week effectiveness outcomes	
PP-NRS score at Week 0	8 [7–9.25]
PP-NRS score at Week 16	1 [0.25–3]***
PN-IGA score at Week 0	3 (3)
PN-IGA score at Week 16	2 (1, 2)***
Daily time spent on topical treatment at Week 0 (hours)[a]	1 [0.5–3]
Daily time spent on topical treatment at Week 16 (hours)[a]	0 [0–0.5]*
Daily preoccupation time with PN at Week 0 (hours)[b]	7 [2-20]
Daily preoccupation time with PN at Week 16 (hours)[b]	0.5 [0–1]**

Comorbidities and prior treatment history are presented as frequencies (percentages). Significance levels are denoted as follows: *p<0.05; **p<0.01; ***p<0.001 (vs baseline). Data are presented as median [interquartile range (Q1–Q3)]. All data were statistically assessed by the Wilcoxon signed-rank test.
[a]Data were available for only 10 patients by using observed cases. [b]Data were available for only 14 patients by using observed cases.
PN:prurigo nodularis; PN-IGA:prurigo nodularis investigator's global assessment; PP-NRS:peak pruritus numerical rating scale.

16 recall, including 10 patients for topical treatment time and 14 for preoccupation time. Missing data were not imputed; all analyses were performed using only observed cases. All statistical analyses were performed using Easy R.

Questionnaire assessments and results

Furthermore, a questionnaire consisting of 10 items (Questions 1–10), an unvalidated clinical measurement shown in **Table II**, was administered within 1 month after completion of week 16. Questionnaire results (Fig. S1) indicated at least moderate impairment in all patients, with severe/very severe impact in 65% of symptoms and 75% of daily life. Work impairment and mental burden showed similar trends, reflecting a substantial overall disease burden. Moreover, 65% of the patients strongly recommended nemolizumab to others. Despite cost concerns, 70% rated its effectiveness as good or better. Although some patients reported anxiety before treatment, their understanding of PN and nemolizumab improved by approximately 75% through physician explanations and educational materials.

DISCUSSION

Trials have primarily evaluated treatment efficacy concerning lesions and pruritus (8–10). Consistent with these findings, nemolizumab significantly improved the PP-NRS and PN-IGA scores in our study. More, we evaluated PROs to quantitatively measure the extent to which PN affects daily life and imposes limitations over a 24 h period, focusing on the time spent on topical treatment and preoccupation with PN. Our results showed that both parameters were significantly reduced after 16 weeks of nemolizumab treatment. Although these measures differ from conventional clinical indices, they suggest a meaningful reduction in disease burden. To further explore patients' perceived burden and subjective evaluation of nemolizumab, we conducted a questionnaire survey. These results reaffirm that PN affects daily activities, work productivity and mental well-being, consistent with previous findings (5, 6). Although health insurance covers nemolizumab for PN, out-of-pocket costs remain a concern. Nevertheless, many patients regarded nemolizumab as worthwhile, reflecting its perceived effectiveness. The improved understanding of PN and nemolizumab through physician explanations and educational materials highlights the importance of patient education in enhancing treatment satisfaction and adherence. Although treatment satisfaction is closely associated with treatment efficacy, treatment goals vary among patients. Therefore, treatment satisfaction – although subjective – may provide additional patient-centred information to complement the numerical clinical results. Factors such as treatment costs or device usability may also influence satisfaction;

Table II. Details of the 10-item questionnaire (Questions 1–10)

Number	Question	1	2	3	4	5
Q1	To what extent do you describe the severity of your symptoms?	Very mild	Mild	Moderate	Severe	Very severe
Q2	To what extent does PN impact your daily life?	Very mild	Mild	Moderate	Severe	Very severe
Q3	To what extent does PN interfere with your job (for those currently employed)?	Very mild	Mild	Moderate	Severe	Very severe
Q4	To what extent does PN burden your mental health?	Very mild	Mild	Moderate	Severe	Very severe
Q5	Were you anxious about injections?	Not at all	Slightly	Moderately	Very much	Extremely
Q6	Did cost affect your decision to start treatment?	Not at all	Slightly	Moderately	Very much	Extremely
Q7	How would you rate the value of the nemolizumab treatment considering its efficacy or cost?	Poor	Fair	Good	Very good	Excellent
Q8	Would you recommend nemolizumab to other patients with PN?	Not at all	Slightly	Moderately	Very much	Extremely
Q9	Did the consultation with your physician improve your understanding of PN and nemolizumab?	Not at all	Slightly	Moderately	Very much	Extremely
Q10	Was the pharmaceutical company's brochure helpful for understanding nemolizumab?	Not at all	Slightly	Moderately	Very much	Extremely

PN:prurigo nodularis.

however, larger studies are needed to evaluate their independent effects.

This study had several limitations, including its single-centre retrospective design, small sample size and use of subjective PROs. Because daily topical treatment and preoccupation time with PN were assessed retrospectively after treatment, recall bias cannot be excluded. Furthermore, some data were unavailable because of recall limitations, and some data were missing because of investigator oversight. The use of nonvalidated measures limits direct comparisons with standard clinical indices. Nevertheless, nemolizumab achieved clinical improvements within 16 weeks; many patients supported its cost-effectiveness and recommended it to others. Larger prospective studies using standardized PROs are warranted to confirm these findings.

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Data availability statement: Data concerning this article may be requested from the corresponding author for reasonable requests.

IRB approval status: This study was approved by the Ethics Committee of the Tokyo Metropolitan Police Hospital (approval no. 25-A08) and was conducted in accordance with the Declaration of Helsinki (2004). Informed consent was obtained from all participants through an opt-out process.

Conflict of interest: Yoshihito Mima and Ken Iozumi received lecture fees from Maruho Co., which markets nemolizumab.

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