The Short Form Endometriosis Health Profile Questionnaire (EHP-5): psychometric validity assessment of a Croatian version

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Abstract

Purpose: To translate, adapt and validate the Endometriosis Health Profile-5 (EHP-5) in Croatian population.

Methods: This validation study is a part of a prospective, observational study (EHP-5 CRO) with aim of implementation of EHP-5 and to provide better insight in quality of life consideration of women with endometriosis in Croatian clinical practice. A 150 consecutive patients with surgically proven endometriosis were enrolled. The translation to Croatian followed standardized procedure. Cronbach's Alpha was calculated to calculate internal consistency reliability of EHP-5. The test-retest reliability was calculated using intraclass correlation coefficient (ICC). The t-test for independent samples was used to assess known-groups validity.

Results: Both EHP-5 core and EHP-5 modular parts of the questionnaire had good internal consistency, assessed by the Cronbach's Alpha coefficient ($\alpha=0.793$ and $\alpha=0.842$, respectively). Obtained results indicate very good reliability for core as well as for modular part of EHP-5 questionnaire (ICC=0.896 and 0.936, respectively). The independent t-test showed that women who reported their pain with VAS scale 7 or more had significantly higher results ($p<0.001$) on EHP-5 (M=50.63) compared with women who reported their pain 6 or less (M=26.91). Furthermore, we found statistically significant difference between women who are infertile with women who are fertile ($p<0.001$), whereby infertile women had higher average result on EHP-5 (M=49.55) compared with fertile women (M=34.36).

Conclusion: The Croatian version of the EHP-5 have very good psychometric characteristics and can be used as a reliable tool for assessing patients with endometriosis in everyday clinical practice.

Introduction

Endometriosis presents one of the most common chronic gynecological conditions associated with cyclic pelvic pain, infertility or both [1, 2]. It affects approximately 20% women hospitalized for pelvic pain and 50% of infertile women [3]. There is a median delay of eight years from first symptom onset to an endometriosis diagnosis which causes a negative impact on the health-related quality of life (HRQoL) [4]. The symptoms of endometriosis vary from mild to severe, but in most cases, women suffering from endometriosis are exposed to monthly intake of analgesics and generally have a poorer HRQoL. Nevertheless, the typical recurrent lower abdominal pain, possible side effects of treatment and lack of understanding by other people have significant negative impact on the personal and psychosocial status of patients' daily life [5, 6]. Given that numerous studies have confirmed an association between endometriosis and poor HRQoL, disease-specific instruments were needed to be developed to assess the aspects of quality of life affected by a specific disease or disorder [7]. Two decades ago, Jones and associates published the Endometriosis Health Profile-30 (EHP-30), one of the first standardized, disease specific instrument that evaluates the HRQoL in women with endometriosis [8]. Although the EHP-30 questionnaire demonstrated high reliability and validity, it presents a lengthy measure [8, 9]. In order to

overcome time impracticality of EHP-30, same group of authors developed Endometriosis Health Profile-5 (EHP-5) [10]. The EHP-5 questionnaire is proved to be a reliable and valid questionnaire with its special feature in clinical settings where an expeditious endometriosis health status measure is required [10–14].

In the Croatian language, there is no validated questionnaire for evaluating the impact of endometriosis on quality of life. The present study was conducted with the aim to translate, adapt and validate the EHP-5 in Croatia.

Methods

Participants and study design

A prospective observational study was conducted between July 2019 and August 2020 at the Department of Obstetrics and Gynecology, University Hospital Center Zagreb, Croatia. The study was approved by the Institutional Review Board and all participants gave their written consent before inclusion. This validation study is a part of a prospective, observational study (EHP-5 CRO) with aim of implementation of EHP-5 and to provide better insight in quality of life consideration of women with endometriosis in Croatian clinical practice. Since our Department has almost 250 operative procedures annually which include ovarian, pelvic and/or extra pelvic endometriosis, we believe that this study will bring new tool not only for preoperative assessment but postoperative surveillance. The study has been previously registered and described at clinicaltrials.gov (Identifier: NCT04491305). To be eligible for participation, subjects are required to fulfill the following conditions: 1) females 18 years or older; 2) pathohistologically confirmed endometriosis after surgical treatment or indicated diagnostic laparoscopy; 3) fluent and literate in Croatian language; and 4) ability to independently understand the questions in the questionnaires. The following are the exclusion criteria: 1) neurological or psychiatric disorders (e.g. epilepsy, multiple sclerosis, depression, schizophrenia); 2) diagnosed vulvodynia and active vulvovaginitis; 3) pregnancy; 4) any form of prior conservative and/or surgical treatment for endometriosis; 5) missing data in any of the responses of the core part of questionnaire and 6) lack of informed consent.

Questionnaires

Endometriosis Health Profile-5 (EHP-5) is a reliable and valid self-report questionnaire to assess health-related quality of life in endometriosis, reffering to the 4 previous weeks. The first part of the questionnaire consists 5 items about pain, control and powerlesness, emotions, social support and self image. The second part contains 6 items about work life, relation with children, sexual intercourse, medical profession, treatment and infertility. Items are scored from 0 (never) to 4 (always). Total score is then transformed on a scale with a range 0 to 100, with the latter indicating worst possible health status [10, 11, 13].

Depression, Anxiety and Stress Scale – 21 (DASS-21) is a 21-item scale designed to assess emotional states of depression, anxiety and stress [15, 16]. Each of those three subscales is based on 7 items, which are all scored from 0 (did not apply to me at all) to 3 (applied to me very much or most of the time). The

total score for each one of the subscales is obtained by summing 7 items and then multiplying them by 2. A higher result indicate higher degree of emotional states of depression, anxiety and stress. The questionnaire has been translated and validated to Croatian and showed very good psychometric characteristics [17].

Visual Analogue Scale (VAS) is a self-report unidimensional measure of pain intensity. A 100 milimeters line represents the continuum from 0 mm (abscence of pain) to 100 mm (unbearable pain). Scores are expressed by measuring the line in millimeters, with results ranging from 0 to 100. The scale has been widely used in diverse adult populations, including those with women suffering from endometriosis [18, 19].

Translation and culture adaptation

The translation to Croatian followed standardized procedure in which expert group, consisted of two gynecologists, a methodologist and an authorized translator, ensured cross-cultural equivalence of questionnaire. The initial translation was carried out independently by the two gynecologists, expert in field of gynecological surgery. They met and discussed discrepancies in translation and created a new, joint version of EHP-5 questionnaire afterwards. A new version was then sent to an authorized translator who did not have access to the original version. Finally, an expert group have reviewed all versions of the translations and concluded that there were no major discrepancies and to ensure that the final version of a translated questionnaire is culturally congruent. Preliminary pilot-testing was conducted on a small sample (N = 20) in order to check if participants understood questions and were asked for suggestions on how to improve the questionnaire. Preliminary results showed that all items from EHP-5 were easily understandable and that the questionnaire was well received. The Croatian version of EHP-5 were then established (Appendix).

Statistical analysis

Continuous data is presented as mean ± standard deviation (SD), while discrete data is presented as frequencies and percentage. Cronbach's Alpha was calculated to calculate internal consistency reliability of EHP-5. The test-retest reliability was calculated using intraclass correlation coefficient (ICC). The t-test for independent samples was used to assess known-groups validity, a type of construct validity, where was explored the ability of the EHP-5 questionnaire to reflect differences between groups who are expected to differ due to their known characteristics. Concurrent validity, a type of criterion validity, was computed in order to assess similar domains between newly translated EHP-5 questionnaire and already known existing measures (VAS and DASS-21). Therefore, Spearman's correlation coefficients were calculated in order to examine the strength of the relationship between similar items from EHP-5 with VAS and DASS-21 subscales. Significance level was set as $p < 0.05$. Data analysis was perfomed using SPSS 23.0 (IBM Corp., Armonk, NY).

Results

Sample characteristics

During the study period, 150 consecutive women with surgically proven endometriosis were enrolled. Among them, 27 women did not fulfill inclusion criteria and 12 women refused to participate. Final analysis included 111 women who completed questionnaires at the initial visit (T_0) and 81 of them completed questionnaires again two weeks after on a control visit or via e-mail (T_1). Baseline characteristics are shown in Table 1.

Table 1
Demographic and clinical data.

	min − max	M ± sd
Age	19−52	34.98 ± 6.784
Bodyweight	49−105	65.43 ± 10.900
BMI	16.8−39.5	23.56 ± 4.411

	0	1	2	3	4
Parity	64 (57.7%)	25 (22.5%)	17 (15.3%)	4 (3.6%)	1 (0.9%)
Cesarean delivery	97 (87.4%)	12 (10.8%)	2 (1.8%)		
		Primary school	High school	University	
Education		28 (25.2%)	37 (33.3%)	46 (41.5%)	
	NO	YES			
Employment	12 (10.8%)	99 (89.2%)			
	Single	Married	Divorced		
Marital status	21 (18.9%)	80 (72.1%)	10 (9.0%)		
	NO	YES			
Prior contraceptive use	79 (71.2%)	32 (28.8%)			
	NO	YES			
Primary sterility	78 (70.3%)	33 (29.7%)			
	1	2	3	4	
rASM stage	29 (26.1%)	59 (53.2%)	20 (18.0%)	3 (2.7%)	
	NO	YES			
DIE	95 (85.6%)	16 (14.4%)			

Reliability

As seen from Table 2, both EHP-5 core and EHP-5 modular parts of the questionnaire had good internal consistency, assessed by the Cronbach's Alpha coefficient ($\alpha = 0.793$ and $\alpha = 0.842$, respectively). Furthermore, test-retest reliability was computed by the Intraclass Correlation Coefficient (ICC), with 81 patients completing EHP-5 on two time points: baseline and two weeks after. Obtained results indicate

very good reliability for core as well as for modular part of EHP-5 questionnaire (0.896 and 0.936, respectively).

Table 2
Cronbach's Alpha internal consistency and Intraclass Correlation Coefficient reliability

	Number of items	Cronbach's Alpha	Test-retest reliability ICC
EHP-5 CORE	5	0.793	0.896 (95% CI 0.859−0.927)
EHP-5 MODULAR	6	0.842	0.936 (95% CI 0.881−0.972)

Construct validity

Known-groups validity was carried out to test the validity of EHP-5 (Table 3). We hypothesized that women who report less pain with VAS scale and who are infertile will report lower quality of life measured by the EHP-5 questionnaire. The independent t-test showed that women who reported their pain with VAS scale 7 or more had significantly higher results ($p < 0.001$) on EHP-5 (M = 50.63) compared with women who reported their pain 6 or less (M = 26.91). Furthermore, we found statistically significant difference between women who are infertile with women who are fertile ($p < 0.001$), whereby infertile women had higher average result on EHP-5 (M = 49.55) compared with fertile women (M = 34.36).

Concurrent validity

Concurrent validity was assessed by correlating VAS and DASS-21 subscales, which both have very good psychometric properties in Croatian, with EHP-5 core items (Table 4). We found statistically significant high correlation between similar domains – 1st item on EHP-5 questionnaire that measures pain with VAS scale ($r = 0.766$, $p < 0.01$). Furthermore, 3rd item (mood swings during the last 4 weeks because of endometriosis) moderately correlated with depressive and anxiety subscales from DASS-21 indicating that women who had more often mood swings have also reported more depressive and anxious symptoms ($r = 0.560$ and $r = 0.486$, respectively).

Table 3
Construct validity – known-groups comparisons

	EHP-5 M ± sd	t-statistic	p-value
Pain VAS			
<7 (N = 55)	26.91 ± 18.571	-6.598	< 0.001
≥7 (N = 56)	50.63 ± 19.284		
Infertility			
No (N = 78)	34.36 ± 22.868	-3.884	< 0.001
Yes (N = 33)	49.55 ± 16.834		

Table 4. Concurrent validity – correlation coefficients between EHP-5 items, VAS and DASS-21 subscales

	1	2	3	4	5	VAS	DEPR	ANX	STR
1	1.000	0.497**	0.138	0.251**	0.417**	0.766**	0.200*	0.184	0.299**
2		1.000	0.401**	0.530**	0.491**	0.645**	0.389**	0.204*	0.384**
3			1.000	0.616**	0.579**	0.127	0.560**	0.486**	0.602**
4				1.000	0.527**	0.247**	0.450**	0.386**	0.513**
5					1.000	0.394**	0.419**	0.284**	0.533**
VAS						1.000	0.165	0.108	0.275**
DEPR							1.000	0.566**	0.686**
ANX								1.000	0.687**
STR									1.000
**p < 0.01; *p < 0.05									

Discussion

The present study provides validity and reliability evidence to support the use of the Croatian version of the EHP-5 in everyday monitoring and measuring HRQoL of women with endometriosis. Our findings, although with negligible distinctions, are principally consistent with only three other EHP-5 cross-cultural adaptations and psychometric evaluations published to date [11, 14, 20]. It is important to emphasize that we have demonstrated very good internal consistency and test-retest reliability of both core and modular part of questionnaire. Moreover, our study signifies pain and infertility as the most detrimental factors on overall quality of life among Croatian women with endometriosis.

In order to avoid a risk of spectrum bias, we have included consecutive patients with pathohistologically proven endometriosis. The rationale for not involving asymptomatic controls in this study was to display EHP-5 performance as true as possible. In the French version of EHP-5 psychometric evaluation, Fauconnier and associates have used purposeful sampling design from two different medical centres in order to have better EHP-5 discriminative validity analysis [20]. Although limitations are inevitable in creating the most favourable target population sample, methodological consensus is still lacking [21].

Another debatable issue is optimal EHP-5 scoring method since there is no precise recommendation from original questionnaire developers [10]. We have adopted evaluation of the dimensional aspect of the EHP-5 separately for the core and the modular part which is consistent to the Turkish and Iranian study [11, 14]. In opposition to separate dimensional aspect evaluation, French EHP-5 version developers have merged all the ratings from core and modular part of questionnaire [20]. A similar scoring method was applied in retrospective study which have estimated impact of laparoscopic treatment of endometriosis on HRQoL [12]. Regardless of implemented scoring method, all abovementioned studies, including ours, have found adequate internal consistency [11, 14, 20].

In terms of internal consistency, our findings are nearly equivalent to Turkish study, showing very good Cronbach's Alpha coefficient of both core and modular part of EHP-5 [11]. This similarity can be explained by comparable initial study setting, inclusion/exclusion criteria and final distribution of disease severity in analyzed sample. Excellent internal consistency (Cronbach $\alpha = 0.92$) reported by Fauconnier et al. should be interpreted with caution, suggesting that some questionnaire items may be redundant [22]. The evaluation of the core and modular part of questionnaires with 2-week test–retest reliability was performed by Turkish authors using Pearson's product moment correlation coefficient, revealing very good consistence across repeated administration of questionnaire [11]. Their findings are consistent with ours although we have evaluated 2-week test–retest reliability via ICC. Other two published EHP-5 validation studies did not assess test-retest reliability [14, 20].

Our study has demonstrated that pain and infertility had the highest possible negative impact on quality of life for patients with endometriosis which is consistent with findings of Turkish and Iranian authors [11, 14]. However, possible cultural differences and baseline characteristics of sample population determined different responding pattern in French validation study, emphasizing sexual intercourse as one of the most detrimental factors on overall quality of life among patients with endometriosis [20].

In conclusion, the Croatian version of the EHP-5 was successfully translated, adapted and validated so the questionnaire is now ready for use as a reliable tool for assessing patients with endometriosis in everyday clinical practice. We believe that this validation study will encourage more researches in field of endometriosis preoperative assessment and postoperative surveillance using EHP-5. This short and simple tool will certainly successfully replace current lack of biomedical markers in tracking the progression of endometriosis.

Declarations

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Author Contributions

All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by Mislav Mikuš, Luka Matak, Goran Vujić, Bernarda Škegro and Ivan Škegro. The first draft of the manuscript was written by Mislav Mikuš and Mario Ćorić and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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