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Original article

**Validity and Reliability of Itch Assessment Scales for Chronic Pruritus in Adults:
A Prospective Multicenter Study**

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ABSTRACT

Background: Several tools can provide a reliable and accurate evaluation of pruritus, including the visual analogue scale (VAS), numeric rating scale (NRS), verbal rating scale (VRS), and multidimensional questionnaires such as the itch severity scale (ISS). However, no single method is considered a gold standard.

Objective: We evaluated the validity and reliability of VAS, NRS, VRS, and ISS and their correlation with a pruritus-specific quality of life instrument, ItchyQoL.

Methods: A total of 419 patients with chronic pruritus (215 men and 204 women, mean age of 46.58 years) recorded their pruritus intensity on VAS, NRS, VRS, and ISS. Retest reliability was analyzed in a second assessment (3 hours after the initial assessment). All participants answered ItchyQoL.

Results: A strong correlation between VAS, NRS, and VRS was found. ISS showed a low intercorrelation validity with these tools. However, ISS was more strongly correlated with ItchyQoL. The retest reliability scores were similar for VAS, NRS, and VRS but lower than that obtained for ISS.

Limitations: Limitations include patient heterogeneity and recall bias.

Conclusion: The assessment of pruritus is challenging because of the subjective symptoms and the multifactorial nature. Therefore, more studies are needed to determine the best strategy to assess itch intensity.

Key words: Atopic dermatitis, Eczema, Itch, Pruritus, Quality of life, Urticaria

69 **CAPSULE SUMMARY**

- 70 • Although there are various itch measurement scales, comparative studies on validity
71 and reliability are lacking.
- 72 • The itch severity scale, a multidimensional scale, showed better retest reliability than
73 the visual analogue scale, numeric rating scale and verbal rating scale, and higher correlation
74 with the itch-specific quality of life measure.

INTRODUCTION

Chronic pruritus is a common symptom in many dermatological diseases. Because of the high prevalence and substantial impact of this condition on the quality of life, a valid and reliable measurement of pruritus intensity is required for the accurate control of the symptoms. However, the causes of chronic pruritus remain obscure and need to be revealed because this condition is very subjective feeling and provoked by numerous possible underlying causes¹.

Pruritus intensity can be measured by using unidimensional scales such as the visual analogue scale (VAS)², numeric rating scale (NRS)³, and verbal rating scale (VRS)⁴, and many multidimensional questionnaires, including the itch severity scale (ISS)⁵. Although several studies investigated the correlation between VAS and VRS⁶ as well as the validity and reliability of three unidimensional itch intensity scales¹, no comprehensive studies have determined the validity and reliability of these unidimensional and multidimensional itch intensity scales and the correlation of these scales with the patients' quality of life (QoL).

Therefore, in this study, we investigated the validity and reliability of VAS, NRS, VRS, and ISS, and their correlation with a pruritus-specific quality of life instrument, the itch-related quality of life (ItchyQoL)⁷

MATERIAL AND METHODS

A nationwide questionnaire-based study was conducted in 11 hospitals in Korea from July 2016 to January 2017. All patients (age ≥ 20 years old) presented chronic pruritus for more than 6 weeks regardless of the cause and submitted their written informed consent before survey enrollment. The structured questionnaire ItchyQoL contained demographic and pruritus characteristics, including sex and age. Patients were asked to record their average pruritus intensity in an initial assessment (baseline) on the VAS (on a horizontal 10-cm line), NRS (using a score from 0 to 10), 5-point VRS (in a questionnaire), and ISS (in a questionnaire). The reliability of the evaluation was assessed by asking all patients to report the pruritus intensity using VAS, NRS, VRS, and ISS at follow-up (after 3 hours of the initial assessment). The correlation between each itch intensity scale was evaluated at baseline, and the reliability of each scale was assessed by comparing the values between baseline and follow-up. In addition, we determined whether the validity of each scale agreed with ItchyQoL. The study protocol complied with the Declaration of Helsinki and was approved by the Institutional Review Board (IRB#, KNUH 2016-07-001).

Demographic and pruritus characteristics

The demographic characteristics included age and sex. The pruritus characteristics included the duration of pruritus, use of oral medications for pruritus in the study period, and the effect of medications. The distribution of pruritus (localized or generalized), clinical appearance of the skin (primary inflammation, clinically normal skin without inflamed lesions, or secondary scratch lesions), and the etiology of pruritus (dermatologic, systemic, neurological, psychogenic, mixed, or others) were also analyzed. Subgroups were assigned according to the demographic and pruritus characteristics of the patients.

Itch assessment scales

The VAS is a visual scale with a 10-cm horizontal scale, on which the left end is marked as “no itch” and the right end is marked as “worst imaginable itch.” The patients were asked to mark on the horizontal scale a score that corresponded to the intensity of pruritus. The length from the left end of the scale to the chosen mark was measured in centimeters.

The NRS is a similar tool and has been validated for the measurement of itch. Patients were asked to assign a numerical score that corresponded to the intensity of pruritus on a scale from 0 to 10, in which 0 indicated absence of itch and 10 indicated the worst possible itch.

The VRS included scores that indicated different itching intensities as follows: 0 (none), 1 (mild), 2 (moderate), 3 (severe), 4 (very severe).

The ISS was developed by Majeski *et al.*⁵ and included seven categories: frequency, itch description, body surface area involved, itch intensity according to the itching state (best, average, or worst), effect on mood, effect on sexual desire/function, and effect on sleep.

The quality of life questionnaire

The QoL of patients with pruritus was assessed using the ItchyQoL, which was developed by Desai *et al.*⁷ and included 22 pruritus-specific items. ItchyQoL contained the following constructs: six symptoms, seven functional limitations, and eight emotions. The responses to all questions were scored using the following frequency scale: 1 (never), 2 (rarely), 3 (sometimes), 4 (often), 5 (always).

Translation of the questionnaire

The Korean version of ISS and ItchyQoL were generated following protocols. Briefly, the original questionnaire was first translated independently by 2 native Korean-speaking healthcare professionals and reviewed by several medical experts. A preliminary consensus Korean version was then back-translated into English by an English-speaking professional translator. This version and the original were compared for discrepancies, and a final consensus version was created.

Statistical analyses

Spearman's correlation coefficient was used to determine the concurrent validity and the correlation of each itch severity scale with ItchyQoL. Intraclass correlation coefficient and the Bland-Altman plot were used to validate the retest reliability. All analyses were conducted using SPSS software package (version 18.0, SPSS Inc., USA).

RESULTS

Demographic and pruritus characteristics

A total of 419 patients with chronic pruritus were recruited in this study. The participants included 215 men (51.3%) and 204 women (48.7%), and the mean age was 46.58 ± 17.42 years (range, 20–86).

The mean duration of pruritus was 150.3 ± 266.6 weeks (range, 6–1500). Three hundred five patients (72.8%) were undergoing systemic drug therapy for the treatment of itch.

Among the 389 patients who received medication at least once, 101 patients (26.0%) reported a continuous effect (lasting more than 24 hours) and 218 patients (56.0%) reported a temporary effect (lasting less than 24 hours) of the medication. Seventy patients (18.0%) reported no improvement of pruritus after taking the drugs.

Two hundred twelve patients (50.6%) showed localized pruritus limited to a defined body area, and 207 patients (49.4%) had generalized pruritus on the entire body surface.

With respect to the clinical appearance of the skin, 272 patients (66.3%) showed inflamed skin with primary lesions accompanied by pruritus, 95 patients (23.0%) showed clinically normal skin without inflamed lesions, and 46 patients (11.0%) had chronic secondary scratch lesions.

With regard to the etiology of pruritus, 317 patients (75.7%) had dermatologic pruritus due to cutaneous diseases, 40 patients (9.5%) had mixed etiology involving more than two causes, and 35 patients (8.4%) had systemic pruritus due to diseases in other organs. Twenty-seven patients (6.4%) had other etiologies, including neurologic pruritus due to disorders of the central or peripheral nervous system, psychogenic pruritus due to psychiatric and psychosomatic disorders, senile pruritus due to aging, and idiopathic pruritus (Table 1).

Concurrent validity of the itch intensity scales

At initial visit, there was a strong correlation between VAS, NRS, and VRS using Spearman's correlation coefficient, corresponding to 0.86 for VAS-NRS, 0.81 for NRS-VRS, and 0.72 for VAS-VRS. However, ISS showed a low intercorrelation validity with these three tools: 0.54 for VAS-ISS, 0.60 for NRS-ISS, and 0.62 for VRS-ISS (Table 2). The correlation coefficient between VAS and NRS was comparatively higher ($r=0.86$). In addition, at the follow-up, strong correlation between VAS, NRS, and VRS was found, 0.92 for VAS-NRS, 0.83 for NRS-VRS, and 0.80 for VAS-VRS, respectively. However, low intercorrelation validity was shown between ISS and other three tools: 0.63 for VAS-ISS, 0.66 for NRS-ISS, and 0.64 for VRS-ISS (Table 2).

Retest reliability of the itch intensity scales

The average itch intensities during the initial assessment (baseline) were higher than those obtained at follow-up (3 hours after the initial assessment), and the difference was statistically significant for all tools ($p \leq 0.01$; Table 3). ISS showed a much higher intraclass correlation coefficient (ICC) than VAS, NRS, and VRS: 0.89 for ISS, 0.77 for VAS and NRS, and 0.75 for VRS. The Bland-Altman plot showed similar results (Fig. 1).

Correlation between ItchyQoL and the itch intensity scales

At initial, ISS showed the best correlation with ItchyQoL using Spearman's correlation coefficient whereas the correlations of VAS, NRS, and VRS with ItchyQoL were significantly lower: 0.73 for ISS, 0.45 for VAS, 0.49 for NRS, and 0.47 for VRS. In addition, in the follow-up, ISS showed the best correlation with ItchyQoL whereas there was a significantly lower correlations VAS, NRS, and VRS with ItchyQoL: 0.70 for ISS, 0.46 for VAS, 0.48 for

NRS, and 0.45 for VRS (Table 4). The correlation scores of VAS, NRS, and VRS with ItchyQoL were not significantly different.

Validity, reliability, and correlation between ItchyQoL and the itch intensity scales in the subgroups

The concurrent validity and correlation with ItchyQoL using Spearman's correlation coefficient were not statistically different between the subgroups considering demographic and pruritus characteristics. Similarly, the difference in the retest reliability of each itch intensity scale was not statistically significant between the subgroups (data not shown).

DISCUSSION

Studies evaluating pruritus have tended to focus on the pathogenesis and effective treatment and often overlook the measurement of symptoms⁵. However, the investigation of validated and reliable itch intensity scales may provide a more accurate representation of pruritus and play a useful role as a benchmark for research and clinical practice.

Many itch intensity scales (e.g., VAS, NRS, VRS, ISS, 5-D pruritus scale, pruritus grading system)^{2-5,8,9}, questionnaires (e.g., ItchyQoL, DLQI)^{7,10}, and even the measurement of scratching using movement-analysis devices (e.g., wrist movement, fingernail vibration transducer)^{11,12} have been used.

Previous study initiated by the International Forum for the Study of Itch reported high reliability and concurrent validity of three unidimensional scales (VAS, NRS, VRS) in randomly selected patients with chronic itch¹. In this study, a high reliability and concurrent validity ($r > 0.8$; $p < 0.01$) was found for all tools. Reigh *et al.*² also showed that these three scales had excellent reproducibility ($ICC > 0.8$), and they concluded the VAS is a valuable method of pruritus measurement. In addition, a strong correlation has been found between VAS and VRS for the Korean population⁶. Our nationwide multi-centered study confirmed a significantly strong correlation between VAS, NRS, and VRS ($r > 0.7$).

Chronic itch is multidimensional and assessment of chronic itch needs to measure various dimensions of pruritus. Specifically, both sensory qualities and unpleasant affective dimensions should be included in the assessment¹³. Among multidimensional scales, ISS, a self-reported seven-item scale, can be alternatively used but is not routinely established in clinical practice. ISS combines itch intensity, sleep disturbance and burden by the symptom aiming to give a comprehensive rating of the itch impact¹⁴. ItchyQoL is focused on the characteristics of the symptoms and the severity of psychological burden as well as the

impact of pruritus on the activities of daily living^{7,15}. The ItchyQoL together with DLQI has been widely used to assess the severity and burden of pruritus¹⁶. However, few studies compared these two questionnaires, ISS and ItchyQoL, with unidimensional itch intensity scales. In this study, as expected, ISS showed a low intercorrelation validity with three unidimensional tools. However, interestingly, ISS showed a significantly higher retest reliability and stronger correlation with ItchyQoL compared with VAS, NRS, and VRS.

Despite the large sample size and robust statistical analysis, our results should be considered in the light of several limitations. First, the inclusion of patients who visited university hospitals may have created a selection bias for patients whose symptoms were accompanied by a lot of anxiety and subjects whose pruritus was refractory to standard therapies. Second, uncontrolled use of antipruritic drugs and the occurrence of circadian changes in itch severity from the initial assessment (baseline) to follow-up (3 hours after initial assessment) should be considered. Third, recall bias may significantly affect the evaluations using multidimensional scales such as ISS compared with intuitive unidimensional scales. Fourth, although it was a robust multi-center study, all participants were only at Korean hospitals. Thus, a study of patients with chronic pruritus from different ethnic groups will be needed to improve understanding of this issue.

In conclusion, it is difficult to use quantitative and objective methods for the measurement of the subjective feelings of itching. Although complex methods have been proposed for the measurement of itching, methods that require a lot of time and effort are difficult to use in clinical practice. Therefore, the demand for the development and establishment of simple, valid, and reliable measurement methods has increased. In this study, ISS showed good retest reliability and the highest correlation with ItchyQoL compared with three unidimensional scales. However, it is too time consuming for routine clinical use. Therefore, it is necessary to

263 develop less time-consuming alternative itch measurement scale that is highly reproducible
264 and that can well reflect the patients' QoL, which might be a simplified or abbreviated
265 version of the ISS.

ABBREVIATIONS USED:

DLQI (dermatology life quality index), ICC (intraclass correlation coefficient), ISS (itch severity scale), ItchyQoL (itch-related quality of life), NRS (numeric rating scale), QoL (quality of life), VAS (visual analogue scale), VRS (verbal rating scale)

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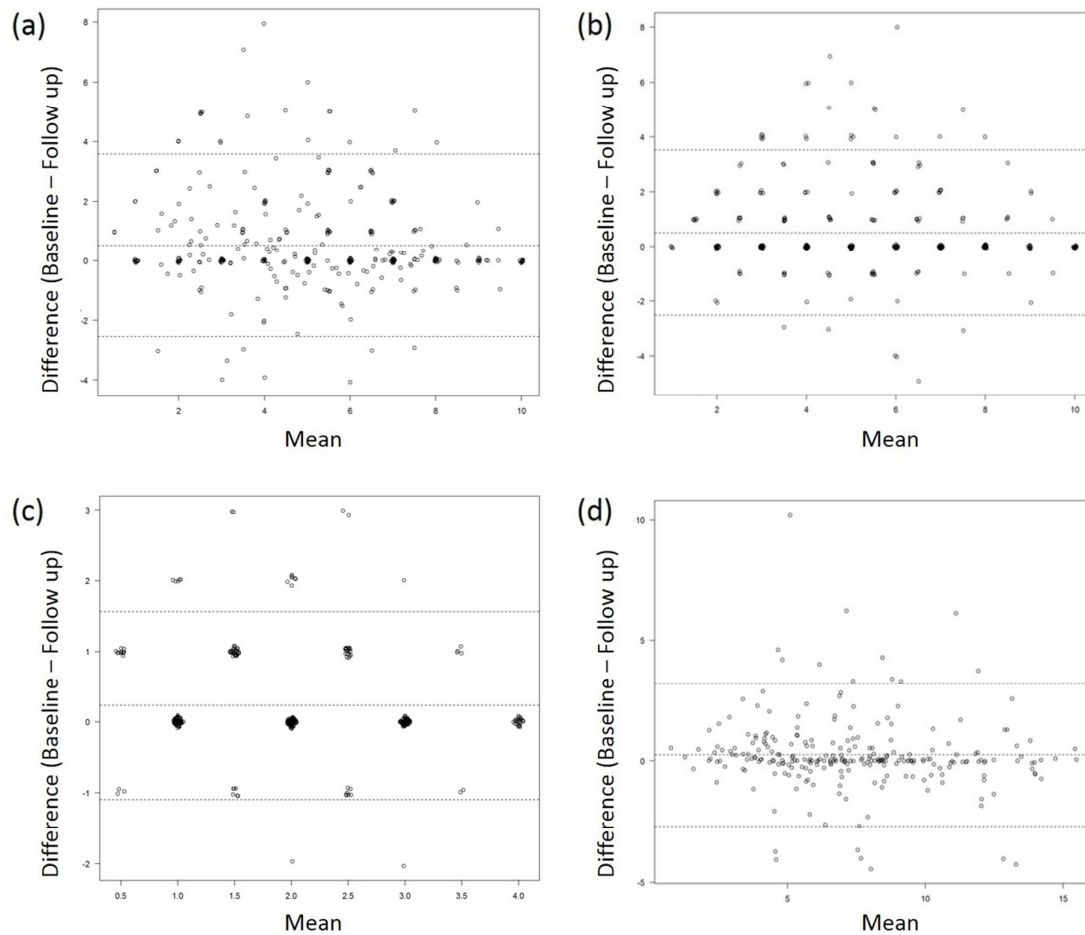
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318 **FIGURE LEGEND**

319 **Figure 1.** The Bland-Altman plot of VAS (a), NRS (b), VRS (c), and ISS (d). VAS, visual
 320 analogue scale; *NRS*, numeric rating scale; *VRS*, verbal rating scale; *ISS*, itch severity scale.



321

322 **TABLES**323 **Table 1.** Clinical characteristics of patients with chronic pruritus

Characteristics	Number (%)
Sex	
Male	215 (51.3%)
Female	204 (48.7%)
Mean age (years $\pm$ SD, range)	46.6 $\pm$ 17.4 (20-86)
Mean duration (weeks $\pm$ SD, range)	150.3 $\pm$ 266.6 (6-1500)
Current state of taking oral medication	305 (72.8%)
Effect of oral medications	389 (92.8%)
Continuous effect (lasting more than 24 hours)	101 (26.0%)
Temporary effect (lasting less than 24 hours)	218 (56.0%)
No improvement	70 (18.0%)
Itch distribution	
Localized	212 (50.6%)
Generalized	207 (49.4%)
Clinical appearance of the skin	
Inflamed skin with primary lesions	272 (66.3%)
Chronic secondary scratch lesions	46 (11.0%)
Clinically normal skin	95 (23.0%)
Etiology of pruritus	
Dermatologic pruritus*	317 (75.7%)
Systemic pruritus	35 (8.4%)
Mixed pruritus	40 (9.5%)
Others	27 (6.4%)

324 *Dermatologic causes: urticaria (61), atopic dermatitis (43), lichen simplex chronicus and prurigo
325 nodularis (23), allergic contact dermatitis (22), seborrheic dermatitis (19), psoriasis (14), nummular
326 eczema (11), xerotic eczema (8), drug eruption (6), hand eczema (5), others (105)

Table 2. Concurrent validity and Spearman's correlation coefficient between VAS, NRS, VRS, and ISS

Correlation	Initial visit		Follow-up	
	Spearman's correlation coefficient	95% confidence interval	Spearman's correlation coefficient	95% confidence interval
VAS-NRS	0.86	0.83-0.89	0.92	0.90-0.93
VAS-VRS	0.72	0.67-0.77	0.80	0.76-0.84
VAS-ISS	0.54	0.46-0.62	0.63	0.54-0.70
NRS-VRS	0.81	0.77-0.84	0.83	0.79-0.86
NRS-ISS	0.60	0.52-0.67	0.66	0.58-0.73
VRS-ISS	0.62	0.54-0.68	0.64	0.56-0.71

VAS, visual analogue scale; NRS, numeric rating scale; VRS, verbal rating scale; ISS, itch severity scale

Table 3. Retest reliability, mean difference in the scores between the initial assessment and follow-up (3 hours after the initial assessment), and intraclass correlation coefficient

Itch intensity scale	Wilcoxon signed-rank test			Intraclass correlation coefficient	
	Mean difference between the first assessment and second assessment (3 hours later)	95% confidence interval	P value	Coefficient	95% confidence interval
VAS [*]	0.52	0.36-0.69	< 0.001	0.77	0.70-0.83
NRS [†]	0.50	0.34-0.67	< 0.001	0.77	0.70-0.83
VRS [‡]	0.23	0.16-0.30	< 0.001	0.75	0.66-0.81
ISS	0.24	0.06-0.43	0.01	0.89	0.86-0.91

VAS, visual analogue scale; NRS, numeric rating scale; VRS, verbal rating scale; ISS, itch severity scale

^{*}The actual average score (0-10): 5.48 ($\pm$ 2.31) at the initial visit and 4.96 ($\pm$ 2.51) at follow-up

[†]The actual average score (0-10): 5.61 ($\pm$ 2.26) at the initial visit and 5.09 ($\pm$ 2.45) at follow-up

[‡]The actual average score (0-4): 2.14 ($\pm$ 0.94) at the initial visit and 1.91 ($\pm$ 1.03) at follow-up

340 **Table 4.** Spearman's coefficients between the ItchyQoL and other itch intensity scales

	Correlation	Spearman's correlation coefficient	95% confidence interval
Initial	ItchyQoL-VAS	0.45	0.36-0.52
	ItchyQoL-NRS	0.49	0.41-0.56
	ItchyQoL-VRS	0.47	0.39-0.54
	ItchyQoL-ISS	0.73	0.67-0.78
Follow-up	ItchyQoL-VAS	0.46	0.37-0.54
	ItchyQoL-NRS	0.48	0.39-0.56
	ItchyQoL-VRS	0.45	0.36-0.54
	ItchyQoL-ISS	0.70	0.63-0.76

341 *ItchyQoL*, itch-related quality of life; *VAS*, visual analogue scale; *NRS*, numeric rating scale;

342 *VRS*, verbal rating scale; *ISS*, itch severity scale