## Tailoring the Cut-off Values of the Visual Analogue Scale and Numeric Rating Scale in Itch Assessment

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Itch is a common symptom in many dermatological patients, but also in various systemic, neurological and psychiatric conditions. However, due to its subjective nature, an objective measurement of itch severity represents a significant challenge both in routine daily practice and in clinical trials (1). Several different instruments and methods have been used in itch studies in the past; however, none can currently be considered as a gold standard. Unidimensional itch intensity scales, such as the visual analogue scale (VAS), the numeric rating scale (NRS) or the verbal rating scale (VRS) are the most widely used due to their simplicity and rapidity (2, 3). Recently published data have also suggested that, aside from some limitations, these instruments provide valid and reliable values of itch evaluation (2-8). They showed good convergent and content validity and good test-retest reproducibility as well as responsiveness to change in itch assessment (2-8).

Briefly, the VAS is a 10-cm long line on which patients mark their pruritus intensity on a scale from "no itch" (0 points) to "worst imaginable itch" (10 points) (9). The NRS is similar to the VAS method but assess pruritus intensity as a number from 0 to 10 (1). In turn, the VRS is coded with graduated adjectives (usually ranging from "no itch" to "severe" or "very severe itch") (1). In 2012 we suggested a provisional categorization of VAS scores (3), supported by the results of Kido-Nakahara et al. (5). Here, we have provided further data on VAS and NRS categorization, based on a large, population-based study performed within the special interest group "Scoring Itch in Clinical Trials" of the International Forum for the Study of Itch (IFSI).

# **MATERIALS AND METHODS**

Data for 1,666 patients with various chronic itchy conditions were extracted from a local, prospectively collecting database (10). In detail, basic socio-demographic data, clinical data, and first- and follow-up visit itch intensity ratings (VAS, NRS and VRS) were assessed. The patients performed 5,620 assessments of pruritus intensity (up to 9 assessments per patient). Detailed characteristics of participating subjects are shown in Table SI<sup>1</sup>.

Determination of the VAS and NRS categories was performed as described previously (3). The  $\kappa$  coefficient of agreement was calculated for VRS and various sets of bands of the VAS and NRS scores. The following assumptions regarding  $\kappa$  coefficient were made: <0 no agreement, 0–0.2 slight, 0.21–0.4 fair, 0.41–0.6 moderate, 0.61–0.8 substantial, and 0.81–1 almost perfect agreement. In addition, the Spearman's rank correlation coefficients between the VRS and individual sets of bands of the VAS and NRS were determined.

### RESULTS

All participants assessed their pruritus with VRS at all time-points. There were 5 (0.1%) missing values in the NRS scoring and 79 (1.4%) in the VAS scoring. According to the VRS, at 466 (8.3%) assessments patients reported no itch during the day of examination, at 2,276 (40.5%) assessments patients reported mild itch, at 2,239 (39.8%) assessments patients reported from moderate itch, and at the remaining 639 (11.4%) assessments from severe/very severe itch. Itch intensity was scored slightly, albeit significantly higher with the NRS (mean:  $4.7 \pm 2.8$ points) than with the VAS (mean:  $4.4 \pm 3.1$  points) (paired Student's *t*-test: p < 0.001). Highly significant correlations were observed between each of the scales used for itch assessment (VRS and VAS  $\rho = 0.83$ , p < 0.001; VRS and NRS:  $\rho = 0.85$ , p < 0.001; VAS and NRS:  $\rho = 0.91$ , p < 0.001).

Statistical analysis (calculated  $\kappa$  coefficient of agreement and correlation coefficients) found that the cut-offs for 3-7-9 provided both high correlation coefficients [VAS:  $\kappa$ =0.692 (95% CI: 0.678–0.706),  $\rho$ =0.803; NRS:  $\kappa$ =0.649 (95% CI: 0.634–0.664),  $\rho$ =0.794] and reliable mean values (mild pruritus, mean VAS/NRS: 1.4±0.7/1.6±0.5 points; moderate pruritus: 4.7±1.1/4.3±1.1 points; severe pruritus: 7.8±0.6/7.5±0.5 points; very severe pruritus: 9.6±0.4/9.5±0.5) in the investigated collective. Good correlation coefficients of the cut offs of 4-6-9 and 4-7-9 were also found (Table SII<sup>1</sup>).

### DISCUSSION

A robust development of new anti-pruritic treatment strategies are, at least partly, limited by difficulties in the assessment of their effectiveness. In this study we

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aimed to investigate in more detail the recommendations regarding the cut-offs of VAS and NRS (2, 3). Some years ago we proposed a set of cut-off values of VAS, in order to distinguish between mild, moderate, severe, and very severe itch on the basis of analysis of a small collective (3). Since then another research group has performed a similar study on a larger population with different ethnicity to validate proposed cut-off values for VAS (5), showing convergent results with our data, indicating that proposed cut-offs may also be used for the NRS. Our current analysis included data for 5,620 itch assessments obtained from 1,666 patients with chronic pruritus, including VAS and NRS assessments during their first and follow-up visits to our centre. We found the following cut-off values of 3-7-9, 4-6-9 and 4-7-9 to show the highest correlation coefficients for VAS and NRS with VRS. A similar distribution was observed by Kido-Nakahara et al. (5) These cut-offs appear to be equivalent, without a clear argument based on statistics or clinics for or against one of the bands. Based on the previous recommendations, and the results of previous studies and international consensus discussions within the Special Interest Group of IFSI, we recommend that the cut-off values for both the VAS and the NRS should be 3-7-9 (i.e. >0—<3 points represents mild pruritus,  $\geq$ 3–7 points moderate pruritus,  $\geq$ 7–9 points severe pruritus, and  $\geq 9$  points severe pruritus). We decided to promote a conservative approach, considering scoring  $\geq$  3 and <4 as moderate pruritus, as in our opinion such categorization is more patient-oriented and might help in taking a decision on more intensive antipruritic treatment. However, there is a need in the near future to discuss proposed cut-offs with patients.

According to the consensus papers of a European network of experts (PruNet) (10, 11) questionnaires on pruritus intensity and quality of life are of primary importance in itch assessments, and the VAS is the most important tool, followed by the NRS and VRS, in evaluation of itch intensity. A recent study by Pedersen et al. (8) on psoriasis itch, based on 2 randomized trials including a total of 889 subjects, confirmed our observations by using Psoriasis Itch VAS. In addition, longitudinal measurement properties, including test–retest reliability and sensitivity to change, further confirmed the measurement integrity of the Psoriasis Itch VAS (8, 12).

This study has some limitations. First, for some patients we have analysed multiple itch assessments at various time-points (maximum 9). This might influence our results, albeit exclusion of repeated measurements did not change the results markedly, as the number of single assessments remained very high. Secondly, it is possible that our proposal for cut-offs of pruritus intensities might be slightly different in different populations (age and sex differences) and pruritus subtypes (e.g. chronic vs. acute itch, dermatological vs. systemic itch, etc.) (13). However, our aim was to unify pruritus assessment regarding its intensity; therefore, we did not separate patients. We believe that having a single set of cut-offs will be more feasible for use in studies and daily clinical practice than using different sets for each pruritus subtype.

In conclusion, this large, population-based study provides further data on VAS and NRS categorization, confirming previous observations that the most suitable categorization for both scales is 3-7-9 points.

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