65

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ITALIAN ELECTRONIC PERSONAL ASSESSMENT QUESTIONNAIRE-PELVIC FLOOR (I.EPAQ-PF®): PSYCHOMETRIC VALIDATION OF THE THE URINARY SECTION

Hypothesis / aims of study
Patient Reported Outcome (PRO) questionnaire are increasingly considered the keystone in Pelvic Floor Disorders assessment[1]. An innovative English language multidisciplinary electronic Personal Assessment Questionnaire (ePAQ-PF®) has been psychometrically validated in 2006[2]. A certified Italian version of ePAQ® (I.ePAQ-PF®) has been made available by the Italian Society of Urodynamics (www.siud.it). To assess usefulness and validity of the urinary dimension of I.ePAQ-PF® we tested its psychometric properties.

Study design, materials and methods
Patients presenting for Lower Urinary Tract Symptoms (LUTS) and undergoing Urodynamics (UDS) at our Unit were included. The study received IRB approval. After consent women filled-in the I.ePAQ-PF® via a dedicated touch-screen display (T0). The patients also completed an acceptability questionnaire to rate I.ePAQ-PF® for positive and negative features and some concurrent questionnaires: ICIq-SF, USS, UDI and PGI-I. To test *reliability* the questionnaire was completed again after one week (test-retest) in 47 cases and the Pearson's Coefficient was analyzed. The Spearman's correlation and the acceptability questionnaire were adopted for *validity and face validity*. Finally to assess *responsiveness* the questionnaire was administered again after treatment (T1) and results were analyzed with the Cohen's Effect-Size, the Standardized Response Mean, the Responsiveness Statistic (>30% = considerable change)[2] and the Wilcoxon's test (*p<0.05* for significance).

Results
132 patients (mean age 56 yrs; mean BMI 24; 62% in menopause; UDS diagnosis in 111 women: 28 USI, 28 DO, 31 MI, 8 VD and 18 Normal UDS) were included.Results for *reliability* are shown in table 1, while *Face Validity* is reported in table 2. *Concurrent validity* comparing I.ePAQ-PF® with other questionnaires can be found in table 3. Tests on *responsiveness*, are reported in table 4 and 5.

Interpretation of results
I.ePAQ-PF® seems to be highly *reproducible* (>0,9 Pearson's coefficient) in all domains both at T0 and T1 with the single exception of QoL at T0. More than 95% of patients express a positive view and more than 70% disagree with negative features while judging the questionnaire, with the major concern as to the questionnaire being too long. Spearman's correlation test shows a good correlation (>0.6) between I.ePAQ-PF® domains and corresponding domains of conceptually competitors questionnaires. The questionnaire is also *responsive* to changes: answers in every domain are significantly different between T0 and T1 (tab 4) and this is further confirmed by Cohen's Effect-Size, the Standardized Response Mean and the Responsiveness Statistic, all above the 30%.

Concluding message:
The Italian version of ePAQ-PF® (I.ePAQ-PF®), in its urinary section, fully meets the psychometric properties of *validity, reliability* and *responsiveness*. The questionnaire is now ready for clinical application in Italian language patients.

TAB 1.: Test-retest *reliability* assessment via Pearson's coefficient in 47 women

Test-Retest	PEARSON'S COEFFICIENT		
Domain	*Global* (47 patients)	*T0* (18 patients)	*T1* (29 patients)
Pain	0.9657	0.9628	0.9496
Voiding	0.9405	0.9106	0.9594
Overactive Bladder	0.9501	0.9167	0.9814
Urinary Stress Incontince	0.9778	0.9635	0.9931
Quality of Life	0.9186	0.7577	0.9852

TAB 2.: *Acceptability* questionnaire: average score for every question

Positive features				
(Strongly Agree = 1, Somewhat Agree = 2 , Indifferent = 3, Somewhat Disagree = 4, Strongly Disagree= 5)				
Helpful	Relevant	Straightforward	Comprehensive	Willing to repeat
1,22	1,22	1,31	1,38	1,35

Negative features			
(Strongly Agree = 1, Somewhat Agree = 2 , Indifferent = 3, Somewhat Disagree = 4, Strongly Disagree= 5)			
Overlong	Upsetting	Complicated	Embarrassing
4,02	4,60	4,55	4,58

TAB3.: *Concurrent validity*: I.ePAQ® vs concurrent questionnaires

SPEARMAN'S CORRELATION

Concurrent Validity	USS	ICIq	UDI		
	USS	ICI score	Score OS	Score IS	Score SUI
ePAQ Pain	0,3782	0,2535	0,5783	0,4327	0,2149
Voiding	0,3489	0,2389	0,7067	0,3727	0,1070
Overactive Bladder	0,6904	0,5572	0,3189	0,6730	0,3769
Urinary Stress Incontinence	0,3973	0,7322	0,2117	0,5009	0,6157
Quality of Life	0,5108	0,6822	0,3280	0,5415	0,4648
Concurrent Questionnaires USS	1	0,5597	0,4024	0,6453	0,2848
ICI score	0,5597	1	0,3339	0,6505	0,5374
Score OS	0,4024	0,3339	1	0,4761	0,2381
Score IS	0,6453	0,6505	0,4761	1	0,5042
Score SUI	0,2848	0,5374	0,2381	0,5042	1

TAB4.: *Responsiveness* via Wilcoxon test in 67 women after treatment

WILCOXON'S TEST

Significance			
Domains	T0 average ± SD ; median (range)	T1 average ± SD ; median (range)	p-value
Pain	11,37 ± 18,39; 0 (0-67)	5,43 ± 13,78; 0 (0-56)	0.0020
Voiding	20,37 ± 20,44; 17 (0-75)	13,15 ± 18,80; 0 (0-83)	0.0030
Overactive Bladder	28,00 ± 22,36; 25 (0-83)	12,55 ± 15,95; 8 (0-67)	< 0.0001
Urinary Stress Incontince	38,73 ± 21,65; 40 (0-87)	15,96 ± 18,52; 13 (0-80)	< 0.0001
Quality of Life	49,39 ± 30,12; 44 (0-100)	22,64 ± 26,99; 11 (0-100)	< 0.0001

TAB5.: *Responsiveness* via specific coefficients in 67 women after treatment

Domain	Effect Size di Cohen	Standardized response mean	Responsiveness statistic
Pain	-32.4%	-41.1%	-57.6%
Voiding	-35.3%	-40.3%	-62.3%
Overactive Bladder	-69.0%	-59.0%	-98.0%
Urinary Stress Incontinence	-105.2%	-82.8%	-241.7%
Quality of Life	-89.1%	-71.1%	-81.6%

References
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2. Radley, S. C., Jones, G. L., Tanguy, E. A., Stevens, V. G. & Nelson, C. Computer interviewing in urogynaecology?: concept , development and psychometric testing of an electronic pelvic floor assessment questionnaire in primary and secondary care.