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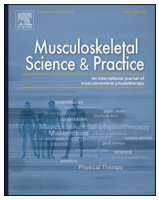

Original article

Italian versions of the optimal screening for Prediction of Referral and Outcome Yellow Flag (OSPRO-YF) and the Örebro Musculoskeletal pain screening questionnaire (ÖMPQ-21) and their short forms, in patients with low back pain: Cross-cultural adaptation, reliability and validity

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A B S T R A C T

Background: Low back pain (LBP) is a leading cause of disability worldwide. Early detection of prognostic factors using the Optimal Screening for Prediction of Referral and Outcome Yellow Flag (OSPRO-YF) or the Örebro Musculoskeletal Pain Screening Questionnaire (ÖMPQ-21) can predict improvement in pain and disability for patients with nonspecific LBP.
Objectives: To translate and cross-culturally adapt the OSPRO-YF and the ÖMPQ-21 with their short versions into the Italian language and to test their measurement properties in patients with LBP.
Design: Clinimetric study.
Methods: OSPRO-YF and ÖMPQ-21 were translated and administered to LBP patients with questionnaires on pain intensity, disability, pain self-efficacy, and pain catastrophizing. We evaluated test-retest reliability, measurement error, and construct validity.
Results: Eighty-three patients with LBP were included. No floor or ceiling effects were reported. Test-retest reliability of the OSPRO-YF, the ÖMPQ-21, and their short forms were excellent. The measurement error analysis revealed a Standard Error of Measurement (SEM) of 6.7 points, a Minimal Detectable Change (MDC) of 18.6 points for ÖMPQ-21, a SEM of 2.3 points, and a MDC of 6.4 points for OSPRO-YF. The construct validity of the OSPRO-YF and ÖMPQ-21 and its 10-item short version was satisfactory and moderate. OSPRO-YF performed better than ÖMPQ-21 on all three measurement properties.
Conclusion: OSPRO-YF, ÖMPQ-21, and their short versions are reliable and valid for identifying 'yellow flags' in Italian patients with LBP, with the former generally performing better than the latter. Further research is needed to confirm their ability to predict outcomes in patients with LBP.

1. Introduction

Low back pain (LBP) is a symptom defined as "pain in the area on the posterior aspect of the body from the lower margin of the twelfth ribs to the lower gluteal folds with or without pain referred into one or both lower limbs that last for at least one day" (Hoy et al., 2014). LBP is the leading cause of disability globally. Moreover, central Europe has the highest age-standardized prevalence rate in the Global Burden of Disease study (Collaborators, 2023). The prevalence projection for 2050 is increasing, with an expectation of over 800 million LBP patients being prevalent cases worldwide (Collaborators, 2023). In most patients, it is impossible to find a specific pathoanatomical cause through history and physical examination; therefore, patients are labeled as having nonspecific LBP (Chiarotto and Koes, 2022). The most relevant prognostic factors for developing persistent LBP are coping behavior, nonorganic signs, functional impairment, general health status, and

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psychiatric comorbidities (Chou and Shekelle, 2010).

The early detection of prognostic factors for developing persistent disability and pain is crucial in people with LBP (Melloh et al., 2013). Several questionnaires have been developed to screen for psychosocial prognostic factors (Pauli et al., 2019). The Örebro Musculoskeletal Pain Screening Questionnaire (ÖMPQ-21) and the StarT Back Screening Tool (Lheureux and Berquin, 2019; Maggiani and Abenavol, 2019) are probably the most frequently studied and used instruments demonstrating superior predictive validity compared with other instruments (Pauli et al., 2019). Another recent tool, i.e., the Optimal Screening for Prediction of Referral and Outcome Yellow Flag (OSPRO-YF), distinguishes itself from other multidimensional tools by measuring catastrophizing, positive coping, negative mood, and fear avoidance factors, and it is suitable as an assessment tool for pain-related prognostic psychological factors (Butera et al., 2020; George et al., 2018). The OSPRO-YF can predict pain and disability improvement in patients with LBP (Neeley et al., 2022). The OSPRO-YF and ÖMPQ-21 have been validated in several languages (e.g., Hausa, Spanish, Arabic, French, Persian, Chinese) (Cuesta-Vargas, 2014) (Alanazi and Alrwaily, 2023; Ahmed et al., 2021; Hilfiker et al., 2016; Shafeei et al., 2017) with moderate to good construct validity, concurrent criterion-related validity, predictive validity, and test-retest reliability (Butera et al., 2020). However, an Italian version of these instruments is not available.

While the STarT Back Tool was cross-culturally adapted into Italian (Maggiani and Abenavol, 2019), the lack of an Italian version of OSPRO-YF and ÖMPQ-21 limits the clinical use of these tools in national and international studies, like multicenter studies. Therefore, this study aimed to conduct an Italian translation and cross-cultural adaptation of OSPRO-YF and ÖMPQ-21 and their short versions, and to evaluate their measurement properties (i.e., validity and reliability) in patients with LBP.

2. Methods

2.1. Study design and ethical approval

The cross-cultural adaptation of OSPRO-YF and ÖMPQ-21 was performed in line with methodological guidance on cross-cultural adaptations of patient-reported outcome measures (PROMs) (Beaton et al., 2000), and the study methodology and data analysis followed the Consensus-based Standards for the selection of health status measurement instruments (COSMIN) recommendations (Beaton et al., 2000; Mokkink et al., 2016). In addition, this study is reported in line with the COSMIN reporting guideline (Gagnier et al., 2021). The Research Ethics Committee of the "Azienda Sanitaria Locale Brindisi" approved this study (Number: 5027-156/17), and all participants signed a written informed consent form before participation.

2.2. Inclusion criteria

We included adult patients (≥18 years old) with nonspecific LBP with acute (<6 weeks), subacute (from 6 to 12 weeks), or persistent (>12 weeks) duration, seeking care at six outpatient rehabilitation clinics in Italy with consecutive recruitment between the February 1, 2018 to the 28th of March 2021. This sample was similar to the population included in the original validation studies of the PROMs under investigation in this study (Hill et al., 2008; Linton and Hallden, 1998; Lentz et al., 2016).

Patients were excluded if they presented a (non-)serious specific cause for the LBP (e.g., fracture, tumor, axial spondyloarthritis, lumbar spinal stenosis, disc herniation) if they had no fluent knowledge of the Italian language (written and spoken), ongoing legal causes, and cognitive impairment (i.e., Mini-Mental State Examination <24 points) (Folstein and McHugh, 1975).

2.3. Measurement instruments

The OSPRO-YF was published by Lentz et al., in 2016 (Lentz et al., 2016) and estimates questionnaire scores from negative coping, negative mood, and positive affect/coping domains indicating high vulnerability and decreased resilience (Lentz et al., 2016). The OSPRO-YF consists of 17 items with a possible score range of 7–90 points, with higher scores indicating elevated levels of negative mood, fear avoidance, and positive affect/coping. It was validated with neck, shoulder, LBP, and knee disease patients and used in outpatient clinics with paper-mode administration (George et al., 2018). The 10-item (OSPRO-YF 10 items) and 7-item (OSPRO-YF 7 items) short forms have also an acceptable accuracy in predicting yellow flags (81% and 75% respectively), and they include at least 1 item representative of each psychological domain, regardless of the number of items (Lentz et al., 2016).

The ÖMPQ-21 is a screening tool that was developed to detect "yellow flags" and identify potential psychosocial prognostic factors associated with future sick absenteeism (Linton and Hallden, 1998). It was validated on patients with acute, subacute, and persistent back pain and used in primary care clinics with two modes of administration (i.e., paper or computer) (Linton and Hallden, 1998; Linton et al., 2011a; Langenfeld et al., 2018). It is a self-administered questionnaire with 25 items, but only 21 items (not items 1–4) are used to calculate the total score. The total score range is from 0 to 10 points for each item, with one flipped over in the negative questions (i.e., items 16, 17, 21–25). The total score is the sum of the questions from 5 to 25, ranging from 2 to 210 points, with higher scores indicating a higher risk of persistent pain and disability associated with psychosocial factors. In the 10-item short form (ÖMPQ-21 short form), the score ranges from 1 to 10 points for the first item and 0 to 10 points for subsequent items. Negative questions (items 3, 4, 8) are flipped. The total scores may range from 1 to 100 points, and higher scores indicate higher levels of estimated risk for developing pain-related disability (Linton et al., 2011b). The ÖMPQ-21 short form has a high correlation with the long form (0.91) and can be predicted as well as the original version (Linton et al., 2011a).

The ÖMPQ-21 short form has also been validated in Swedish, German, Chinese, and Japanese (Linton et al., 2011a; Gabel et al., 2013) with work-injured populations or patients with acute or persistent musculoskeletal complaints (Linton et al., 2011b).

2.4. Comparator instruments

The Numerical Pain Rating Scale (NPRS) is a self-compiled tool evaluating pain intensity in different conditions (Hartrick et al., 2003). The NPRS is an 11-point scale consisting of integers from 0 through 10 points; 0 represents "no pain", while 10 represents "worst imaginable pain." Respondents select the single number that best represents their pain intensity. The NPRS is a reliable tool for patients with LBP (Chiarotto et al., 2019).

The Oswestry Disability Index (ODI) is a self-administered questionnaire with ten items scored on a 6-point Likert scale to assess disability and pain due to LBP (Fairbank and Pynsent, 2000). Each item ranges from 0 to 5 points, and the sum of the ten scores is expressed in the percentage of the maximum scores. A score of 0 points means no disability, and 100 points is the leading disability achieved. The Italian version administered in this study showed sufficient unidimensionality, high internal consistency, satisfactory construct validity, and good test-retest reliability in patients with LBP (Monticone et al., 2009).

The Pain Catastrophizing Scale (PCS) is a self-administered 13-item questionnaire that assesses negative thoughts and feelings about pain (M.J., 1995). Each item ranges from 0 to 4 points; the total score is the sum of the 13 item scores. Higher scores indicate higher levels of catastrophization (maximum = 52 points). The Italian version was used in this study and showed good measurement properties in persistent LBP patients (Meroni et al., 2015).

The Pain Self-Efficacy Questionnaire Short form (PSEQ) is a self-compiled 10-item questionnaire to assess pain self-efficacy in daily activities or general aspects of life (Nicholas, 2007). Each item score ranges from 0 to 6 points; the sum of the ten scores composes the total score. Higher scores indicate higher pain self-efficacy (maximum = 60 points). In this study, the cross-culturally adapted Italian version was used (Chiarotto et al., 2015).

2.5. Cross-cultural adaptation

Based on Beaton's guidelines for PROMs (Beaton et al., 2000), the OSPRO-YF and the ÖMPQ-21 were cross-culturally adapted into Italian. The translation was performed with the permission of the original authors.

Step 1 - Forward translation into Italian: the Scientific Committee (SC) of the study (consisting of FB, AC, DA, AA, and PM) appointed the English-Italian translation to two graduate professionals in the Italian mother tongue. The SC consisted of five Italian physical therapists specialized in neuro-musculoskeletal disorders and/or assessing PROMs. An Italian retired engineer was the first translator with a proficient English level, no medical background, and no knowledge of ÖMPQ-21 and OSPRO-YF construct. The second was an English writer, a native Italian speaker, without knowledge of the questionnaire construct.
Step 2 - Synthesis: after carefully examining both translations, the SC unanimously decided on the final version. Factors such as clarity, precision, and ease of understanding were considered.
Step 3 - Backward translation to English: The back-translation involved two Italian mother-tongue translators who were fluent in English. The first (EM) was a physiotherapist with 30 years of research experience; the second (ME) was an English professional translator without a medical background. Both translators were blinded to the original manuscript.
Step 4 - Expert committee: the committee comprised three physiotherapists with clinical experience and lectures in manual therapy with LBP diseases (FB, AC, DA), one English mother tongue (PM), and one physiotherapist with expertise in clinimetrics (AC). The two translations were compared from semantic, idiomatic, and conceptual perspectives.
Step 5 - Pretesting: the pre-final draft version was judged for comprehensibility by ten patients with LBP, which was in line with the study inclusion criteria. Finally, the Italian versions of the OSPRO-YF and the ÖMPQ-21 were generated.

2.6. Procedures

At baseline, the OSPRO-YF, ÖMPQ-21, NPRS, ODI, PCS-I, and PSEQ were administered alongside demographic and clinical data. All were outpatients in a primary care clinic and were treated by physiotherapists specialized in neuromusculoskeletal disorders. To assess test-retest reliability, the OSPRO-YF and ÖMPQ-21 were administered in a subsample of subjects after 5–7 days without treatment.

2.7. Statistical analysis

Firstly, descriptive statistics were computed to describe the collected variables at baseline. Secondly, feasibility was evaluated regarding administration time, missing/multiple responses, and floor/ceiling effects (detected if more than 15% of the patients obtained the lowest or highest score, respectively) (Terwee et al., 2007). Thirdly, reliability was assessed in terms of internal consistency, test-retest reliability and measurement error. Cronbach's alpha (Bland and Altman, 1997) was computed to evaluate the internal consistency of both instruments and their short form; Cronbach's alpha values are recommended between 0.70 and 0.95 (Terwee et al., 2007). Test-retest reliability was studied by means of the Intraclass Correlation Coefficient ($ICC_{agreement}$) with its 95% confidence interval. ICC was judged as poor, moderate, good, or excellent for ICC<0.50, 0.50<ICC<0.75, 0.75<ICC<0.90, and ICC>0.90, respectively (Koo and Li, 2016). Measurement error was assessed by calculating the Standard Error of the Measurement (SEM) and the Minimal Detectable Change (MDC). The SEM was determined with the following formula: $SEM = SD^*\sqrt{(1–ICC)}$, where SD is the baseline standard deviation, and the ICC value refers to test-retest reliability. The MDC was calculated by multiplying the SEM by the z-score associated with the 95% confidence level (i.e., 1.96) and the square root of 2 (Terwee et al., 2007). An MDC lower than 20% of the scale range was considered sufficient (Chiarotto et al., 2016). Fourthly, the validity of the construct was assessed through hypothesis testing. As data on the measurement instruments is ordinal, a Spearman correlation coefficient (ρ) was computed to study the correlation between OSPRO-YF, ÖMPQ-21 and their short forms, and the other administrated PROMs. The strength of correlation was judged as follows: $\rho \geq 0.70$ = strong correlation, $0.50 \geq \rho < 0.70$ = moderate correlation, and $\rho < 0.50$ = weak correlation (B, 2000). The following hypotheses were made:

1. The correlation between the OSPRO-YF, ÖMPQ-21 and their short forms with NPRS is (i.e., $\rho < 0.50$) due to the fact the construct of the questionnaires are primarily focused on yellow flags, which are psychosocial risk factors, rather than pain intensity. Previous research has shown that psychosocial factors and pain intensity are related but not strongly correlated, as they reflect different dimensions of the pain experience (Wertli et al., 2014).
2. The correlation between the OSPRO-YF, ÖMPQ-21 and their short forms with ODI is weak (i.e., $\rho < 0.50$). The weaker correlation is because the questionnaires focus more on the psychosocial context rather than the physical aspect of disability. While they are moderately related to disability, they primarily capture different constructs, which leads to weaker correlations with physical disability indices (Linton and Boersma, 2003).
3. The correlation between OSPRO-YF, ÖMPQ-21, and their shortened forms with PCS is moderate (i.e., $0.50 \leq \rho < 0.70$). The Pain Catastrophizing Scale (PCS) measures pain-related cognitive and emotional responses. The OSPRO-YF and ÖMPQ-21 partially address these aspects, and a moderate correlation is expected between the tools (Alhowimel et al., 2018).
4. The correlation between the OSPRO-YF, ÖMPQ-21 and their short forms with PSEQ is moderate (i.e., $0.50 \leq \rho < 0.70$) as a consideration of the challenge to change this aspect during the treatment (Varkey et al., 2022).

Construct validity was judged as satisfactory, moderate, or low if ≥75%, ≥50%, but <75% and <50% of hypotheses were met, respectively (Prinsen et al., 2016).

For the internal consistency, test-retest reliability, measurement error and hypotheses testing were considered the full and the short forms of the OSPRO-YF (7 and 10 items) and the ÖMPQ-21 (short form). The correlation between the two questionnaires was analyzed. SPSS software (version 21 for Windows; SPSS Inc., Chicago, IL; 2004) was used for all statistical analyses, and the α value was set for $p < 0.05$.

3. Results

3.1. Translation and cross-cultural adaptation

The cultural adaptation process of the Italian version of the OSPRO-YF and the ÖMPQ-21 lasted for around 40 days. The Italian translations of the OSPRO-YF and ÖMPQ-21 were completed without issues. Notably, there was no disagreement between the translators during the translation process. The expert committee thoroughly analyzed the two translated versions of the OSPRO-YF and ÖMPQ-21 and agreed on their semantic, idiomatic, experiential, and conceptual equivalence. A few

discrepancies were noted between the initial translations and the original version of the instrument. Still, the Italian translation (a synthesis of the two translations) was largely accurate. The pre-final version was tested on ten patients with nonspecific LBP. They confirmed its comprehensibility, stating that it contained no unclear words or awkward sentences. The Italian versions of the OSPRO-YF and the ÖMPQ-21 are reported in Appendix 1 and 2, respectively.

3.2. Sample characteristics

Eighty-three patients (mean age±SD = 47.0 ± 15.2 years; 56.6% female) with nonspecific LBP participated in this clinimetric study. Detailed demographic and clinical characteristics of the sample are reported in Table 1.

3.3. Feasibility

The questionnaire OSPRO-YF was completed in an average ± SD time of 3.5 ± 2.2 min to complete, ranging from 1.5 to 14.0 min, while the ÖMPQ-21 was completed in 4.6 ± 3.2 min, with completion times ranging from 1.0 to 15.0 min. A few missing responses were found in the OSPRO-YF (2 missing items out of 1411 responses) and the ÖMPQ-21 (17 missing items out of 2075 responses). No floor or ceiling effects were reported for both instruments and their short forms.

3.4. Reliability

The reliability findings and the average score for all the questionnaires are reported in Table 2. For internal consistency (calculated on the entire sample), we observed low Cronbach's alpha for both instruments and their short versions (Cronbach's alpha = 0.654, 0.620, 0.552, 0.685, 0.657 for OSPRO-YF, OSPRO-YF 10-items, OSPRO-YF 7-items, ÖMPQ-21, and ÖMPQ short forms, respectively).

The sample size considered was 31 patients, and the re-test mean ± SD score was 31.5 ± 8.4 points for OSPRO-YF and 93.6 ± 16.2 points for ÖMPQ-21. Test-retest reliability was excellent for OSPRO-YF and its short versions (ICC = 0.92, 95% CI = 0.84–0.97 for OSPRO-YF; ICC = 0.92, 95% CI = 0.84–0.96 for OSPRO 10 items; ICC = 0.92, 95% CI = 0.92–0.98 for OSPRO 7 items). Test-retest reliability was good for ÖMPQ-21and the ÖMPQ short form (ICC = 0.82, 95% CI = 0.65–0.91 for ÖMPQ-21; ICC = 0.80, 95% CI = 0.63–0.90 for ÖMPQ short form).

The measurement error analysis revealed a SEM of 2.3 points (2.8% of the scale range) and a MDC of 6.4 points (7.8%) for the OSPRO-YF. For the OSPRO-YF 10-items and OSPRO-YF 7-items, the SEM was 2.3 points (2.2%) and 1.9 points (1.2%), respectively, with MDC values of 5.2 points (6.2%) and 2.7 points (3.3), respectively.

The analysis of measurement error reported a SEM for the ÖMPQ-21 equal to 6.7 points (3.2% of the scale range) and MDC of 18.6 points (8.9%). In comparison, the ÖMPQ short forms had SEM of 5.0 points (2.4%) and MDC of 14.0 points (6.8%).

3.5. Construct validity

The construct validity of the OSPRO-YF and its short versions was satisfactory, as 4 out of 4 (100%) *a-priori* hypotheses were met. Moreover, the construct validity of the ÖMPQ-21 and ÖMPQ short form was moderate as 2 out of 4 (50%) *a-priori* hypotheses were confirmed (Table 3).

3.6. Correlation between the two instruments

The correlation between different versions of the questionnaires was lower than expected. Specifically, the correlation coefficients for the ÖMPQ-21 and OSPRO-17 ranged from 0.480 to 0.413, indicating a moderate relationship. Similarly, the correlation coefficients for the short form of ÖMPQ and OSPRO-17 ranged from 0.437 to 0.356, which

Table 1
Demographic and clinical characteristics of the sample (N = 83).

	Mean ± SD	Frequency (%)	Median (interquartile range)
Age, *years*	47.0 ± 15.3		
Weight, *kg*	73.5 ± 14.0		
Height, *cm*	171.0 ± 10.1		
BMI, kg/m^2	25.0 ± 3.8		
Gender			
Female		46 (56.1%)	
Male		36 (43.9%)	
Marital Status			
Yes		54 (65.9%)	
No		28 (34.1%)	
Education			
Primary school		4 (4.9%)	
Secondary school		13 (15.9%)	
High school		33 (40.2%)	
College degree		32 (39.0%)	
Occupation			
Employee		35 (42.7%)	
Self-employee		20 (24.4%)	
Retired		13 (15.8%)	
Housewife		6 (7.3%)	
Student		5 (6.1%)	
Not present due to the pain		3 (3.7%)	
Physical Activity[a]			
No activity		33 (40.2%)	
>3 times a week		30 (36.6%)	
<3 times a week		19 (23.2%)	
Treatment time, *months*	12.9 ± 43.8		
Pain duration			
<6 weeks		34 (41.5%)	
between 6 and 12 weeks		13 (15.8%)	
>12 weeks		35 (42.7%)	
Radiating leg pain			
Yes		39 (47.6%)	
No		43 (52.4%)	
Number of physician visits due to pain in the past six months	1.7 ± 2.0		
Number of hours/day resting/ sleeping due to pain	1.9 ± 3.2		
Number of days absent from work due to pain	5.6 ± 22.9		
Current therapies			
Anxiety/Antidepressive		21 (25.6%)	
Fans/steroids		18 (21.7%)	
Painkillers		17 (20.5%)	
Muscle relaxants		9 (10.8%)	
None		18 (21.4%)	
Comorbidities[b]			
Hearth Diseases		25 (30.1%)	
Gastrointestinal diseases		7 (8.4%)	
Anxiety/Depression		7 (8.4%)	
Musculoskeletal disorders other than low back pain		6 (7.2%)	
Endocrine disorders		4 (4.8%)	
Respiratory disease		4 (4.8%)	
Nephrological pathologies		3 (3.6%)	
None		31 (37.3%)	
OSPRO-YF			37.0 (27.5, 43.0)
OSPRO-YF 10 items			20.0 (15.3, 25.0)
OSPRO-YF 7 items			12.0 (8.0, 17.0)
ÖMPQ-21			105.0 (90.0, 121.0)
ÖMPQ short form			52.0 (42.3, 64.5)
NPRS			6.0 (5.0, 7.0)
ODI			22.0 (12.0, 34.9)
PCS			16.0 (11.0, 22.0)
PSEQ			40.0 (32.8, 53.3)

Abbreviations: SD, standard deviation; %, percentage; BMI, Body Mass Index; OSPRO-YF, Optimal Screening for Prediction of Referral and Outcome Yellow

Flag; ÖMPQ, Örebro Musculoskeletal Pain Screening Questionnaire; NPRS, Numeric Pain Rating Scale; ODI, Oswestry Disability Index; PCS, Pain Catastrophizing Scale; PSEQ, Pain Self-efficacy Questionnaire.

[a] Assessed with the datasheet.

[b] 7 patients present more comorbidities.

also reflects a moderate association.

4. Discussion

This study presents the findings of the translation and cross-cultural adaptation process of the OSPRO-YF and ÖMPQ-21 into Italian, and it assesses their measurement properties (i.e., reliability and validity) in patients with nonspecific LBP. Since there were only a few missing values, patients had no difficulty understanding the items of the developed instruments. The instruments were quick to complete, given the average short compilation time encountered. The OSPRO-YF showed excellent test-retest reliability in all versions (ICC >0.90), whereas the ÖMPQ-21 and ÖMPQ short forms reported good test-retest reliability (ICC >0.80). Measurement error was below 20% of the scale range for both instruments. Construct validity was satisfactory for the OSPRO-YF and its short versions, whereas it was moderate for the OMPQ-21 and its short forms. Internal consistency was unsatisfactory for all instruments. Overall, both instruments performed satisfactorily in patients with LBP, with the OSPRO-YF and its short versions performing consistently better than the OMPQ in this study.

For internal consistency, as previously highlighted, we found a low Cronbach's alpha for both instruments and their short versions. However, this measurement property may be of lesser importance for predictive tools. In fact, it is not fundamental that predictive tools have good internal consistency (i.e. high inter-relatedness among items) as long as they can predict future outcomes accurately (Borsboom et al., 2004).

Regarding test-retest reliability results, both instruments are suitable for evaluating an individual's status in clinical practice and research settings. Previous studies supported these results, as OSPRO-YF showed high ICC values in patients with shoulder pathologies (ICC = 0.91, 95% CI = 0.84–0.96). (Razmjou et al., 2021) The original OSPRO-YF considers patients with musculoskeletal pain, also in the low back, for the full version showed excellent reliability (ICC = 0.88), as did the OSPRO-YF 10-items (ICC = 0.85) (Butera, 2020). The ÖMPQ-21 displays comparable outcomes to the Brazilian-Portuguese version (ICC = 0.78; 95% CI = 0.69–0.85) (Fagundes et al., 2015). On the other hand, the Turkish (Öncü et al., 2016), Norwegian (Grotle et al., 2006), German (Langenfeld et al., 2018), Hausa (Ahmed et al., 2021), and Arabic (Alanazi and Alrwaily, 2023) versions of the ÖMPQ-21 showed high test-retest reliability (ICC >0.90).

The measurement error analysis showed an SEM of 2.3 points (2.8%), 1.9 points (2.2%) and 1.0 points (1.2%) and MDC of 6.8 points (7.8%), 5.2 points (6.2%) and 2.7 points (3.3%) for the OSPRO-YF, OSPRO-YF 10-items, and OSPRO-YF 7-items, respectively. At the same time, ÖMPQ-21 and ÖMPQ short form showed a SEM of 6.7 points (3.2%), 5.0 points (2.4%), and a MDC of 18.6 points (8.9%), and 14.0 (6.8%), respectively. To the best of our knowledge, this is the first study to establish the SEM and the MDC for all versions of the OSPRO-YF. The MDC was low in both questionnaires because it was lower than 20%, which is an arbitrary threshold previously used by other authors (Chiarotto et al., 2016). It is important to note that this threshold lacks consensus among clinimetric experts. However, to evaluate the quality of the MDC, clinicians should compare it with the Minimal Important Change (MIC) (Prinsen et al., 2016). The MDC value should be lower than the MIC. These values help the clinicians determine whether a change in score is clinically significant or due to a measurement error. Since there are no published values on the OSPRO-YF MIC, it is difficult to make such a comparison for this measurement tool. The SEM and MDC for the ÖMPQ-21 in patients with LBP found in this study were lower than those of the Brazilian-Portuguese (SEM = 5.0 points for ÖMPQ-21; 6.7 points for ÖMPQ short form; MDC = 25.1 points for ÖMPQ-21and 15.5 points for ÖMPQ short form) and German versions of ÖMPQ-21 (SEM 6.9 points; MDC 19.3 points) (Langenfeld et al., 2018; Fagundes et al., 2015). Also, for the ÖMPQ-21, it is difficult to compare the measurement error values with the MIC, as there are no published MIC values on this instrument.

For construct validity, the hypotheses for OSPRO-YF and its short forms were met. The magnitude of the correlation findings regarding pain intensity, back-related function, pain catastrophizing, and pain self-efficacy align with Razmiou et al.'s study of patients with shoulder diseases (Razmjou et al., 2021). To the best of our knowledge, this is the first study that used the PSEQ for studying the correlation with ÖMPQ-21 for construct validity. In addition, PCS is an outcome considered only in the Arabic ÖMPQ 12-item version and has found a low Pearson's correlation (=0.11) (Alanazi and Alrwaily, 2023). The self-efficacy and catastrophizing constructs are not represented in the ÖMPQ-21 questionnaire, unlike in the OSPRO-YF. On the other hand, OSPRO-YF has an association with the depression component higher than StarTBack (Global and regional, 2018).

This study has several limitations: the relatively small sample size (n = 83), the fact that we have only considered Italian LBP patients to validate the OSPRO-YF and ÖMPQ-21 and not other musculoskeletal pathologies like in the study of Razmjou et al. (2021) According to the COSMIN recommendations, a sample size of at least 100 patients constitutes an element evaluated as 'very good' for the assessment of internal consistency and construct validity. Furthermore, a sample size of between 50 and 99 patients is considered 'adequate' to study test-retest reliability and measurement error (Mokkink et al., 2018). In our study, we included a sample of 82 patients to assess construct validity and a sample of 31 patients to evaluate test-retest reliability and measurement error, which are limitations of the current study. At the same time, considering only LBP patients limits the heterogeneous population study compared to other studies. However, to our knowledge, this is the first study that performed a head-to-head comparison of the reliability and validity of OSPRO and OMPQ in patients with LBP. Head-to-head clinimetric comparison studies have the clear advantage of comparing

Table 2
Test-retest reliability and measurement error of the Italian version of Optimal Screening for Prediction of Referral and Outcome Yellow Flag, Örebro Musculoskeletal Pain Screening Questionnaire and their short versions (N = 31).

Questionnaire	Descriptive statistics		Test-retest reliability	Measurement error			
	Test±SD	Re-test±SD	ICC (95% CI)	SEM	SEM (%)	MDC	MDC (%)
OSPRO-YF	33.2 ± 8.1	31.5 ± 8.4	0.92 (0.84–0.97)	2.3	2.8	6.4	7.8
OSPRO-YF 10 items	18.2 ± 6.4	17.4 ± 6.6	0.92 (0.84–0.96)	1.9	2.2	5.2	6.2
OSPRO-YF 7 items	11.6 ± 4.8	10.8 ± 4.9	0.96 (0.92–0.98)	1.0	1.2	2.7	3.3
ÖMPQ-21	93.7 ± 16	93.6 ± 16.2	0.82 (0.66–0.91)	6.7	3.2	18.6	8.9
ÖMPQ short form	47.0 ± 11.9	46.9 ± 12.1	0.82 (0.65–0.91)	5.0	2.4	14.0	6.8

Abbreviations: SD, Standard deviation; OSPRO-YF, Optimal Screening for Prediction of Referral and Outcome Yellow Flag; ÖMPQ, Örebro Musculoskeletal Pain Screening Questionnaire; ICC, Intraclass Coefficient Correlation; CI, Coefficient Interval; SEM, Standard Error Measurement; %, percentages; MDC, Minimal Detectable Change.

Table 3
Hypothesis testing for Spearman's rank correlation between the Italian version of Optimal Screening for Prediction of Referral and Outcome Yellow Flag, Örebro Musculoskeletal Pain Screening Questionnaire and their short version, and the other administrated patient reported outcome measures (N = 83).

	Hypothesis testing	*Estimated Correlation*	*Hypothesis met?*
OSPRO-YF			
1	The correlation between the OSPRO-YF and NPRS is < 0.50	0.35**	Yes
2	The correlation between the OSPRO-YF and ODI is < 0.50	0.50**	No
3	The correlation between the OSPRO-YF and PCS is ≥ 0.50 and < 0.70	0.53**	Yes
4	The correlation between the OSPRO-YF and PSEQ is ≥ 0.50 and < 0.70	−0.57**	Yes
OSPRO-YF 10 items			
1	The correlation between the OSPRO-YF 10 items and NPRS is < 0.50	0.28*	Yes
2	The correlation between the OSPRO-YF 10 items and ODI is < 0.50	0.50**	No
3	The correlation between the OSPRO-YF 10 items and PCS is ≥ 0.50 and < 0.70	0.51**	Yes
4	The correlation between the OSPRO-YF 10 items and PSEQ is ≥ 0.50 and < 0.70	−0.59**	Yes
OSPRO-YF 7 items			
1	The correlation between the OSPRO-YF 7 items and NPRS is < 0.50	0.21**	Yes
2	The correlation between the OSPRO-YF 7 items and ODI is < 0.50	0.35**	Yes
3	The correlation between the OSPRO-YF 7 items and PCS scores is ≥ 0.50 and < 0.70	0.41**	No
4	The correlation between the OSPRO-YF 7 items and PSEQ is ≥ 0.50 and < 0.70	−0.40**	No
ÖMPQ-21			
1	The correlation between the ÖMPQ-21and NPRS is < 0.50	0.24*	Yes
2	The correlation between the ÖMPQ-21and ODI is < 0.50	0.36**	Yes
3	The correlation between the ÖMPQ-21and PCS is ≥ 0.50 and < 0.70	0.34**	No
4	The correlation between the ÖMPQ-21and PSEQ is ≥ 0.50 and < 0.70	−0.34**	No
ÖMPQ short form			
1	The correlation between the ÖMPQ short form and NPRS is < 0.50	0.28*	Yes
2	The correlation between the ÖMPQ short form and ODI is < 0.50	0.27*	Yes
3	The correlation between the ÖMPQ short form and PCS is ≥ 0.50 and < 0.70	0.37**	No
4	The correlation between the ÖMPQ short form and PSEQ is ≥ 0.50 and < 0.70	−0.30**	No

two or more instruments in the same patient population, determining which may have better measurement properties. This study seems to suggest that the OSPRO-YF has higher test-retest reliability, smaller measurement error, and more satisfactory construct validity than the ÖMPQ-21 in Italian patients with LBP. This has implications for selecting the most appropriate tool in patients with LBP, even though similar instruments (e.g., STarT Back) were not included in the current study. Additionally, this study did not assess the predictive ability of the Italian versions of the OSPRO and ÖMPQ in patients with LBP. It is unclear at this stage which of these tools may perform better in predicting core outcomes. A future head-to-head comparison study involving the two newly developed tools and at least the STarT Back seems important to determine which of the three most frequently used prognostic tools in patients with LBP performs best.

Physiotherapy can be an effective way to treat persistent LBP, improving pain levels and reducing disability and self-efficacy (Varkey et al., 2022).

In future research, a greater sample in different settings and a study that includes different musculoskeletal pathologies will be needed to confirm the single features of the two questionnaires and compare them with similar tools.

In conclusion, the Italian versions of OSPRO-YF and ÖMPQ-21 are valid and reliable tools for screening 'yellow flags' in patients with LBP. In this head-to-head comparison, the OSPRO-YF performed better than the OMPQ-21 in all three assessed measurement properties: test-retest reliability, measurement error, and construct validity. However, their ability to predict outcomes such as pain, disability, pain catastrophizing, and global recovery has to be assessed with future research.

CRediT authorship contribution statement

Francesca Bonetti: Writing – review & editing, Writing – original draft, Project administration, Methodology, Formal analysis, Data curation, Conceptualization. **Domenico Angilecchia:** Data curation, Conceptualization. **Alessandro Agostini:** Data curation. **Paolo Marighetto:** Data curation. **Silvia Minnucci:** Data curation. **Gloria Giglioni:** Data curation. **Leonardo Pellicciari:** Writing – review & editing, Supervision, Methodology, Formal analysis, Conceptualization. **Alessandro Chiarotto:** Supervision, Methodology, Conceptualization.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.msksp.2024.103206.

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