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REPORTS OF ORIGINAL INVESTIGATIONS

Transcultural validation of a French–European version of the Prescription Opioid Misuse Index Scale (POMI-5F)

Validation transculturelle d'une version franco-européenne de l'échelle de mésusage des prescriptions d'opioïdes (POMI-5F)

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Abstract

Purpose *The Prescription Opioid Misuse Index scale (POMI) is a brief questionnaire used to assess opioid prescription misuse. In view of the increase in the prescription of opioid analgesics for chronic noncancer pain (CNCP), this tool is particularly useful during medical consultations to screen opioid misuse in patients using opioids. We sought to generate and validate a French–European translation of the POMI.*

Methods *We conducted an observational, longitudinal, and multicenter psychometric study with crosscultural validation. All adult CNCP patients who were treated with opioids for at least three months, were followed in pain clinics, and spoke French were eligible. From September 2015 to November 2017, we included 163 patients and analyzed 154. We performed a pretest on a sample of representative patients to evaluate acceptability and understanding of translation. Study patients completed the POMI scale at a pain clinic (test phase), and we assessed test–retest reliability after two to four weeks by a second completion of the POMI scale at home by patients (retest phase). We subsequently explored psychometric properties of the POMI (acceptability, internal consistency, reproducibility, and external validity).*

Results *Due to poor internal consistency and reproducibility, items 4, 7, and 8 of the original POMI scale were removed, and we proposed a five-question French–European version (POMI-5F). The internal*

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consistency of POMI-5F was good (Cronbach's α = 0.71), as was test–retest reliability (r = 0.65 [0.55–0.67]). The external validity of POMI-5F, compared with the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, was moderate but significant (r = 0.45; P < 0.001). The optimal POMI-5F cut-off score to indicate misuse was 2/5 (sensitivity = 0.95 and specificity = 0.54).
Conclusion *We generated and validated a French–European translation of the POMI scale, POMI-5F, for use by French researchers and physicians to identify opioid misuse in CNCP patients.*

Résumé
Objectif *L'échelle Prescription Opioid Misuse Index (POMI) est un questionnaire court utilisé pour évaluer le mésusage de la prescription d'opioïdes. Face à l'augmentation de la prescription d'antalgiques opioïdes pour les douleurs chroniques non cancéreuses (DCNC), cet outil est particulièrement utile lors des consultations médicales pour dépister le mésusage chez les patients utilisateurs d'opioïdes. Nous avons cherché à générer et à valider une traduction franco-européenne de la POMI.*
Méthodes *Nous avons mené une étude psychométrique observationnelle, longitudinale et multicentrique avec une validation transculturelle. Tous les patients souffrant de DCNC, traités par opioïdes depuis au moins trois mois, suivis en structures douleur chronique et parlant le Français étaient éligibles. De septembre 2015 à novembre 2017, 163 patients ont été inclus et 154 analysés. Un pré-test a été réalisé sur un échantillon de patients représentatifs pour évaluer l'acceptabilité et la compréhension de la traduction. Les patients de l'étude ont rempli l'échelle POMI (phase TEST) au sein du centre investigateur et la fiabilité du test–retest a été évaluée après deux à quatre semaines par un second remplissage de l'échelle POMI à domicile par les patients (phase RETEST). Ensuite, les propriétés psychométriques de l'échelle POMI ont été explorées (acceptabilité, cohérence interne, reproductibilité et validité externe).*
Résultats *En raison d'une faible cohérence interne et reproductibilité, les items 4, 7 et 8 de l'échelle POMI originale ont été supprimés, et nous avons proposé une version française (Europe) à cinq questions (POMI-5F). La cohérence interne de l'échelle POMI-5F était bonne (α de Cronbach = 0,71), tout comme la fiabilité test–retest (r = 0,65 [0,55–0,67]). La validité externe du POMI-5F, comparée à la cinquième édition du Manuel diagnostique et statistique des troubles mentaux (DSM-5), était modérée mais significative (r = 0,45; P < 0,001). Le score seuil optimal du POMI-5F pour indiquer un mésusage était de 2/5 (sensibilité = 0,95 et spécificité = 0,54).*
Conclusion *Nous avons généré et validé une traduction franco-européenne de l'échelle POMI, POMI-5F, pour une utilisation par les chercheurs et les médecins français afin d'identifier le mésusage des opioïdes chez les patients souffrant de DCNC.*

Keywords opioid use disorder · chronic pain · transcultural validation · POMI scale

Chronic pain prevalence in the general population has been estimated at about 30% worldwide,[1-4] which makes it a major public health problem, not only because of its high impact on patients' quality of life[5] but also because of its significant economic impact on society, with direct and indirect costs.[6] Despite the lack of scientific evidence showing their long-term benefits, opioid analgesics are widely used for treating chronic noncancer pain (CNCP),[7-9] leading to an increase of opioid use in recent decades in developed countries.[10-12] Worldwide, the prescription of opioid analgesics more than doubled from 2001 to 2013, most significantly in North America and in Western and Central Europe, and mainly for strong opioids.[13-17]

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Nevertheless, the use of opioids is not without risk, and several international studies have shown an increase in opioid use disorder, hospitalizations, and deaths.[14,18-20] In France, rates of prescribed opioid-related hospital admissions increased by 167% from 2000 to 2017, and opioid-related deaths increased significantly by 146% from 2000 to 2015.[14] A similar observation was made in the USA, where deaths from prescription opioid overdoses have risen sharply in recent years,[19,21] but in a much higher proportion than in France.[20]

In patients with CNCP, opioid analgesics are subject to increasing misuse related to more prescriptions and other ways of obtaining them ("doctor shopping"), which may contribute to increased opioid-related risks (hospitalization, death). Only a few studies in France have assessed analgesic opioid misuse based on the evaluation of "doctor shopping" from healthcare databases;[14,22,23] in particular, Chenaf *et al.* showed a 34% increase in opioid analgesic shopping behavior from 2004 to 2017.[14] It is therefore important to clearly identify opioid analgesic misuse in French patients using opioids.

At present, three scales are used to identify opioid misuse: 1) the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5), which is not specific to misuse alone because it also assesses addiction, which may confuse and misestimate the real rate of misuse;[24] 2) the Current Opioid Misuse Measure, which is not used much in clinics but mainly for research because of its length;[25] and 3) the Prescription Opioid Misuse Index (POMI), which specifically assesses clinical misuse.[26] The POMI scale was validated in 2008 in 137 patients recruited from community substance abuse treatment programs, regional jails, pain clinics, and private internal medicine practices in the USA. The primary objective of our study was the crosscultural validation of the French–European version of the POMI scale in chronic pain patients in pain clinics.

Methods

We conducted an observational longitudinal and multicenter psychometric study for the crosscultural validation of the POMI scale in patients with CNCP in pain clinics. This study was authorized by the French personal data protection authority (CNIL, ref: DR-2015-455, n°915065). French legislation did not require authorization from an ethics committee for this type of observational study. All participants gave their informed consent to participate. The study is registered at ClinicalTrials.gov (NCT04979364).

Study outcomes

The study outcomes were the psychometric properties of the French–European version of the POMI scale (POMI-5F), including its construct validity, internal consistency, test–retest reliability, and convergent validity.

Prescription Opioid Misuse Index (POMI) scale

The first English version of the POMI scale was developed in the USA to assess oxycodone misuse[26] (Electronic Supplementary Material, eFigure). The POMI scale is a self-evaluation scale with eight items scored 0 (absent) or 1 (present). The questionnaire comprises eight questions, six of which are used to calculate a score which is the sum of positive answers. The psychometric data according to Knisely *et al.* 2008 are as follows: presence of misuse with a cut-off ≥ 2 (sensitivity 0.820 and specificity 0.923) and Cronbach's alpha of 0.848 for all items and 0.883 with six items. Items 1–3 and 6–8 have correlation coefficients from 0.663 to 0.769 and items 4 and 5 have correlation coefficients of 0.0483 and 0.359, respectively. Receiver operating characteristic (ROC) analyses equal 0.887.

Translation of the POMI scale into French

The French translation of the POMI scale was adapted according to the recommended guidelines for crosscultural adaptation.[27-29] The goal was to write the scale in the native language of the target population and to take into account their culture (e.g., their habits, beliefs, and interpretations). The following criteria were observed:

(1) Translations of the POMI scale were carried out independently by four French-speaking translators who were linguistically competent (able to use both languages equally well in speech and writing). These translators looked for ambiguities or unexpected meanings in the original items.
(2) The different translations were discussed in synthesis sessions with a committee of experts (algologists, addictologists, and translators) to create a final translation based on these discussions. Unsatisfactory questions or answers were reiterated in the process.
(3) The translation was back-translated into English by two French-speaking translators from the same companies but who had not seen the original questionnaire and were not aware of the concepts being explored. The role of this back-translation was to amplify errors or deviations from the original scale.

Table 1 French version of Prescription Opioid Misuse Index scale (POMI-5F)

1/ Avez-vous déjà pris ce/ces médicament(s) anti-douleur en quantité PLUS importante, c'est-à-dire une quantité plus élevée que celle qui vous a été prescrite ?	**Oui**	**Non**
2/ Avez-vous déjà pris ce/ces médicament(s) anti-douleur plus SOUVENT que prescrit(s) sur votre ordonnance, c'est-à-dire de réduire le délai entre deux prises ?	**Oui**	**Non**
3/ Avez-vous déjà eu besoin de faire renouveler votre ordonnance de ce/ces médicament(s) anti-douleur plus tôt que prévu ?	**Oui**	**Non**
*4/ Avez-vous déjà eu suffisamment de ce/ces médicaments anti-douleur (sur prescription) pour soulager votre douleur à un niveau acceptable ?	**Oui**	**Non**
5/ Un médecin vous a-t-il déjà dit que vous preniez trop de ce/ces médicament(s) anti-douleur ?	**Oui**	**Non**
6/ Avez-vous déjà eu la sensation de planer ou ressenti un effet stimulant après avoir pris ce/ces médicament(s) anti-douleur ?	**Oui**	**Non**
*7/ Avez-vous déjà pris ce/ces médicament(s) anti-douleur parce que vous étiez contrarié(e), c'est-à-dire pour soulager ou supporter des problèmes autres que la douleur ?	**Oui**	**Non**
*8/ Avez-vous déjà consulté plusieurs médecins, y compris aux urgences, pour obtenir plus de ce/ces médicament(s) anti-douleur ?	**Oui**	**Non**

*Questions à éliminer pour le calcul du score principal.

(4) The back-translation was compared with the source questionnaire during a synthesis session of the expert committee to arrive at a final version.
(5) A pretest was conducted to verify the acceptability of the translation in our target population. During individual semidirective interviews, the French version of the POMI questionnaire was presented to ten patients aged 18 yr or older with chronic pain (≥ six months) and who were treated with opioid analgesics for at least three months. These individuals were able to understand the questionnaire and answer questions about its acceptability (i.e., they could understand and interpret the questions) (Table 1).

Participants

All eligible patients from the active file of two French pain clinics (Clermont-Ferrand and Toulouse) were asked to participate in the study from 1 September 2015 to 31 November 2017. All the patients aged 18 yr or older, experiencing CNCP for at least six months, taking at least one analgesic opioid daily for three months, and being followed up in pain clinics were enrolled. All the patients received oral information about the study and gave oral consent to participate. Exclusion criteria were inability to read/comprehend or complete the test and retest questionnaires and ongoing cancer. At each center, participants were clinically assessed by a pain specialist during the inclusion visit (test phase). Together, the pain specialist and the patient completed the five-part study questionnaire and collected the following information: 1) demographic data: sex, age, family status; 2) medical data: type of pain (neuropathic, nociplastic, and/or nociceptive), duration of pain (6–12 months, 1–5 years, > 5 years), and average pain intensity (11-point numeric rating scale; no pain = 0 and unbearable pain = 10); 3) analgesic treatments: strong and weak opioid analgesics, concomitant non-opioid analgesics, average daily dose, and duration of treatment (3–6 months, 6–12 months, 1–5 years, > 5 years); 4) substance use disorder questionnaire (DSM-5); and 5) POMI scale questionnaire (completed by the patient alone).

To assess test–retest reliability, the POMI questionnaire was completed at home by patients a second time, two to four weeks after the inclusion visit (the retest phase). A reminder phone call was made if the completed questionnaire was not submitted. Once completed, the patients returned the questionnaire to the study coordinating center (Clermont-Ferrand University Hospital). The reliability of the test–retest was preserved thanks to the duration between the two test phases. This time frame was chosen as being neither too short nor too long to avoid patients remembering their test answers and to avoid changes in their pathology and its management.[30]

Statistical analysis

Sample size estimation was fixed according to COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) recommendations.[31,32] Rules-of-thumb for the number of participants needed to ensure internal consistency varied from four to ten participants per variable, with a minimum number of 100 participants to ensure the stability of the variance–covariance matrix, whereas for reproducibility, at least 50 participants were necessary.

The statistical analyses used in this study were those usually used in studies to validate scales.[33] In addition to descriptive statistics, we explored the following psychometric properties of the POMI scale using Stata Software version 15 (StataCorp LLC, College Station, TX, USA): 1) acceptability: data quality was considered satisfactory if more than 95% of the scale data were fully computable (floor and ceiling effects were analyzed); 2)

internal consistency: assessed through Cronbach's alpha coefficient (minimum accepted value, 0.70), and the item-total correlation corrected for overlap (criterion value, $\geq$ 0.30); 3) reproducibility: Lin's concordance coefficient was used to assess the test–retest reliability for continuous outcomes, whereas Kappa's concordance coefficient was estimated for categorical data with values $\geq$ 0.70 deemed satisfactory; and 4) external validity: hypotheses were tested regarding convergent validity, relationships between DSM-5 and POMI scale scores were studied using correlation coefficients (Spearman, according to statistical distribution), and ROC analysis followed by the estimation of Youden and Liu indexes determined the best threshold to discriminate DSM-5 categorized as > 3. The comparison of patients' characteristics according to the POMI-5F score was conducted using the Chi square or Fisher's exact test for categorical data, and Student's *t* test or the Mann–Whitney test for continuous variables. Homoscedasticity was checked using the Fisher–Snedecor test.

Results

Pretest

Ten patients with CNCP were interviewed by an investigator (N.D.) during the pretest phase. Patients had various forms of CNCP with opioid treatment for at least three months and were being followed up in the Clermont-Ferrand pain clinic. The feedback obtained by the participants did not modify the proposed translation, indicating a good acceptability and understanding of the translation by our target population.

Population

One hundred and sixty-three patients (113 in Clermont-Ferrand and 50 in Toulouse) were included in this study from September 2015 to November 2017, and 154 were analyzed. Nine patients could not be analyzed because they did not return the questionnaire. Females represented 98/154 (64%) participants, the mean (standard deviation) age was 50 (12) yr, and 103/154 (73%) lived in couples. The type of pain was mainly described as nociplastic (94/154, 61%) and 93/154 (61%) patients had experienced pain for at least 5 years. The most frequently used analgesic opioid drug was tramadol (38%). All the population's characteristics are described in Table 2.

Table 2 Characteristics of patients

	Total (N = 154)
Female sex, *n*/total *N* (%)	98/154 (64%)
Age (yr), mean (SD)	50 (12)
In spousal relationship, *n*/total *N* (%)	103/154 (73%)
Type of pain, *n*/total *N* (%)	
Neuropathic	66/154 (43%)
Nociplastic	94/154 (61%)
Nociceptive	33/154 (21%)
Pain duration, *n*/total *N* (%)	
6–12 months	1/154 (1%)
1–5 years	58/154 (38%)
$\geq$ 5 years	93/154 (61%)
Pain intensity	
Total score (/10), mean (SD)	6.3 (1.9)
Intensity $<$ 3/10, *n*/total *N* (%)	6/154 (4%)
Intensity 3/10–6/10, *n*/total *N* (%)	71/154 (46%)
Intensity $\geq$ 7/10, *n*/total *N* (%)	77/154 (50%)
Relief by treatment (%), mean (SD)	50 (25)%
DSM-5 score	
Total score, mean (SD)	1.7 (2.0)
$\leq$ 3: mild, *n*/total *N* (%)	132/154 (86%)
4–5: moderate, *n*/total *N* (%)	13/154 (8%)
$\geq$ 6: severe, *n*/total *N* (%)	8/154 (5%)
Opioid treatment used, *n*/total *N* (%)	
Morphine	29/154 (19%)
Fentanyl	9/154 (6%)
Oxycodone	34/154 (22%)
Hydromorphone	0/154 (0%)
Tramadol	59/154 (38%)
Codeine	17/154 (11%)
Dihydrocodeine	0/154 (0%)
Opium	14/154 (9%)
Concomitant analgesic treatments, *n*/total *N* (%)	
Acetaminophen	59/154 (38%)
NSAIDs	10/154 (6%)
Nefopam	3/154 (2%)
Triptan	0/154 (0%)
Gabapentin	15/154 (10%)
Pregabalin	23/154 (15%)
Amitriptyline	25/154 (16%)

DSM-5 = Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition; NRS = numeric rating scale; NSAIDs = nonsteroidal anti-inflammatory drugs; SD = standard deviation

Acceptability

The results for the data quality and acceptability of the POMI scale are shown in Fig. 1. Fully computable data were obtained for the entire sample (N = 154). The rates of patients responding positively to individual items were lowest for items 7 and 8 (5% and 3%, respectively) and highest for items 1 and 6 (46% and 45%, respectively).

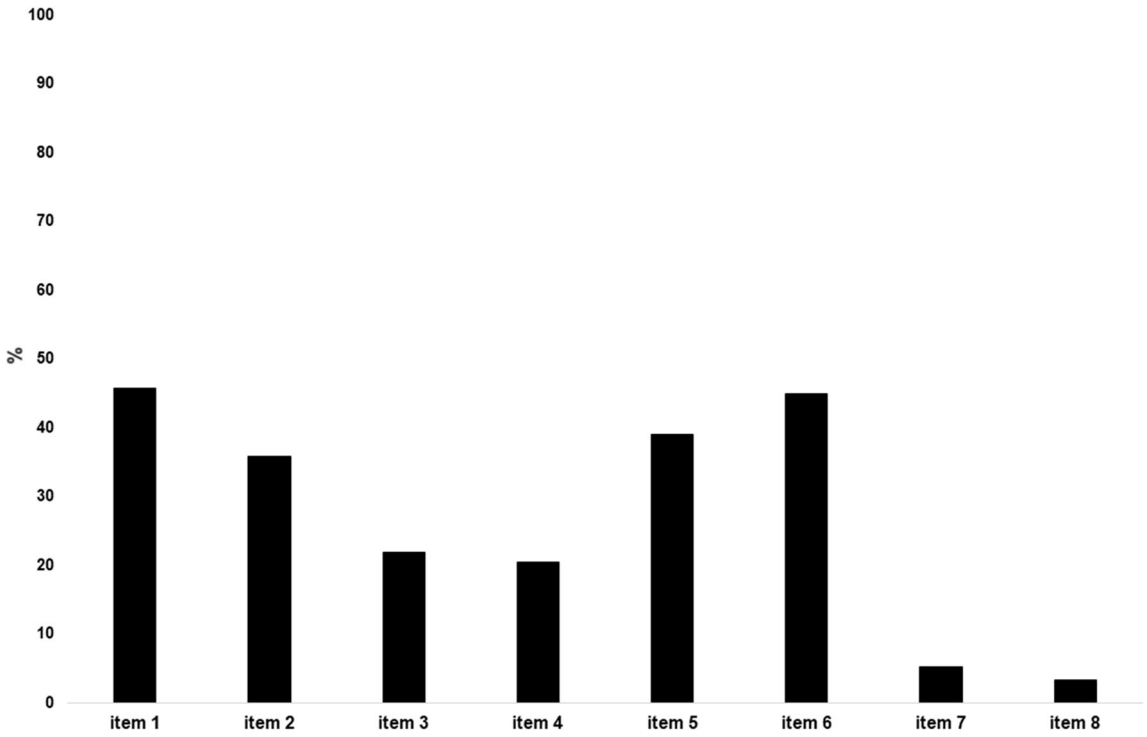

Fig. 1 Analysis of acceptability. Responses (% yes) for each Prescription Opioid Misuse Index item.

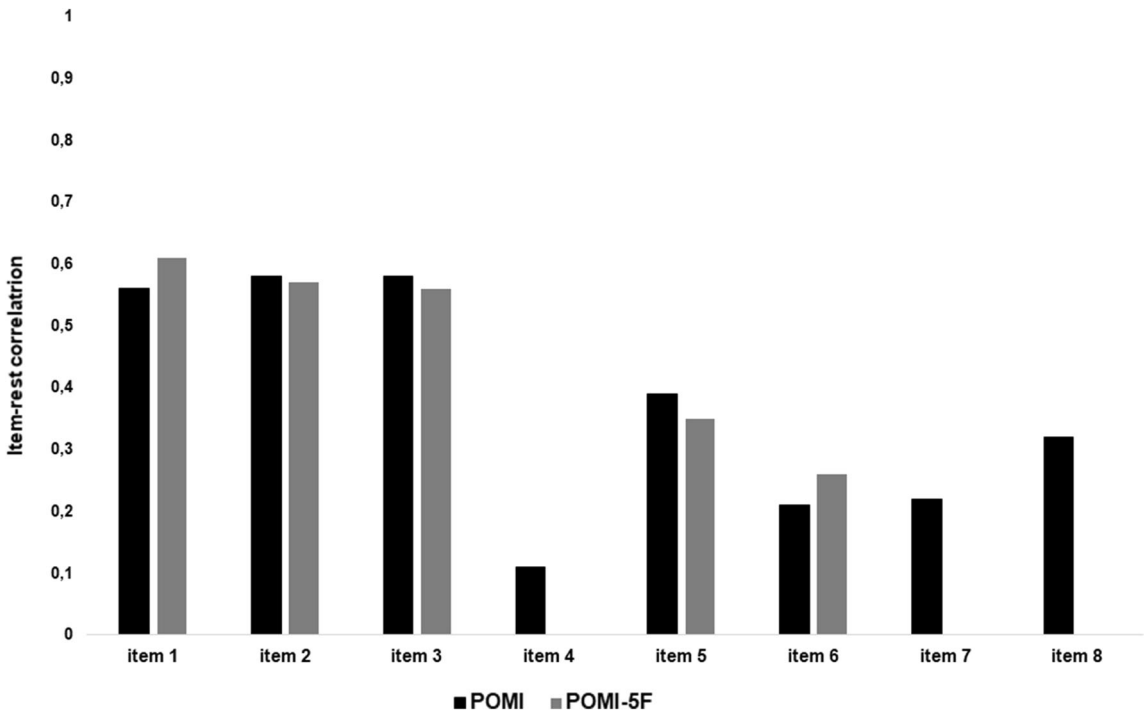

Fig. 2 Internal consistency. Item-rest correlation between POMI and POMI-5F. POMI: all items; POMI-5F: excluding items 4, 7, and 8. POMI = Prescription Opioid Misuse Index

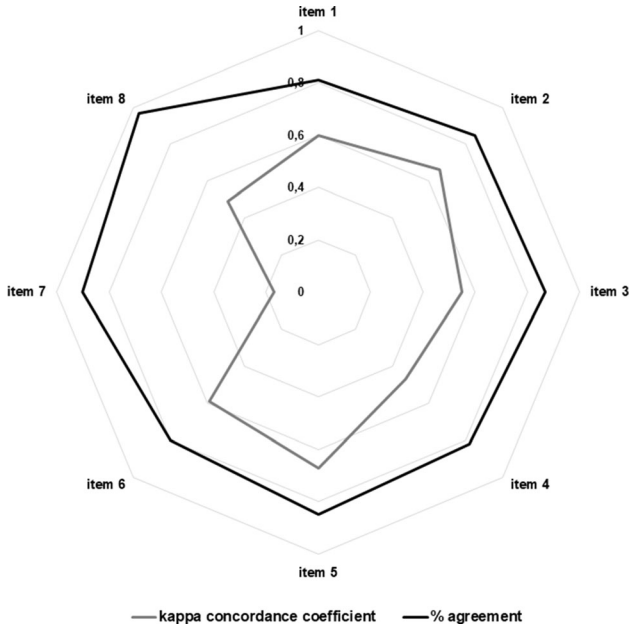

Fig. 3 Test–retest reliability. Agreement for each item.

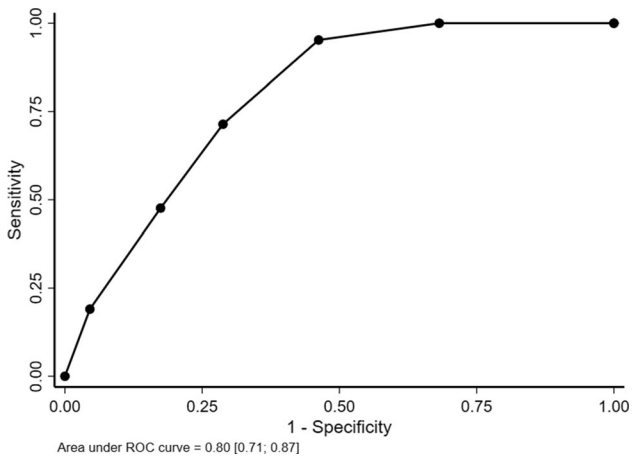

Fig. 4 Receiver operating characteristic curve

Internal consistency

The Cronbach's alpha reliability coefficient was 0.67. The item-rest correlation for the entire scale ranged from 0.11 (item 4) to 0.58 (items 2 and 3). When item 4 was deleted because of the lower item-rest correlation, Cronbach's alpha increased to 0.70, with other item-rest correlation coefficients ranging from 0.22 (item 7) to 0.60 (item 1). When items 7 and 8 were also removed, Cronbach's alpha increased to 0.71, with item-rest correlation coefficients ranging from 0.26 (item 6) to 0.61 (item 2) (Fig. 2).

Reproducibility

Kappa's Cohen concordance coefficient ranged from 0.17 (item 7) to 0.67 (item 5) (Fig. 3). For the POMI-5F, items 7 and 8, with non-satisfactory Kappa's Cohen coefficient thresholds, were excluded in addition to item 4, as mentioned previously. Therefore, in the POMI-5F scale, the Kappa Cohen concordance coefficient was 0.65 for the test–retest evaluation (95% confidence interval [CI], 0.55 to 0.67) with agreement equal to 82%.

External validity

The correlation between POMI-5F (excluding items 4, 7, and 8) and DSM-5 was moderate (r = 0.45; $P < 0.001$). Receiver operating characteristic analysis yielded an area under the curve of 0.80 (95% CI, 0.71 to 0.87) (Fig. 4). On the basis of sensitivity and specificity, it was determined that the optimal POMI-5F cut-off score identifying misuse was 2/5 (sensitivity = 0.95 and specificity = 0.54). Lin's concordance coefficient was 0.68 (95% CI, 0.60 to 0.76), with 1.88 (1.61) for the TEST phase and 1.39 (1.42) for the retest phase.

Characterization of patients according to the POMI-5F score

Opioid misuse (POMI-5F score ≥ 2) was found in 53% of patients. Opioid-misuse patients and non-opioid misuse patients had similar characteristics and these are detailed in Table 3. Logically, patients with a POMI-5F score ≥ 2 have higher DSM-5 scores. Interestingly, patients with a POMI-5F score ≥ 2 appear to take less tramadol than those with a POMI-5F score < 2. None of the other characteristics seemed to correlate with either group of patients.

Discussion

This is the first study to have translated and validated the POMI scale into French–European. Our French–European version of the POMI scale (POMI-5F) passed all the controls of transcultural validation,[27-29] external validity, internal consistency, convergent validity, and test–retest reliability.

For this purpose, we included 150 patients with various chronic pain conditions who had been treated with opioids for more than three months. We did not list and characterize patients who did not participate (refusal or ineligibility). Nevertheless, according to the latest ANSM report in 2019 on opioid consumption in France,[34] it appears that our study population is similar to the French

Table 3 Characteristics of patients according to the POMI score

	POMI score < 2 *N* = 73 (47%)	**POMI score ≥ 2** *N* = 81 (53%)	***P* value**
Female sex, *n*/total *N* (%)	50/73 (68%)	48/81 (59%)	0.23
Age (yr), mean (SD)	52 (14)	49 (9)	0.13
In spousal relationship, *n*/total *N* (%)	51/73 (75%)	52/81 (71%)	0.61
Type of pain, *n*/total *N* (%)			
Neuropathic	26/73 (36%)	40/81 (49%)	0.09
Nociplastic	48/73 (66%)	46/81 (57%)	0.26
Nociceptive	17/73 (23%)	16/81 (20%)	0.59
Pain duration, *n*/total *N* (%)			
6–12 months	1/73 (1%)	0/81 (0%)	0.56
1–5 years	29/73 (40%)	29/81 (36%)	
≥ 5 years	42/73 (58%)	51/81 (64%)	
Pain intensity			
Total score (/10), mean (SD)	7.2 (2.0)	7.7 (1.9)	0.10
Intensity < 3/10, *n*/total *N* (%)	2/73 (3%)	3/81 (4%)	0.41
Intensity 3/10–6/10, *n*/total *N* (%)	16/73 (22%)	11/81 (14%)	
Intensity ≥ 7/10, *n*/total *N* (%)	55/73 (75%)	67/81 (83%)	
Relief by treatment (%), mean (SD)	50 (25)%	51 (24)%	0.74
DSM-5 score			
Total score, mean (SD)	0.8 (1.0)	2.4 (2.3)	**< 0.001**
≤ 3: mild, *n*/total *N* (%)	71/73 (99%)	61/81 (75%)	**< 0.001**
4–5: moderate, *n*/total *N* (%)	1/73 (1%)	12/81 (15%)	
≥ 6: severe, *n*/total *N* (%)	0/73 (0%)	8/81 (10%)	
Opioid treatment used, *n*/total *N* (%)			
Morphine	11/73 (15%)	18/81 (22%)	0.26
Fentanyl	2/73 (3%)	7/81 (9%)	0.17
Oxycodone	12/73 (16%)	22/81 (27%)	0.11
Hydromorphone	0/73 (0%)	0/81 (0%)	NA
Tramadol	36/73 (49%)	23/81 (28%)	**0.008**
Codeine	5/73 (7%)	12/81 (15%)	0.12
Dihydrocodeine	0/73 (0%)	0/81 (0%)	NA
Opium	8/73 (11%)	6/81 (7%)	0.44
Concomitant analgesic treatments, *n*/total *N* (%)			
Acetaminophen	27/73 (37%)	32/81 (40%)	0.75
NSAIDs	2/73 (3%)	8/81 (10%)	0.10
Nefopam	0/73 (0%)	3/81 (4%)	0.25
Triptan	0/73 (0%)	0/81 (0%)	NA
Gabapentin	10/73 (14%)	5/81 (6%)	0.17
Pregabalin	9/73 (12%)	14/81 (17%)	0.39
Amitriptyline	12/73 (16%)	13/81 (16%)	0.95

DSM-5 = Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition; NRS = numeric rating scale; NA = not applicable; NSAIDs = nonsteroidal anti-inflammatory drugs; SD = standard deviation

population of opioid users. Indeed, our study population had a majority of weak opioids (58% *vs* 47% for strong opioids, with 38% for tramadol), a majority of women, and an age of about 50 years. The final version of the POMI-5F scale selected, with criterion validity and satisfactory reliability, included items 1, 2, 3, 5, and 6 of the original English version of the POMI scale.[26] The shortness and conciseness (it takes only a few minutes) of the POMI-5F scale facilitated its administration by a physician in daily clinical practice. The threshold of 2/5 for positivity of the

POMI-5F score is the same as that found by Kinsely's team,[26] and was calculated from the ROC analysis, comparing the POMI-5F score and DSM-5.

Cronbach's alpha coefficient assessed the internal consistency and showed the relationships between the items (values > 0.7 are recommended). With eight items, Cronbach's alpha coefficient in the POMI-5F was 0.67 *vs* 0.84 for the English POMI scale. According to Knisely *et al.*,[26] some items seemed to be less good in the POMI-5F. Thus, we chose to eliminate items 4, 7, and 8 from the total score because of their poor internal individual consistency. This improved the internal global consistency of the scale by 0.04 points (0.71). It should be noted that in the final English POMI scale, items 4 and 5 with a lower Cronbach's alpha coefficient were also deleted from the total score (Cronbach's alpha coefficient was 0.85 in total). POMI-5F is somewhat different to the English POMI scale, but this can be explained. Firstly, the size and characteristics of the populations studied were different: Knisely *et al.*[26] recruited 75 patients from community substance abuse treatment programs, regional jails, pain clinics, and private internal medicine practices who were using only oxycodone (40 opioid abusers and 34 pain patients), whereas we recruited 154 patients from pain clinics who were treated with all types of opioid analgesics. The rate of misuse in Knisely's study was 67% whereas in our study the rate of misuse was 53%. This difference may be because of the population and opioid treatments studied and because in the USA, one of the opioid prescription medications that led to the opioid crisis is oxycodone, whose misuse has been endemic.[35] Secondly, prescription habits between American and French individuals are different; American patients seem to renew their treatment prescriptions in the emergency room whereas French patients tend to renew their opioid prescriptions at their general practitioner's.[34] In our study, item 8, which asked about the need to go to the emergency room to obtain analgesic treatment, showed an inconsistent response and did not detect new cases of misuse. Moreover, unlike Knisely *et al.*'s study, our study included test and retest phases at 15-day intervals, ensuring the robustness of the results.

The comparison of POMI-5F with the DSM-5, a reference tool for evaluating medication use disorders (and therefore screening for true treatment addiction), showed a slight correlation. Nevertheless, unlike the POMI scale, the DSM-5 questionnaire is not a self-administered questionnaire but a tool for addiction screening by the practitioner. In addition, it includes items not covered by the POMI scale (craving, withdrawal, tolerance, much time spent using, activities given up to use, repeated attempts to control use, etc.). It helps the practitioner to look for real addictive behaviors. Thus, we propose, after having identified opioid misuse by the POMI scale (POMI or POMI-5F), to complete the patient interview with several questions removed from the DSM-5 to distinguish "pseudoaddiction" (due to insufficient pain relief) from a true addiction. In all cases, the reasons for this misuse should be investigated. These reasons may include the following: 1) pain insufficiently relieved (due to lack of etiological identification or means of relief); 2) undiagnosed associated comorbidities such as anxiety, depression, sleep disorders, asthenia (very often associated with chronic pain); and 3) real addiction with loss of control, craving, "doctor shopping," endangerment, loss of reference points, desocialization, etc.

One of the main limitations of our study is the lack of validation of the POMI-5F scale in other French-speaking countries. Indeed, the French language may vary according to the region of the world (Canada, France, Belgium, Africa, Asia, etc.). In addition, clinical practices for the medical management of patients with chronic pain and having opioid treatment differ from country to country, and this may affect the POMI questionnaire. This was shown by the fact that question 8 of the original POMI was not adapted to French medical management. Further studies are therefore needed to validate the POMI-5F scale in each French-speaking country. A second limitation is that patients with chronic cancer pain (CCP) were not included, so we cannot state that the POMI-5F scale is suitable for this type of patient. There are several reasons for not including these patients. In France, patients with CCP are managed quite differently from those with CNCP, and these patients are rarely seen in pain clinics, but rather in cancer centers. Moreover, 90% of patients on strong opioids in France do not have cancer and 70% of opioid prescriptions are for CNCP.[14,34] Finally, the French recommendations[36] limit the prescription of opioids to three months in CNCP, while there is no limitation to opioid prescription for CCP. Moreover, it seems that patients with CCP had lower addiction rates.[37] It is therefore in the population of patients with CNCP that the use of opioids for more than three months may pose a problem and raise the question of misuse. A third limitation is our pretest methodology. For purely logistical reasons, we only performed the pretest on ten patients, whereas the recommendations suggest 30–40 patients.[28] A final limitation is the method used for the test–retest. Indeed, for logistical reasons, the method of filling in the questionnaires is not identical between the test and the retest. During the test phase, the questionnaires were filled out by patients in front of a clinician, and during the retest phase, the same version was filled out at home by patients. Because of social desirability bias,[38] it is possible that the validity of the test–retest is affected. According to Terwee *et al.*,[33] our results obtained with the Kappa Cohen concordance coefficient and the Lin concordance

coefficient seem to show that our test–retest remains valid despite our methodology.

In conclusion, the easy and short POMI-5F scale with acceptable psychometrical properties can help physicians identify opioid misuse in French–European patients with chronic pain and can be used to adapt and improve the therapeutic management of patients. When identifying misuse, it will first be necessary to confirm the misuse and identify its causes (comorbidities, pain relief, and craving); secondly, it will be necessary to distinguish "pseudoaddiction" behavior due to analgesia from a real addiction, with the help of additional questions, notably from the DSM-5. Furthermore, the POMI-5F scale could be used in future studies to analyze the prevalence of opioid misuse in patients with chronic pain in France, given the current state of the "American opioid crisis," which leads us to question our practices and the behavior of our patients. For other French-speaking countries, further studies are required to validate POMI or POMI-5F scales according to specific languages and clinical practices. Finally, it is important to be especially careful regarding patients with chronic pain who are particularly intolerant to pain and distress or ready to try a novel analgesic despite increasing addiction risk. Both categories are at higher risk of opioid misuse.[39,40]

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