207

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VALIDATION OF A MODIFIED NATIONAL INSTITUTES OF HEALTH SYMPTOM INDEX TO ASSESS GENITOURINARY PAIN IN MEN AND WOMEN

Hypothesis / aims of study

Until now, no condition-specific instrument has been available to assess the degree of symptoms in both men and women with urologic pain conditions. Such an instrument would be useful for assessing treatment response in clinical trials involving men and women.

Study design, materials and methods

We developed the Genitourinary Pain Index (GUPI) from the NIH Chronic Prostatitis Symptom Index, yielding a questionnaire with a score range of 0-45 for both men and women. To assess discriminant validity, concurrent validity, and reliability, we administered the GUPI to 1653 men and 1403 women in the Kaiser Permanente Northwest (KPNW) population. To assess responsiveness, we administered the GUPI to 47 men and women who completed an NIH-sponsored trial of pelvic floor physical therapy.

Results

The GUPI discriminated between men with chronic prostatitis or interstitial cystitis, men with other symptomatic conditions (dysuria, frequency, chronic cystitis), and men with none of these diagnoses ($p<0.05$). It also discriminated between women with interstitial cystitis, women with incontinence, and women with none of these diagnoses ($p<0.05$). The GUPI demonstrated good internal consistency (Cronbach's alpha 0.74-0.88) within subscale domains, and GUPI scores correlated highly with scores on the Interstitial Cystitis Symptom Index and Problem Index. The GUPI was highly responsive to change, and the change in score was similar in both male and female responders. A reduction of 7 points robustly predicted being a treatment responder (sensitivity 100%, specificity 76%).

	Responders (n= 18)				**Nonresponders (n=26)**			
Mean GUPI Scores	**Pre-Tx**	**Post-Tx**	**Change(%)**	**p***	**Pre-Tx**	**Post-Tx**	**Change (%)**	**p***
Men (n =23)								
Total	**29.4±6.6**	**13.0±6.1**	**-16.4 (-55.8)**	**0.0002**	33.0±1.6	28.6±7.7	-4.4 (-13.3)	0.09
Pain	13.5±2.6	5.5±3.6	-8.0 (-59.3)	0.0002	16.0±3.1	13.7±4.4	-2.5 (-15.6)	0.19
Urinary	6.4±3.4	3.2±1.9	-3.2 (-50.0)	0.003	7.2±2.3	6.1±2.5	-0.9 (-12.5)	0.30
QOL	9.5±2.0	4.3±2.6	-5.2 (-54.7)	0.0002	9.9±2.3	8.8±2.6	-0.9 (-9.1)	0.13
Women (n=21)								
Total	**30.6±5.8**	**12.4±7.8**	**-18.2 (-59.5)**	**0.06**	34.8±4.4	32.5±6.5	-2.3 (-6.6)	0.25
Pain	13.5±2.6	6.4±4.6	-7.1 (-52.6)	0.06	16.3±2.7	15.6±3.8	-0.7 (-4.3)	0.67
Urinary	7.6±2.8	2.8±1.8	-4.8 (-63.2)	0.06	7.9±2.4	7.9±2.5	-0.0 (0.0)	0.57
QOL	9.5±1.6	3.2±2.8	-6.3 (-66.3)	0.06	10.5±1.2	9.0±2.3	-1.5 (-14.3)	0.002
All (n=44)								
Total	**29.7±6.2**	**12.8±6.3**	**-16.9 (-56.9)**	**<.0001**	34.1±5.0	31.1±7.1	-3.1 (-9.1)	0.03
Pain	13.5±2.6	5.8±3.8	-7.8 (-57.8)	<.0001	16.2±2.8	14.9±4.0	-1.4 (-8.6)	0.24
Urinary	6.7±3.2	3.1±1.8	-3.7 (-55.2)	<.0001	7.6±2.3	7.2±2.6	-0.4 (-5.3)	0.75
QOL	9.5±1.9	4.0±2.6	-5.5 (-57.9)	0.0001	10.3±1.7	8.9±2.4	-1.3 (-12.6)	0.001

*signed rank test

Interpretation of results

The performance characteristics of the GUPI are very similar in men and women with urologic pain conditions, with similar mean scores and responsiveness characteristics.

Concluding message

The GUPI is a valid, reliable and responsive instrument that can be used to assess the degree of symptoms in both men and women with genitourinary pain complaints. It may be useful a useful instrument in clinical trials and epidemiologic studies which include both men and women.

Specify source of funding or grant	**NIDDK**
Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Kaiser Permanente Institutional Review Board** **UCLA School of Medicine Institutional Review Board**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**