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Translation and applicability of an Italian version of the Uremic Pruritus in Dialysis Patients (UP-Dial) questionnaire

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Abstract

Introduction: The Uremic Pruritus in Dialysis Patients (UP-DIAL)—14-item scale is a validated, multidimensional tool for assessing pruritus severity and clinical burden among patients with chronic kidney disease-associated pruritus (CKD-aP). While the scale has been developed in Thai and other non-Thai languages, an Italian version and cross-cultural adaptation have not been established for Italian-speaking CKD-aP populations.

Aims: This study aimed to translate and validate an Italian version of the UP-Dial—14-item questionnaire for use among hemodialysis (HD) patients.

Materials and Methods: Following international guidelines, a rigorous translation process was undertaken, including independent forward and backward translations to ensure linguistic and conceptual equivalence. The validation cohort comprised HD patients with CKD-aP from seven centers across Calabria, Italy. Patients and healthcare professionals reviewed the Italian version to evaluate usability, readability, and cultural adaptation. Internal consistency was assessed using Cronbach's alpha, and test-retest reliability was evaluated with the intra-class correlation coefficient (ICC) over a 7-day interval.

Results: Of 323 HD patients screened, 132 with CKD-aP were included. Both patients and professionals confirmed satisfactory face validity and adaptation. The Italian UP-DIAL—14-item demonstrated excellent internal consistency (Cronbach's α = 0.91; 95% CI: 0.89-0.93) and reproducibility (ICC = 0.92; 95% CI: 0.90-0.94).

Conclusions: The Italian version of the UP-DIAL—14-item is a valid, reliable, and reproducible instrument for assessing CKD-aP in HD patients. It is suitable as a patient-reported outcome measure for both clinical practice and research.

Keywords: Chronic kidney disease-associated pruritus (CKD-aP), Hemodialysis, UP-Dial, Patient-reported outcome measure, Psychometric properties

Introduction

Chronic kidney disease-associated pruritus (CKD-aP) is a debilitating and often underdiagnosed condition affecting 40-70% of patients undergoing maintenance hemodialysis (HD) or peritoneal dialysis (PD), with severe cases reported in approximately 20-30% of individuals (1). Characterized by persistent, generalized itching—commonly localized to the back, arms, and legs—UP significantly impairs quality of life, disrupts sleep, and negatively impacts mental health. Moreover, it has been associated with increased mortality and hospitalization rates (2).

The pathophysiology of UP is multifactorial, involving dysregulation of immune mediators (e.g., interleukin-31, histamine), imbalances in opioid receptor activity (μ-opioid overactivity and κ-opioid deficiency), hyperparathyroidism,

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and altered cutaneous innervation due to uremic toxin accumulation (2).

Appropriate assessment of the presence and severity of UP is mandatory for successful clinical management. The Visual Analogue Scale (VAS) (3) and validated tools like the 5-D Itch Scale (4) or the Itch Severity Scale (ISS) (5) are useful instruments for assessing symptom burden; however, these lack specificity for uremic etiology and may be influenced by cultural and linguistic differences in symptom perception (6).

The Uremic Pruritus in Dialysis Patients (UP-DIAL) questionnaire was recently developed to address these limitations by assessing pruritus intensity, distribution, sleep disturbances, and the psychosocial impact in this setting (7). Created and validated in English among patients undergoing renal replacement therapy, the UP-DIAL was recently adapted into Polish (30 HD patients) (8) and Chinese (9) (132 + 270 in Mainland China). Unfortunately, to date, these represent the only available language translations and validations of this instrument in non-English speaking populations.

In the present study, we aimed to evaluate—for the first time, the clinical applicability and validity of an Italian translation of the UP-DIAL questionnaire in a multicenter cohort of chronic HD patients. The findings confirmed the validity and reproducibility of this adaptation for evaluating and managing pruritus in HD patients, setting the stage for ample applicability in all Italian HD patients.

Materials and methods

The UP-Dial (Uraemic Pruritus in Dialysis Patients) scale was administered to HD patients with referred pruritus symptoms. UP-Dial scale is a multidimensional tool consisting of 14 items divided into three domains: signs and symptoms (7 items), psychosocial impact (4 items), and sleep disturbance (3 items). Each item is scored on a 0-4 scale, with a total score ranging from 0 to 56; scores ≤12 indicate mild, 13-21 moderate, and ≥22 severe pruritus. The scale shows good validity, correlating well with existing tools such as the NRS, 4IIQ, and ItchyQoL. This study followed internationally recognized guidelines for cross-cultural adaptation of self-reported instruments, including principles of good practice for translation and cultural adaptation and the World Health Organization (WHO) guidelines for translation of instruments. The process prioritized semantic, conceptual, idiomatic, and experiential equivalence between the original English questionnaire and the translated Italian version (10). The study was approved by the Local Ethics Committee, and it conforms to the provisions of the Declaration of Helsinki.

Translation Process

1. *Forward Translation*
   - Two independent bilingual translators (native Italian speakers fluent in English) translated the original English questionnaire into Italian.
   - Both translators were instructed to prioritize conceptual equivalence over literal translation to ensure cultural relevance. One translator had expertise in the questionnaire's subject matter, while the other had no prior exposure to the content to avoid bias.
2. *Synthesis of Translations*

   A reconciled Italian version was created by comparing the two forward translations. Discrepancies were resolved through discussion between the translators and the research team, ensuring clarity and consistency with the original intent.
3. *Back-Translation*
   - The reconciled Italian version was back-translated into English by a third translator, a fluent English and Italian speaker, blinded to the original questionnaire.
   - The back-translated English version was compared with the original to identify inconsistencies, ambiguities, or deviations in meaning.
4. *Pretesting and Cognitive Debriefing*
   - Participants completed the questionnaire and participated in cognitive interviews to elaborate on their interpretation of each item. Feedback focused on clarity, ambiguity, and cultural relevance.
   - Problematic items were revised iteratively based on participant input.

Validation Process: Reliability

Following the translation phase, a validation was conducted on patients on maintenance haemodialysis following these inclusion criteria: patients aged >18 years treated with haemodialysis (HD), longevity of dialysis treatment exceeding 3 months; while the exclusion criteria were represented by: active immunodeficiency virus infection/acquired immunodeficiency syndrome, recent hospitalization (within three months), psychiatric illnesses or other communication problems, ongoing neoplasm, primary skin disorder, other systemic diseases that could explain the itching. Participants were instructed to fill out the questionnaire twice, with a 7-day interval between administrations. This timeframe was selected to minimize the likelihood of respondents recalling prior answers while avoiding significant changes in pruritus severity or presentation. A researcher involved in adapting the Italian version of the UP-Dial instrument oversaw the process, monitoring completion times and ensuring protocol adherence.

Statistical analysis

All data analyses were performed using the SPSS package (version 24.0; IBM corporation), MedCalc Statistical Software (version 14.8.1; MedCalc Software bvba) and the GraphPad Prism package (version 8.4.2, GraphPad Software, San Diego, CA, USA). Data are shown as mean ± SD, median [IQ range] or frequency percentage, as appropriate. The internal consistency of the instrument was assessed using Cronbach's α coefficient, with a threshold of at least 0.70 indicating acceptable reliability and values above 0.90 signifying excellent internal consistency (11). Test-retest reliability was evaluated through the intraclass correlation coefficient (ICC), where results of ≥0.70 were considered indicative of adequate reproducibility (12). Additionally, responses to each question from the first and second completions were compared using the Wilcoxon test. The correlation between individual question responses

and the total score within a single completion was analysed using Spearman's correlation test.

Results

Forward and back translation process

The translators made some changes to adapt the medical environment in Italy, but, substantially, the translated questionnaire reflected the original English version. Since the face validity study revealed that participants had difficulty grasping the meaning of certain items due to the way they were expressed, certain modifications were made.

Patients' characteristics

From July 2024 to January 2025, we screened in different HD centres 323 patients (Hemodialysis Unit of Soverato, Catanzaro, Italy; Hemodialysis Unit of Cosenza, Italy; Nephrology and Hemodialysis Unit of "Pugliese-Ciaccio" Hospital, Catanzaro, Italy; Nephrology and Hemodialysis Unit of "San Giovanni di Dio" Hospital, Crotone, Italy). A total of 132 patients met our inclusion criteria: first, they manifested CKD-aP and completed the UP-Dial questionnaire. The group comprised 68 males and 64 females, with a mean age of 69 years, ranging from 26 to 96 years (69 (59-77) years). Participants' vintage on HD treatment was an average of 47,5 (26-87) months, spanning from 3 months to 271 months. Primary causes of end-stage renal disease included cardiovascular disease 23%, diabetes 16%, genetic diseases (including ADPKD) 14%, glomerulonephritis 10%, urological disease 7%, nephrolithiasis 4% and unknown origin 26%. One hundred four patients (57%) were undergoing conventional hemodialysis while 78 (43%) patients were undergoing hemodiafiltration (HDF). The Kt/v was 1.3 (1.20-1.54), and 65% of patients were taking at least one itching medication. Laboratory findings are summarized in **Table 1**.

TABLE 1 - Patients' sociodemographic, clinical characteristics and laboratory findings

	N = 132
Age (yrs)	69 [59-77]
Gender (%Male)	51.52
Dry weight (kg)	70.19±17.48
Kt/V	1.3 [1.2- 1.54)
Dialysis vintage (mo.)	47.5 [26-87]
Urea (mg/dL)	141.9 ± 37.16
Uric acid (mg/dL)	5.69 ± 1.43
Serum Phosphate (mg/dL)	5.02 ± 1.56
Serum Calcium (mg/dL)	9 [8.6-9.5]
Serum Magnesium (mg/dL)	2.19 ± 0.38
Parathormone (pg/mL)	278.6 [167-477.8]
Albumin (g/dL)	3.88 ± 0.36
LDL Cholesterol (mg/dL)	76.2 ± 31.3
Total Cholesterol (mg/dL)	142.4 ± 35.9
Triglycerides (mg/dL)	125.2 [83.5-157]
Ferritin (mg/dL)	216 [121-345]
Serum iron (mg/dL)	82.6 ± 36.8
Alkaline Phosphatase	92.4 ± 35.2
Hematocrit (%)	33.86 ± 4.95
Hemoglobin (g/dL)	10.74 ± 1.36
White blood cells (n x 10^3)	7.04 ± 2.29
PLT (n x 10^3)	203.86 ± 78,61
C-reactive protein (mg/L)	2.7 [3.3-5.6]
b2-microglobulin (mg/L)	28.2 ± 8.2
Fibrinogen (mg/dL)	331.4 ± 97.1

Reliability and item discrimination

The ICC for the test-retest study for the total scale was 0.92 (95% CI 0.90-0.94) and for the three subscales "*Signs and symptoms*", "*Sleep*", "*Psychosocial*" were 0.91 (5%: 0.89-0.93), 0.90 (95% CI: 0.89-0.92) and 0.94 (95% CI: 0.92-0.96) respectively. Cronbach's α for all items was 0.91 (95% CI 0.89-0.93) and 0.78 (95% CI 0.74-0.86), 0.78 (95% CI 0.75-0.84) and 0.94 (95% CI 0.89-0.96) for the three subscales, respectively **(Table 2)**. Moreover, comparing the first and the second completion, significant statistical differences were found respectively for items 5 and 10 **(Table 3)**.

Discussion

CKD-aP remains a significant and often overlooked complication in dialysis patients, severely impacting both physical and mental well-being.

Data from the Dialysis Outcomes and Practice Patterns Study (DOPPS) highlight the systemic burden of this complication and its influence on various aspects of patients' lives, including sleep quality and mood, as well as the prognostic significance on the risk of infections, hospitalizations, and even mortality (3,13).

One of the primary challenges in managing UP is the lack of standardized diagnostic tools and objective biomarkers (14).

To address this gap, the UP-DIAL questionnaire was developed as the first assessment tool specifically tailored to CKD-aP. It comprises three core domains encompassing critical aspects of chronic pruritus, including itch frequency, intensity, and distribution, the presence of skin lesions from scratching, and the effects of pruritus on sleep quality and emotional well-being[15]. Additionally, the total UP-DIAL score enables the classification of pruritus severity, which may help guide therapeutic decisions and monitoring treatment efficacy over time.

Given the global prevalence of UP among dialysis patients, efforts have been made to translate and validate the UP-DIAL questionnaire into multiple languages. Unfortunately, to date, validated versions exist only in English, Chinese, and Polish. Hence, the lack of more specific language translations may hamper the applicability of this instrument in a consistent proportion of HD individuals worldwide.

In our study, the Italian translation of the UP-DIAL demonstrated excellent internal consistency, with a Cronbach's α coefficient of 0.91 for the total UP-DIAL score. Each of the three domains also showed good internal consistency, with Cronbach's α coefficients of 0.78 for the "signs and symptoms"

TABLE 2 - Reproducibility of results after the first and second administration of UP-Dial

	1st administration			2nd administration			P
	Median	1st quartile	3rd quartile	Median	1st quartile	3rd quartile	
Q1	0	0	1	0	0	1	0.2331
Q2	1	0	2	1	0	2	0.1211
Q3	1	0	2	1	0	2	0.1121
Q4	0	0	1	0	0	1	0.6393
Q5	0	0	0	0	0	0	0.0175
Q6	0	0	1	0	0	1	0.0833
Q7	1	0	3	1	0	2	0.0610
Q8	0	0	1	0	0	1	0.0848
Q9	0	0	0	0	0	1	0.0651
Q10	0	0	1	0	0	1	0.0168
Q11	0	0	1	0	0	1	0.5785
Q12	0	0	1	0	0	1	0.6702
Q13	1	0	1	1	0	2	0.9012
Q14	0	0	0	0	0	1	0.0901
Signs & Symptoms	5	2	9	5	2	10	0.9878
Sleep	0	0	2	1	0	3	0.0773
Psychosocial	1	0	2	1	0	3	0.0557
Total Score	7	3	14	7	3	16	0.0790

TABLE 3 - The correlation coefficients measure the relationships between responses to each question and their association with the total score of the UP-Dial questionnaire

	Qa1	Qa2	Qa3	Qa4	Qa5	Qa6	Qa7	Qa8	Qa9	Qa10	Qa11	Qa12	Qa13	Qa14	a-Total
Qa1	1														
Qa2	0.452[b]	1													
Qa3	0.586[b]	0.618[b]	1												
Qa4	0.292[a]	0.166[c]	0.195[c]	1											
Qa5	0.372[a]	0.231[a]	0.310[a]	0.423[a]	1										
Qa6	0.508[b]	0.314[a]	0.496[b]	0.290[a]	0.719[b]	1									
Qa7	0.396[a]	0.555[b]	0.513[b]	0.224[c]	0.319[a]	0.403[a]	1								
Qa8	0.464[b]	0.298[c]	0.374[a]	0.399[a]	0.438[a]	0.462[b]	0.385[a]	1							
Qa9	0.430[b]	0.363[a]	0.417[a]	0.377[a]	0.480[b]	0.505[b]	0.474[b]	0.858[b]	1						
Qa10	0.362[a]	0.287[a]	0.385[a]	0.428[a]	0.466[b]	0.435[a]	0.394[a]	0.775[b]	0.840[b]	1					
Qa11	0.426[b]	0.470[b]	0.499[b]	0.279[a]	0.412[a]	0.372[a]	0.480[b]	0.583[b]	0.646[b]	0.561[b]	1				
Qa12	0.423[b]	0.526[b]	0.461[b]	0.281[a]	0.360[a]	0.319[a]	0.502[b]	0.544[b]	0.620[b]	0.569[b]	0.806[b]	1			
Qa13	0.441[b]	0.418[b]	0.464[b]	0.521[b]	0.384[a]	0.421[a]	0.453[b]	0.538[b]	0.538[b]	0.607[b]	0.632[b]	0.739[b]	1		
Qa14	0.104[c]	0.034[c]	0.008[c]	0.533[b]	0.336[a]	0.264[c]	0.039[c]	0.345[a]	0.254[c]	0.428[a]	0.128[c]	0.177[c]	0.518[b]	1	
a-Total	0.655[b]	0.604[b]	0.668[b]	0.563[b]	0.631[b]	0.666[b]	0.664[b]	0.777[b]	0.816[b]	0.788[b]	0.760[b]	0.766[b]	0.801[b]	0.412[a]	1

[a] $p < 0.05$; [b] $p < 0.01$; [c] $p > 0.05$

and "sleep" domains and 0.94 for the psychosocial domain. These results are comparable to those obtained in the original Thai and non-Thai validation studies (Cronbach's α range of 0.89-0.93) (7, 9, 16, 17).

Item 14, which addressed sexual problems, revealed that a significant proportion of dialysis patients reported difficulties in this area ($p = 0.090$). This finding is consistent with previous studies (18, 19), which have shown that sexual dysfunction is highly prevalent among patients undergoing dialysis, often due to the combined effects of chronic illness, physical limitations, and psychological factors such as depression and anxiety. Additionally, the presence of chronic pruritus, a common issue in dialysis patients, may exacerbate these sexual difficulties, as the discomfort and stress caused by pruritus can further diminish sexual desire and intimacy.

Although some differences emerged between the first and second administrations of the questionnaire for certain items, we attribute these discrepancies to the inherent

subjectivity of these specific items and potential fluctuations in symptom perception over time.

The overall performance of the Italian adaptation of this instrument thus appears valid, reliable and with a good potential generalizability.

Our study has some limitations that deserve to be mentioned, but also important room for future investigations. First, the sample size was relatively small; although the study was conducted in a multicenter setting, all dialysis centers were located within the same geographical area, leading to a relatively homogeneous patient population. To enhance the external validity of our results, future research should aim to validate the Italian version of the UP-DIAL questionnaire in a larger cohort, including dialysis centers distributed across different regions of Italy.

Additionally, our study did not compare UP-DIAL scores with those obtained from other pruritus assessment tools, even those designed for non-uremic populations. Such comparisons could provide valuable insights into the specificity and discriminative power of UP-DIAL in differentiating CKD-aP from other forms of chronic itch.

Finally, we did not assess longitudinal changes in UP-DIAL scores following the initiation of specific antipruritic treatments. Investigating how UP-DIAL scores evolve in response to therapy could help establish its role in monitoring treatment efficacy and guiding clinical decisions.

Conclusions

In conclusion, UP remains a challenging and underrecognized condition in dialysis patients, with substantial implications for quality of life and overall prognosis. Our study confirms the reliability and validity of the Italian version of the UP-DIAL questionnaire, providing clinicians with a robust instrument to assess UP in Italian-speaking patients. Future research should focus on further validating the tool in larger, diverse populations and investigating its role in guiding personalized treatment strategies.

Disclosures

Conflict of interest: The authors declare no conflict of interest.

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Data availability statement: The data presented in this study are available on request from the corresponding author.

Ethics approval and consent to participate: This study was performed in line with the principles of the Declaration of Helsinki. The study has received ethical approval from Comitato Etico Calabria (Italy). Participants received information about the study, outlining its purpose and emphasizing the voluntary nature of participation.

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