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CLINICAL REPORT

German Version of ItchyQoL: Validation and Initial Clinical Findings

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Pruritus is a major symptom of numerous skin and systemic diseases and causes a substantial burden on patients' quality of life (QoL). We report here the validation of the German version (GerItchyQoL) of the first pruritus-specific QoL instrument ItchyQoL. GerItchyQoL was created from the original version following standard protocols. It was completed by 308 patients with chronic pruritus of different origin and tested for validity, reliability and responsiveness. Factor analysis of GerItchyQoL revealed the 4 domains symptoms, functioning, feelings, and self-perception. Reliability was demonstrated by good internal consistency of all domains. We confirmed convergent validity by comparing the instrument with itch severity, as measured with a visual analogue scale (VAS 0–10), and with the Short-Form-12 (SF-12), a widely used generic health-related QoL instrument. Concurrent validity was shown by the ability to discriminate between patient groups of different itch severity. Changes in GerItchyQoL scores correlated with changes in itch severity (VAS), suggesting responsiveness of the German tool. This study provides preliminary evidence of validity, reliability and responsiveness of GerItchyQoL and also shows a high impact of chronic pruritus on QoL. Further translations of ItchyQoL into additional languages will enable large-scale international, multilingual trials. ***Key words: pruritus; itch; quality of life; itchyQoL.***

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Chronic pruritus or itch, defined by the International Forum for the Study of Itch (IFSI) as lasting for at least 6 weeks (1), is commonly associated with inflammatory skin conditions, metabolic disorders, liver, renal or haematological diseases (2). Although there are only a few studies investigating the prevalence of chronic pruritus, 2 recent cross-sectional studies performed in a German general population and a working population reported a point prevalence of 13.5–16.8% (3, 4).

Chronic pruritus can have a profound impact on quality of life (QoL) (5, 6). Health-related QoL (HRQoL) refers to how the individual's physical, psychological and social wellbeing may be affected by a disease, disability or disorder (7, 8). A reduced HRQoL is observed in many conditions associated with chronic pruritus, in which measures of mood, social relations and sleep correlate well with itch severity (9–11). Furthermore, in chronic skin conditions, such as atopic eczema, pruritus affects all domains (physical, psychological and social aspects) of HR-QoL (12). Also, pruritus is a main driver of HR-QoL impairment, as demonstrated by highest levels of disease-specific QoL impairment relating to pruritus in chronic urticaria (9, 12–14).

Itch severity is difficult to measure, as pruritus appears to include at least 2 dimensions, a sensory and an affective component (15). Nevertheless, the use of a visual analogue scale (VAS) remains the most common tool to determine itch severity (16, 17). To better quantify itch severity a number of additional instruments, including the Eppendorf Itch Questionnaire, the Itch Severity Scale, which also contains HR-QoL aspects, and the 5D Itch Scale have been developed and validated during recent years (18–20). However, QoL assessment provides important additional information on the impact of the condition on patients and on the efficacy and safety of treatment. Furthermore, QoL measures in routine care can help physicians to optimize the treatment of patients with pruritus.

Generic HRQoL instruments, such as the Short-Form-36 (SF-36) (21) and its shorter form SF-12 (22), are widely used to compare HRQoL across different diseases. More recently, dermatology- and disease-specific QoL instruments have been developed. Dermatology-specific tools, e.g. the Dermatology Life Quality Index (DLQI), allow for comparing QoL across different dermatological diseases (23). Disease-specific instruments, such as the Chronic Urticaria Quality-of-life Questionnaire (CU-Q_2oL) (13) are used to identify the intensity as well as the disease-specific pattern of QoL impairment. The concurrent use of the CU-Q_2oL and the DLQI has shown that a disease-specific questionnaire includes items and dimensions more specific and relevant and therefore addresses the patients' bur-

den and needs much better than a non-disease specific instrument (14). These findings are in line with the recommendations to prefer disease-specific tools over generic tools when assessing HRQoL in clinical trials on allergy (10).

In 2008, the first pruritus-specific QoL instrument ItchyQoL was developed for English-speaking countries (24). This questionnaire can be applied to patients with pruritus, independent of the underlying cause of their pruritus. ItchyQoL is a 3-dimensional instrument, which contains the domains symptoms, functioning and emotions. However, for use in non-English speaking countries a simple translation of the questionnaire is not sufficient. Questionnaires need to be culturally adapted, re-translated and then validated in the new language and culture (25). The aim of this study was to create and validate an ItchyQoL version for German-speaking countries.

METHODS

Translation and cultural adaptation of the questionnaire

The German version of ItchyQoL, GerItchyQoL, was generated following standard protocols (10). Briefly, the original questionnaire was first translated independently by 2 native German-speaking healthcare professionals and reviewed by several medical experts. A preliminary consensus German version was then back-translated into English by a native English-speaking local professional translator. This version and the original were compared for discrepancies, and a final consensus version was created together with the authors of the original ItchyQoL (24). It should be noted that all questionnaire items were easily translated, with the exception of the English term "self-conscious", which took some effort to find the right German expressions, "verlegen" or "peinlich". Afterwards, the questionnaire was successfully tested for clarity and comprehension in 10 adult patients without medical education. Following joint approval of the final German ItchyQoL version the questionnaire was used without further modifications in patients with pruritus (Table SI; available from: http://www.medicaljournals.se/acta/content/?doi=10.2340/00015555-1544).

Patients

GerItchyQoL was administered to 308 consecutive German speaking patients with chronic pruritus (urticaria (88), atopic eczema (58), psoriasis (37), prurigo (31), kidney disease (29), liver disease (20), neoplasm (17), other or unknown disease (28)) treated between February and November 2009 at the Departments of Dermatology and Allergy, Hepatology, Nephrology and Hematology, Charité – Universitätsmedizin Berlin, Germany. Underlying diseases were assessed by patient inquiry and, if available, by patient records. The GerItchyQoL questionnaire was completed during the initial hospital appointment and patients were asked to complete it a second time either at the hospital or at home 8–12 weeks later. From the second survey 196 completed questionnaires were received. As there is no definite rule for sample size calculation, the actual sample size of our study was guided by the sample size of the original ItchyQoL population and other validation studies of HRQoL questionnaires (14, 24).

The study was performed in accordance with national, state and institutional rules and regulations and the Declaration of Helsinki. All patients gave written informed consent. In case of underage patients ($n=4$) their parents gave written informed consent.

Calculation of GerItchyQoL scores

The GerItchyQoL questionnaire consists of 22 items, which are scored on a 5-point scale ranging from 1 (never) to 5 (all the time). In accordance with the original ItchyQoL version the mean scores of the patients' responses to all 22 items represent the GerItchyQoL total score. We assumed that the 22 items can be assigned to certain domains. Based on this hypothesis GerItchyQoL subscores were calculated by computing the mean scores of the responses to the items in a given domain. In case of missing data of individual items, for scale determination the mean value of available items was used.

Other assessments

Itch severity was assessed using a 10-cm unmarked VAS. In addition, patients completed the German version of the SF-12, a validated and well-established generic HRQoL questionnaire (22). Physical and mental health domains of the SF-12, a shorter version of the SF-36, were computed to give a maximum total score for each domain of 100, indicative of the highest level of health.

Test validation

The primary scientific question was to test whether the factor structure of the original American version of the ItchyQoL could be confirmed in a German population. In addition, we examined several types of validity (face, convergent, concurrent) for the German instrument.

Identification of GerItchyQoL scales. Confirmatory factor analysis (CFA) was performed to test for construct validity. In CFA the observed correlation structure among domains is compared with the one predicted by the model to verify its factor structure. Mathematically, this leads to a specific type of χ^2 test with degrees of freedom (df) determined by the number of pair-wise correlations and the number of estimated parameters. To assess fit quality statistically, discrepancy χ^2 values, their df and the comparative fit index (CFI) are presented. The CFI compares the model under investigation to the model assuming independent domains. It ranges between 0 and 1, and values >0.90 or 0.95 indicate an acceptable or satisfactory fit (26). In addition to the CFI, further goodness of fit measures, namely the root mean square error of approximation (RMSEA) and the standard root mean square residual (SRMR) were applied. As a rule of thumb an RMSEA of 0.05 indicates good fit and an RMSEA of 0.08 mediocre fit. The cut-off for the SRMR averages <0.11. The CFA was performed using the software AMOS release 20 (IBM, United States).

Face validity. To confirm face validity the global meaning of GerItchyQoL domains, as well as the belonging of individual items to appropriate domains, were assessed.

Internal consistency. We tested for GerItchyQoL's internal consistency by calculating Cronbach's α coefficient for each of the identified domains. Cronbach's α coefficient may theoretically range from 0–1 with values ranging from 0.70–0.80 indicating acceptable internal consistency, 0.80–0.90 excellent internal consistency and >0.90 excessive consistency, implying item redundancy.

Convergent validity. We hypothesized that GerItchyQoL scores were related to itch severity scores. In addition, we assumed that GerItchyQoL scores correlated, at least to a certain extent, with generic HR-QoL instruments. Thus, we performed a correlation analysis of GerItchyQoL with itch severity (VAS 0–10) and SF-12 domains (Spearman's correlation).

Concurrent validity. Concurrent validity is determined by the degree to which an instrument can distinguish between different groups known to vary on the variables being measured. In order to test whether GerItchyQoL can discriminate between different degrees of pruritus-induced QoL impairment, patients were assigned to 3 groups according to their itch severity (VAS 0–3; 4–6; 7–10). Differences between pruritus-induced QoL impairment for the different groups according to itch severity were assessed by analysis of variance (ANOVA).

Responsiveness. In order to verify that GerItchyQoL responds to alterations in itch severity, changes in GerItchyQoL scores from the first survey to the second survey were correlated with changes in itch severity scores (VAS). During the time between the first and second surveys the majority of patients received symptomatic anti-pruritic treatment, such as topical agents, non-sedating antihistamines, anti-inflammatory or immunosuppressive drugs, which were newly initiated, continued or changed. Response to treatment was not assessed systematically, but we expected improvement in itch severity scores as well as the condition to be unchanged or even worsened.

Multiple linear regression analyses. Linear regression was used to assess the strength of the relationship between GerItchyQoL and a number of independent variables, including underlying disease, gender and age. Itch severity (VAS) was not included in the regression analysis as our interest was to identify predictors that are not directly related to the disease.

Statistical analysis

Statistical analyses were performed with SPSS (IBM SPSS Statistics Version 19) and AMOS release 20. Statistical significance was considered by $p \leq 0.05$ (2-sided).

RESULTS

Patient characteristics

There were 308 subjects included in this study, 198 females and 110 males (ratio 1.8:1) with a mean ± SD age of 51.8 ± 17.3 years (range 15–89 years) (Fig. S1; available from: http://www.medicaljournals.se/acta/content/?doi=10.2340/00015555-1544). In women, the ages were spread evenly, whereas in men more than 80% were over 40 years old. The mean ± SD itch severity, as measured by VAS, was 5.0 ± 2.8 (range 0–10) and the mean ± SD duration of pruritus was 8.3 ± 11.7 years (range 1 week to 60 years). While the majority of patients had pruritus for less than 5 years (58%) almost one-third (31%) had had the condition for more than 10 years. Severity and duration of pruritus were not correlated (Spearman $r = 0.08$, $p = 0.34$), and itch severity was normally distributed among different diagnostic groups. The mean ± SD itch severity scores ranged from 4.78 ± 2.27 for neoplasm to 6.03 ± 2.76 for liver disease. The assessment of the general HR-QoL revealed mean ± SD SF-12 scores of 45.2 ± 7.8 (range 28.7–70.5) for the mental domain and 41.6 ± 6.3 (range 20.0–63.6) for the physical domain.

Identification and validation of GerItchyQoL domains

Assuming an underlying 3-factor structure, as published in the original ItchyQoL, the CFA of our data demonstrated a χ^2 of 684 (df=206) with a CFI of 0.811, which did not meet the criteria of a satisfactory fit (CFI > 0.9). To obtain a valid factor structure with a better fit we constructed 2 4-factor models with 3 and 12 correlations, respectively. The less complex model included correlations of item pairs 1–4, 7–13 and 15–19. It revealed a χ^2 of 444 (df = 198) with a satisfactory CFI of 0.902, a mediocre RSMEA of 0.076 and an acceptable SRMR of 0.106 (< 0.11). The use of a 4-factor model with 12 additional correlations included correlations of item pairs 1–3, 1–4, 3–4, 2–3, 14–16, 14–18, 16–18, 7–13, 11–13, 12–13, 15–19 and 15–22. It indicated a χ^2 of 380 (df=191) and was preferred as it provided the best CFI (0.925) (Table I). Additional goodness-of-fit measures for this model revealed acceptable results, with an RMSEA of 0.068 and an SRMR of 0.095. It has to be noted that additional correlations were only accepted between items belonging to a single factor.

For comparison, we also created a 1-factor model, which produced a non-acceptable CFI of 0.745 and a 5-factor model with a satisfactory CFI of 0.908. The 4-factor model was not only chosen for its goodness-of-fit measures but was primarily selected for face-validity considerations. Its use allowed for assignment of all 22 items to 4 appropriate domains of which 2 (symptoms and functioning) were consistent with the corresponding factors of the original ItchyQoL validation study (24). The German 4-factor model includes the domains symptoms, functioning, feelings, and self-perception (Table I).

Table I. *Classification, factor loadings and internal consistency of the GerItchyQoL domains*

Subscales and items	Factor loadings	Cronbach's α correlation coefficient
Symptoms		0.757
1. Bleeding	0.552	
2. Pain	0.697	
3. Burning	0.720	
4. Scars	0.538	
5. Scratching	0.547	
6. Season	0.435	
Functioning		0.846
7. Money	0.547	
8. Work	0.768	
9. Interaction	0.852	
10. Sleep	0.594	
11. Concentration	0.755	
12. Clothes	0.657	
13. Body care	0.478	
Feelings		0.863
14. Frustrated	0.794	
16. Loss of control	0.771	
17. Angry	0.828	
18. Depressed	0.853	
20. Never ending	0.710	
Self-perception		0.859
15. Self-esteem	0.795	
19. Image	0.747	
21. Embarrassed	0.833	
22. Personality	0.770	

Internal consistency reliability

The 3 GerItchyQoL domains functioning, feelings, and self-perception all demonstrated excellent internal consistency (Cronbach's α coefficients 0.846, 0.863 and 0.859, respectively) while the symptoms domain showed acceptable consistency (Cronbach's α coefficient 0.757) (Table I).

Correlation analyses with itch severity and SF-12

Evidence for convergent validity was obtained by observing a significant correlation between GerItchyQoL total scores and subscores with itch severity (VAS) (self-perception: $r = 0.28$, total and all other subscores: r between 0.39 and 0.44, all $p \leq 0.001$) (Fig. 1). In addition, GerItchyQoL total scores ($r = -0.35$, $p \leq 0.001$) and subscores for symptoms and self-perception ($r = -0.27$ and $r = -0.33$, both $p \leq 0.001$) correlated with the SF-12 mental health domain. In contrast, GerItchyQoL total scores and subscores did not correlate with the physical health domain of the SF-12.

Concurrent validity

The assignment of patients to 3 groups according to their itch severity demonstrated significant differences between GerItchyQoL scores (Table II). Patients with mild pruritus (VAS 0–3) showed statistically significant lower GerItchyQoL total and subscores compared to those with moderate pruritus (VAS 4–7) and severe pruritus (VAS 8–10) ($p < 0.001$). GerItchyQoL scores rose with an increase in itch severity.

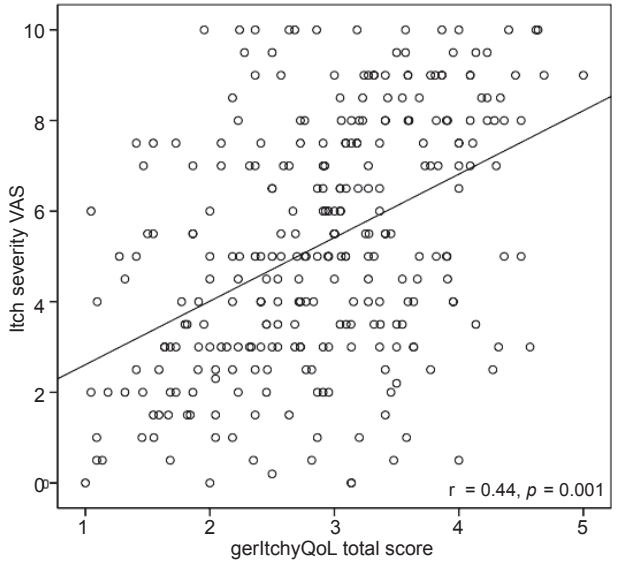

Fig. 1. The scatter plot shows the Spearman's correlation ($r = 0.44$, $p = 0.001$) between GerItchyQoL total scores and itch severity (visual analogue scale; VAS). Each dot represents one subject.

Responsiveness

Changes in GerItchyQoL scores showed a significant Spearman's correlation with changes in itch severity (VAS) scores (total score, symptoms, functioning and feelings scores $r = 0.35$–0.46, all $p \leq 0.01$; self-perception score $r = 0.15$, $p \leq 0.05$) (Fig. S2; available from: http://www.medicaljournals.se/acta/content/?doi=10.2340/00015555-1544), suggesting responsiveness of the instrument. A formal drop-out analysis revealed no differences in terms of age, gender, diagnostic groups or GerItchyQoL scores between drop-outs ($n = 112$) and patients with follow-up data ($n = 196$) (Table III).

Quality of life scores in the total sample and in patient subgroups

Mean ± SD GerItchyQoL total scores in the complete study sample was 2.89 ± 0.86. Mean ± SD GerItchyQoL subscores lay between 2.38 ± 1.14 (feelings) and 3.11 ± 1.07 (self-perception) (Table II). The mean single item scores ranged from 2.12 ± 1.35 (item 4) to 3.97 ± 1.01 (item 5). The mean scores of the original ItchyQoL showed similar levels (3.01 ± 1.31 for the total score) and ranged from 2.13 ± 1.28 (QoL 26) to 4.08 ± 0.80 (QoL 5) for single-item scores.

A comparison of GerItchyQoL scores of patient subgroups, as defined by the underlying cause of pruritus, could not identify significant differences between diagnostic groups in the pair-wise comparisons adjusted for multiple testing ($p > 0.07$ for each pair of groups) even though the overall analysis of variance (ANOVA) was significant. Without adjustment there were 2 diagnostic groups (atopic eczema, prurigo) with significantly stronger pruritus-specific QoL impairment (superior GerItchyQoL total scores) compared with 3 other groups (urticaria, kidney disease, and neoplasm, $p < 0.05$ for each comparison). Intermediate results were found for the groups liver disease, psoriasis, and other/unknown diseases. We also noted that in all patient subgroups the GerItchyQoL domains symptoms, functioning and feelings were more severely affected, as demonstrated by consistently higher scores compared with the self-perception domain.

Factors predicting GerItchyQoL scores

Patients with atopic eczema or prurigo exhibited significantly higher scores on the GerItchyQoL total score, the symptoms domain, and the functioning domain, but not the self-perception and feelings domains compared with other diagnostic groups ($p \leq 0.001$, no correction for multiple testing). Also, the female gender predicted significantly higher GerItchyQoL total scores ($p = 0.003$), functioning subscores ($p = 0.02$), self-perception subscores ($p = 0.013$), and feelings subscores ($p = 0.001$) (Table II). The mean differences

Table II. *GerItchyQoL: total and subscores in relation to itch severity (visual analogue scale; VAS) and for the whole group with multiple linear regression analysis*

	Total score	Symptoms	Functioning	Feelings	Self-perception
VAS[a], Mean ± standard deviation (SD)					
VAS 1–3	2.49 ± 0.83	2.52 ± 0.85	2.56 ± 0.98	2.67 ± 1.00	2.04 ± 1.10
VAS 4–6	2.84 ± 071	2.90 ± 0.79	2.98 ± 0.86	2.99 ± 0.95	2.32 ± 1.07
VAS 7–10	3.34 ± 0.80	3.34 ± 0.81	3.44 ± 0.96	3.62 ± 1.01	2.78 ± 1.13
Total					
Mean ± SD	2.89 ± 0.86	2.92 ± 0.88	3.00 ± 1.00	3.11 ± 1.07	2.38 ± 1.14
Median	2.94	2.83	3.00	3.20	2.25
Min–max	1–5	1–5	1–5	1–5	1–5
1st–2nd quartile	2.31–3.50	2.33–3.50	2.29–3.72	2.40–4.00	1.25–3.25
Multiple linear regression analysis					
Adjusted R^2	0.085	0.107	0.097	0.039	0.024
Gender					
Beta weight	0.17	–	0.13	0.20	0.15
p-value	0.003	0.108	0.020	0.001	0.013

[a]$p < 0.001$ within the subgroups.

Note: each analysis was adjusted for diagnostic group. Age was not a significant predictor and therefore not shown. Gender was not significant for the symptoms subscore ($p = 0.108$), thus no beta weight was obtained.

per item ranged between 0.28 (functioning) and 0.46 (feelings domain). The patients' age, however, did not significantly predict any GerItchyQoL scores.

DISCUSSION

Chronic pruritus severely affects patients' QoL (5, 6). Therefore, validated QoL questionnaires, such as ItchyQoL, are needed to better characterize the impact of pruritus on QoL and to assess the efficacy of treatment. Our results demonstrate the validity, reliability and responsiveness of the German version of ItchyQoL in patients with chronic pruritus. Furthermore, we provide first data on QoL impairment in a German population of patients with pruritus.

GerItchyQoL scales

CFA did not support the hypothesized 3-factor model. Instead, by means of modifying individual model specifications, a 4-factor model was found to fit the data better. Based on the 4-factor model the 4 GerItchyQoL domains symptoms, functioning, feelings, and self-perception were defined. The domain symptoms groups all items related to looks and sensory perceptions associated with pruritus. Functioning combines limitations in everyday life including buying decisions (e.g. restrictions for cosmetics, clothes). Feelings represent the mental status while self-perception includes an impaired self-image affecting social relationships. All GerItchyQoL items could be definitely placed in respective domains with none in more than one domain, thus verifying good validity of the instrument. Construct validity was confirmed by showing a satisfactory CFI and acceptable additional goodness of fit measures (RMSEA and SRMR) for the 4 hypothesized GerItchyQoL domains.

The presence of 4 domains in the GerItchyQoL contrasts with the original ItchyQoL (24) which has only 3 domains (symptoms, functioning, and emotions). As the factor analyses for the original and the translated

Table III. *Patient characteristics including study drop-outs*

	Total (%) *n* = 308	Drop-outs (%) *n* = 112	Remained in study (%) *n* = 196	*p*-value
Age, years, mean ± standard deviation (SD)	51.8 ± 17.3	50.7 ± 19.7	52.4 ± 15.8	0.43
Male, *n* (%)	110 (35.7)	44 (39.3)	66 (33.7)	0.32
Female, *n* (%)	198 (64.3)	68 (60.7)	130 (66.3)	0.32
Atopic eczema, *n* (%)	58 (19.1)	24 (22.4)	34 (17.3)	0.76
Psoriasis, *n* (%)	37 (12.2)	10 (9.3)	27 (13.8)	0.76
Urticaria, *n* (%)	88 (29.0)	29 (27.1)	59 (30.1)	0.76
Prurigo, *n* (%)	29 (9.6)	8 (7.5)	21 (10.7)	0.76
Liver disease, *n* (%)	20 (6.6)	7 (6.5)	13 (6.6)	0.76
Kidney disease, *n* (%)	29 (9.6)	11 (10.3)	18 (9.2)	0.76
Neoplasm, *n* (%)	17 (5.6)	7 (6.5)	10 (5.1)	0.76
Other/unknown, *n* (%)	25 (8.3)	11 (10.3)	14 (7.1)	0.76
Total GerItchyQoLScore, mean ± SD	2.89 ± 0.86	2.82 ± 0.94	2.92 ± 0.80	0.36
Symptoms, mean ± SD	2.92 ± 0.88	2.89 ± 0.96	2.93 ± 0.83	0.69
Functioning, mean ± SD	3.00 ± 1.00	2.90 ± 1.07	3.05 ± 0.95	0.20
Feelings, mean ± SD	3.11 ± 1.07	3.09 ± 1.16	3.12 ± 1.02	0.80
Self-perception, mean ± SD	2.38 ± 1.14	2.25 ± 1.14	2.45 ± 1.14	0.16

questionnaire were conducted in 2 different patient populations, some differences were to be expected. To confirm the 4-factor model it would be necessary to obtain a new data set and test whether the data represents the 4-factor structure. However, the use of a 4-factor model in the German version will only slightly affect the comparability of results to those obtained by using the original 3-factor model. The domains symptoms and functioning are equal in both versions, and only the original emotions domain is split in the German model. Also, the total score can be used in both populations.

General health-related QoL impairment

The low SF-12 scores found in this study demonstrate pronounced QoL impairment in the patient population investigated. The mean ± SD scores in our sample (45.2 ± 7.8 for the mental domain and 41.6 ± 6.3 for the physical domain) were lower than the mean values of 52.3 for mental and 49.6 for physical domains obtained in a sample of non-diseased German people (22), thus indicating a poorer QoL in our study sample as in the general German population.

Sensitivity to changes in itch severity

Itch severity often underlies diurnal or seasonal variations and can be exacerbated by certain trigger factors or modified by treatment. It is therefore important that a pruritus-specific QoL instrument can detect these changes. GerItchyQoL was shown to discriminate well between patient groups of different itch severity. Also, our instrument appeared to be able to detct QoL changes following changes in itch severity.

Clinical findings in German pruritus patients

The use of GerItchyQoL provides a better understanding on what drives QoL impairment in pruritus patients. Notably, female gender predicts higher GerItchyQoL total scores and domain scores (functioning, feelings, and self-perception) compared with the male gender. This is in line with previous reports from the original ItchyQoL population (24) and matches the findings in patients with chronic urticaria (14). In particular, the feelings scores were much higher in women compared with men, suggesting that women are more prone to introspection and more concerned about their image and how they present to others. In addition, the underlying diseases atopic eczema and prurigo were found to predict higher GerItchyQoL symptoms scores. The higher scores may account for the greater impairment in looks found in these dermatological conditions compared with the other diseases. Also, Desai et al. (24) observed higher symptoms scores in eczema compared with idiopathic itching. The higher functioning scores found in atopic eczema and prurigo could reflect a greater impairment associated with the need to treat their skin disease.

A further interesting observation in our patient population was that the self-perception domain showed distinctly lower scores in all diagnostic groups compared with the other scales. This may indicate that QoL impairment in patients with pruritus only sparsely affects social relationships with others, but this has to be re-evaluated in larger study samples.

Limitations

In some aspects the data presented here show limitations of our study. First, the heterogeneous study sample in terms of different diagnostic groups has to be taken into account. For example, pruritus in systemic diseases, such as neoplasm, liver or kidney disease, is often accompanied by greater general health impairment compared with dermatological diseases. We cannot rule out that these differences affect the individual perception of pruritus-specific QoL. On the other hand, there are some GerItchyQoL items, such as "bleeding" or "scars", which apply only to some dermatological conditions but not pruritus without any skin findings. To address the issue of the heterogeneous study sample, it will be important to assess differential item functioning in future studies. Since the instrument is intended for use in a variety of conditions associated with pruritus, differential item functioning may help to evaluate whether items in different conditions show measurement invariance.

It should also be noted that the sample of patients included in this study were all seen at a University Hospital and have mostly had chronic pruritus for years. This may indicate a selection bias for severe and therapy-refractory pruritus in our study, which was already noted in the original ItchyQoL publication.

In addition, it must be acknowledged that reproducibility (test-retest reliability) was not examined, as different interventions ranging from no treatment at all to diverse pruritus-specific therapies took place between the first and the follow-up survey 8–12 weeks later. Further validation of the instrument should include such an examination.

Conclusion

Assessment of QoL should always be an important outcome measure in the assessment of symptom-relieving therapies for conditions such as chronic pruritus. Objective measurements of pruritus are impossible, and since chronic pruritus in itself does not represent a threat to the patients' physical health or life, outcome measures, such as parameters of morbidity or survival, are not applicable. In contrast, the ItchyQoL, as a patient-reported outcome instrument, represents a more appropriate and reliable way of assessing one of the most important aspects of chronic pruritus, the impairment in QoL. As demonstrated by the responsiveness data for GerItchyQoL, the questionnaire is also sensitive for pruritus changes and, therefore, the

efficacy of treatment. In this regard, ItchyQoL can serve as an addition or alternative to the recently developed and validated patient benefit index for pruritus (PBI-P) which was created as a patient-reported outcomes measure in response to pruritus treatment (27).

The ItchyQoL created by Desai et al. (24) is an essential tool for research on itch and its therapy. The German version, GerItchyQoL, which contains several subtle changes to fit to the German speaking population, has demonstrated validity in our study sample of patients with pruritus. Nevertheless, our findings should be confirmed in further independent patient samples.

Assessing the individual ItchyQoL total scores is a suitable method to determine the overall QoL impairment in patients with pruritus. However, if researchers are interested in examining the pattern of QoL impairment, calculating the subscale scores is a valid method to determine which of the domains are most affected. Ideally, the availability of GerItchyQoL will trigger research in the field of pruritus. We also hope that ItchyQoL will be translated into more languages, thus enabling larger scale international, multilingual trials.

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