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ORIGINAL RESEARCH

Validation of the Slovakian Version of the "Post-acute (Long) COVID-19 Quality of Life Instrument" and Pilot Study

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Purpose: The aim of our study was to validate a Slovakian translation of the PAC-19QoL instrument among Slovakian patients with post COVID-19 syndrome.

Patients and Methods: The PAC-19QoL instrument was translated into the Slovakian language and administrated to patients with post COVID-19 syndrome. Cronbach's alpha coefficient was used to analyse the internal consistency of the instrument. Construction validity was evaluated by using Pearson's correlation coefficient and Spearman's rank correlation. Scores of patients and controls were compared using Mann–Whitney *U*-test.

Results: Forty-five asymptomatic and forty-one symptomatic participants were included. Forty-one patients with post COVID-19 syndrome completed the PAC-19QoL and EQ-5D-5L questionnaires. PAC-19QoL domain scores were significantly different between symptomatic and asymptomatic participants. All items achieved a Cronbach alpha greater than 0.7. There was a significant correlation between all domains on the test ($p < 0.001$), with the highest correlation of Total ($r = 0.994$) and Domain 1 ($r = 0.991$). Spearman's rank correlation analysis confirmed that the instrument items correlated with the objective PAC-19QoL examination findings.

Conclusion: The Slovakian version of the instrument is valid, reliable and can be a suitable tool for research and daily clinical practice among patients with post COVID-19 syndrome.

Keywords: PAC-19QoL, EQ-5D-5L, validation, post COVID, quality of live

Introduction

As of December 2022, more than 600 million people worldwide have been infected by COVID-19. In Slovakia, more than 2,650,000 people have been infected.[1] Most people with coronavirus (COVID-19) diseases make a full recovery within 12 weeks, however for some people, symptoms can last longer. This syndrome is called long or post COVID-19 syndrome. It is a new condition which is still being studied and there are many definitions[2,3].

According to the World Health Organization (WHO), post/long COVID-19 condition occurs in individuals with a history of probable or confirmed SARS-CoV-2 infection, usually 3 months from the onset of COVID-19 with symptoms that last for at least 2 months and cannot be explained by an alternative diagnosis. The most common symptoms are fatigue, shortness of breath, cognitive dysfunction, muscle aches, loss of smell, problems with concentration and memory (brain fog), insomnia, heart palpitations and others, which generally have an impact on everyday functioning. Symptoms may be a new onset, following initial recovery from an acute COVID-19 episode or persist from the initial illness. Symptoms may also fluctuate or relapse over time.[2,4,5]

Among the specific measures, the five-level EuroQol five-dimensional questionnaire (EQ-5D-5L) is the most recently devised scale. The EQ-5D-5L consists of 2 parts – the EQ-5D-5L descriptive system (EQ-INDEX) and the EQ Visual Analogue scale

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(EQ-VAS). The EQ-INDEX comprises 5 dimensions (mobility, selfcare, usual activities, pain/discomfort, anxiety/depression) and each dimension has 5 levels: no problems, slight problems, moderate problems, severe problems and extreme problems. The EQ-VAS is a patient's subjective assessment of generic health ranging from 0 to 100, with higher scores representing better subjective health experience.[6] As one of the specific disease measures to assess the quality of life of patients with post COVID-19 syndrome is the Post-acute (long) COVID-19 quality of life (PAC-19QoL) instrument.[7] It is one of the new tools used to assess the quality of life, and therefore, it is not yet widely used or validated in other languages. Furthermore, there are currently no published comparable studies that used this tool. It is necessary to focus on understanding the factors leading to poor quality of life and developing follow-up procedures accordingly. Longer follow-up studies in a larger population are necessary to understand the full spectrum of health and social consequences from COVID-19.

The aim of our study was to validate a Slovakian translation of the PAC-19QoL instrument among Slovakian patients with post COVID-19 syndrome.

Materials and Methods

The process of validation was performed according to validation standards.[8] The original PAC-19QoL instrument was created and validated in English.[7] The first step was the author's agreement to translate the instrument into the Slovakian language in accordance with standards. Two English expert translators worked independently to produce two Slovakian versions of the instrument. After consultation and agreement, one version was selected. The confirmed instrument was interpreted back into the original language to check for any possible content inequality between the original instrument and the final translated version.

The instrument consists of 4 domains and 19 subdomains:

1. Psychological (Mood, Isolation, Motivation, Anxiety, Cognition, Expression, Mental Exertion): items 1–18,
2. Physical (Exertion, Pain, Travel, Somnolence, Smell/taste, Breathlessness, Fine motor, Libido): items 19–34,
3. Social (Isolation, Relationships, Hobbies): items 35–41,
4. Work (Ability to work): items 42–44.

The questionnaire uses a five-point scoring system. A lower score indicates a better quality of life. The author of the original instrument was then consulted. After the author's agreement, the final Slovak questionnaire was tested for ambiguous answers among five patients to determine its comprehensibility. After which, the final version was created, and it was this version that was used. The next step was the validation of the Slovak version of the instrument.

All participants had a laboratory-confirmed diagnosis of COVID-19. Participants were identified as asymptomatic when they did not have any persistent symptoms after the outbreak of the COVID-19 disease and did not fulfill the criteria of post COVID-19 syndrome according to WHO (post/long COVID-19 condition occurs in individuals with a history of probable or confirmed SARS-CoV-2 infection, usually 3 months from the onset of COVID-19 with symptoms that last for at least 2 months and cannot be explained by an alternative diagnosis). Participants were identified as symptomatic/with post COVID-19 syndrome (patients) if they presented symptoms and fulfilled the criteria of post COVID-19 syndrome according to WHO. All patients seen at the pneumology outpatient clinic were included in the study between September 2022 and December 2022. All patients who fulfilled the criteria of post COVID-19 syndrome were determined by a pulmonologist. All participants were aware of the purpose of the study and completed the PAC-19QoL and EQ-5D-5L questionnaires. This study was performed in line with the principles of the Declaration of Helsinki. The study was approved by the Ethics Committee. Informed consent was obtained from respondents before completing the questionnaires.

The authors of this study obtained consent to use the EQ-5D-5L questionnaire. Participants also responded to demographic questions (gender, age, height, weight, the course of COVID-19, persistent symptoms, chronic diseases, abuses, etc.).

PAC-19QoL has been tested for content validity, construct validity and internal consistency.

Statistical Analysis

The reliability of the instrument was investigated by its internal consistency using Cronbach alpha. Internal consistency refers to the degree of correlation between the items. A Cronbach alpha of >0.7 has been recommended as acceptable. The responsiveness of PAC-19QoL and EQ-5D-5L were examined by calculating the standardised response mean and the

Table 1 Demographic Characteristics of the Patients and Controls (n = 86)

Variables	Patients (n = 41)	Controls (n = 45)	P value
Male N (%)	26 (63.4)	13 (28.8)	0.0013*
Age (years; average ± SD)	52.53 ± 12.91	46.28 ± 13.09	0.0287**
BMI (average ± SD)	28.24 ± 5.17	25.81 ± 4.94	0.0285**
Chronic diseases N (%)	29 (70.7)	21 (46.6)	0.0239*
Smoking N (%)	13 (31.7)	12 (26.6)	0.6539

Notes: *p < 0.05 (chi-square test); **p < 0.05 (Student's *t*-test).
Abbreviations: N, number; SD, standard deviation.

effect size. To measure the test–retest reliability of the final version, all patients were asked to participate by completing a second instrument (retest) 2 weeks later. The responses of the two completed instruments were then analysed using the Spearman correlation. Scores of patients and controls were compared using the Mann–Whitney *U*-test. The statistical processing of the results was performed in IBM SPSS Statistics for Windows, Version 29.0. We considered $p < 0.05$ to be statistically significant.

The Slovakian and also original (English) version of the instrument are shown in Supplements 1 and 2.

Results

A total of 86 participants were enrolled. Forty-three participants were symptomatic with post COVID-19 syndrome; however, 41 (93.2%) completed the study and 2 (6.8%) were excluded due to incomplete completion of the instrument. Males made up 63.4% of the total number. Duration of post COVID-19 symptoms was 560.63 ± 219.38 (median 579; range 168–1044 days). Thirteen (31.7%) were hospitalised due to COVID-19. The average time of hospitalisation was 21.62 days (median 12; range 3–90 days). Six patients (14.6%) were hospitalized on Intensive Care Unit due to the COVID-19. The average time of hospitalization Intensive Care Unit was 17.33 days (median 18.5; range 5–30 days). Twenty-nine (70.7%) had a chronic disease (diabetes mellitus, hypertension, stroke, asthma, chronic obstructive pulmonary disease, high cholesterol). Demographic characteristics for the patients and controls are shown in Table 1.

In Figure 1, we present a list of the occurring symptoms of post COVID-19 syndrome in sample group.

We can observe the significant differences between the symptomatic and asymptomatic groups in all domains as well as the total score. The mean, standard deviation (SD) of the PAC-19QoL (domain 1–4, and total) and EQ-5D-5L (EQ INDEX, EQ VAS) are shown in Table 2.

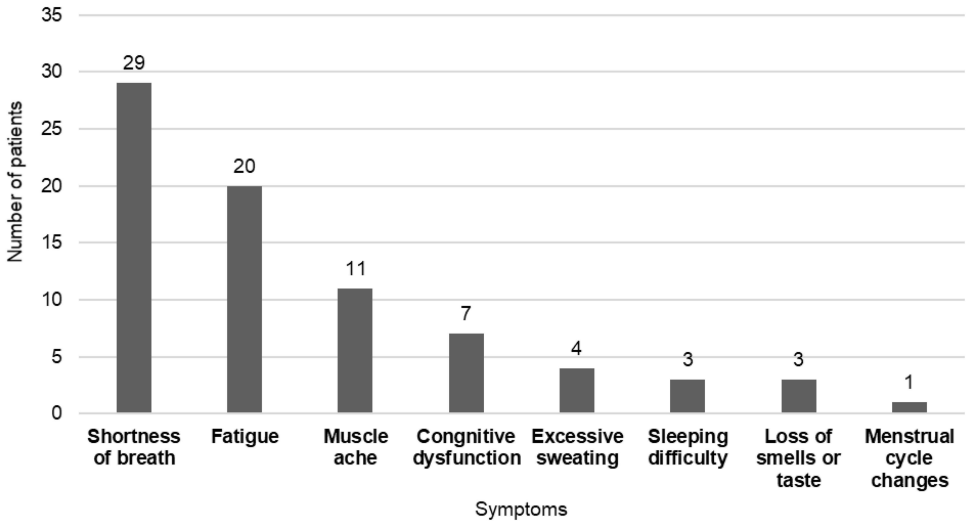

Figure 1 List of post COVID-19 symptoms (N = 41).
Note: patients could also report more than one symptom.

Table 2 Mean Scores for PAC-19QoL and EQ-5Q-5L (n = 86)

Instrument scale	Patients (n = 41)	Controls (n = 45)	P value
	Mean ± SD	Mean ± SD	
Domain 1	44.90 ± 11.6	39.64 ± 7.18	0.0125*
Domain 2	45.90 ± 10.46	27.86 ± 6.32	0.0001**
Domain 3	16.93 ± 6.55	12.80 ± 3.35	0.0003**
Domain 4	8.34 ± 3.47	5.16 ± 1.76	0.0001**
Total	115.66 ± 24.93	85.47 ± 13.48	0.0001**
EQ INDEX	0.73 ± 0.19	0.87 ± 0.20	0.0013*
EQ VAS	63.76 ± 14.05	75.31 ± 17.67	0.0013*

Note: *p < 0.05, **p < 0.001 (Mann–Whitney *U*-test).
Abbreviations: N, number; SD, standard deviation.

All items achieved a Cronbach alpha showing acceptable internal consistency. Cronbach's alpha coefficient for variables of the Slovakian version of the PAC-19QoL instrument is shown in Table 3. There was a significant correlation (test-retest) between all domains on the test ($p < 0.001$), with the highest correlation of Total ($r = 0.994$; $p < 0.001$) and Domain 1 ($r = 0.991$; $p < 0.001$) (Table 3).

Spearman's rank correlation analysis confirmed that the instrument items correlated with the objective PAC-19QoL examination findings. Table 4 shows a comparison of the results of the PAC-19QoL instrument and comparison tool - EQ-5D-5L, there were significant differences in the total score.

Table 3 Cronbach Alpha Coefficient and Reproducibility of PAC-19QoL According to the Test–Retest of the Slovakian Version of the PAC-19QoL Instrument (n = 41)

Variables	Cronbach's Alpha	Test-Retest	
		PCC	p value
Domain 1	0.899	0.991	<0.001
Domain 2	0.864	0.981	<0.001
Domain 3	0.740	0.834	<0.001
Domain 4	0.786	0.919	<0.001
Total score	0.936	0.994	<0.001

Abbreviation: PCC, Pearson's correlation coefficient.

Table 4 Nonparametric Correlations Between PAC-19QoL and EQ-5D-5L

	Domain 1	Domain 2	Domain 3	Domain 4	Total Score
EQ-INDEX	−0.574**	−0.523**	−0.228	−0.339*	−0.565**
EQ-VAS	−0.543**	−0.577**	−0.131	−0.232	−0.559**

Notes: *p < 0.05; **p < 0.01 (Spearman's rank correlation).

Discussion

The quality of life assessment (quality-of-life questionnaire) is a very important tool for assessing the course of the disease or its consequences and treatment. An excellent example is the post COVID-19 syndrome; according to many studies, post COVID-19 syndrome results in a poor quality of life in addition to clinical symptoms.[9–12]

Post COVID-19 syndrome is a multisystem disease characterised by a range of symptoms and clinical signs. In this study, the most common symptoms of post COVID syndrome were shortness of breath, fatigue and muscle pain. According to the prospective cohort study from Italy and retrospective study from Iran, female gender was independently associated with post COVID syndrome. Interestingly, women were characterised by a higher proportion of most physical symptoms and all psychological symptoms than men.[13,14]

The new validated instrument (PAC-19QoL) contains 4 domains (psychological, physical, social and work), which are essential for assessing the quality of life in patients with post COVID-19 syndrome. The questionnaire we used as a reference standard (5Q-5D-5L) contains 5 domains (mobility, selfcare, usual activities, pain/discomfort and anxiety/depression). Nevertheless, it is necessary to evaluate the overall quality of life of patients with post COVID-19 syndrome. Finally, the total score correlates with the compared questionnaire; therefore, we evaluated the instrument as suitable. Our results show a significant difference in the total score of the PAC-19QoL instrument and EQ-5D-5L. Domain 3 (social) of the PAC-19QoL instrument does not correlate with the 5Q-5D-5L questionnaire, because this domain concerns social aspects that the reference standard does not.

Since the PAC-19QoL is a new instrument for assessing the quality of life in patients with post COVID-19 syndrome, there are currently no available studies using this instrument. Our validation study confirmed very good validity and test–retest reliability of the Slovakian version PAC-19QoL. All items achieved a Cronbach alpha greater than 0.7, which is comparable to the original version. In our sample, we can observe significant differences between the symptomatic and asymptomatic groups in all domains as well as the total score.

Furthermore, there are currently no published comparable studies that used PAC-19QoL. Authors of a meta-analysis found that 58% of the post COVID-19 patients had reported poor quality of life. In post COVID-19 patients, the pooled analysis of individual factors in the EQ-5Q-5L questionnaire showed that 41.5% had pain/discomfort, 37.5% had anxiety/depression, followed by 36% had problems with mobility, 28% had problems with usual activities and only 8% had self-care problems.[15] EQ-5D is used to measure the quality of life in patients with post COVID-19 syndrome; it adequately describes the reduction in quality; that's why we chose it as a reference standard for the validation of the PAC-19QoL instrument.

According to the authors from France, the mean EQ-VAS was 70.3 ± 21.5 and the mean EQ-5D index was 0.86 ± 0.20. Authors claim that most patients requiring hospitalisation for COVID-19 still have persistent symptoms.[16] A study conducted by authors from China found that the mean EQ-VAS was 80, and one potential explanation for this phenomenon is that COVID-19 may result in post-traumatic stress disorder.[17] For the health-related quality of life, the mean EQ-VAS and EQ-INDEX values in our sample were 63.76 ± 14.05 and 0.73 ± 0.19.

Our pilot study is the first to evaluate the quality of life in patients with post COVID-19 syndrome via the PAC-19QoL instrument. Consequently, we consider our study for unique and important. We contemplate PAC-19QoL to be a suitable tool that includes all aspects of life that are affected by post COVID contrasting the universal EQ-5Q-5L questionnaire. Another strength is the use of a definite criterion for the selection of patients in the case - The definition according to WHO and also the selection of patients by one pulmonologist. One of the limitations of our study is the small sample size, which we are planning to expand in the future.

Conclusion

In conclusion, we can conclude that the Slovakian version of PAC-19QoL is a reliable, consistent and valid instrument for assessing the quality of life of patients with post COVID-19 syndrome. The Slovakian validated version of PAC-19QoL is a suitable tool for research and daily clinical practice among patients with post COVID-19 syndrome. Due to the large COVID-19 infected population, which has developed post COVID-19 syndrome, we consider the PAC-19QoL instrument to be a unique and specific tool needed for assessing the quality of life among patients with post COVID-19 syndrome.

Ethics Approval and Consent to Participate

This study was performed in line with the principles of the Declaration of Helsinki. The study was approved by the Ethics Committee at the University Hospital in Martin (reference no. EK UNM n. 71/2022). Informed consent was obtained before completing the questionnaires.

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Disclosure

The authors declare that they have no competing interests in this work.

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