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Title (type in CAPITAL LETTERS, leave one blank line before the text):
PSYCHOMETRIC ASSESSMENT AND RESPONSIVENESS OF THREE DIFFERENT HRQoL INSTRUMENTS IN FEMALE URINARY INCONTINENCE

Aims of Study
Subjective measurements of urinary incontinence (UI) severity, and symptom impact on health-related quality of life (HRQoL) as well as assessment of treatment efficacy from the patients' point of view is now recognized as an important aspect, both in clinical practice and research (1).
The purpose of this study was psychometric assessment and functional correlation of three different types of HRQoL measurements: 1. A generic 15D-QoL questionnaire, *2.* A disease-specific Urinary Incontinence Severity Score (UISS)- questionnaire and 3. The visual analogue scale (VAS). The latter is also an accepted tool in research concerning measurement of the impact of disease and effects of medical interventions on HRQoL. However, the studies of the reliability and responsiveness of the VAS designed to measure subjective evaluation of female urinary incontinence are lacking.

Study Methods
This prospective study involved 82 incontinent females suffering of urinary incontinence (mean age 52,range 25-80) referred to a gynaecological department and 29 control women who had urinary incontinence but were not bothered by it and didn't want any medical intervention. All women underwent a standardised 48h pad-testing and frequency/volume chart and 82 patients had complete urodynamic evaluation. 57 (68%) patients had stress,14 (17%) had urge, 11 (13%) mixed incontinence.
All subjects completed the above mentioned quality of life measures. The 15D –generic standardised measure of HRQoL contains fifteen-dimensions :moving, seeing, hearing, breathing, sleeping, eating, communicating, eliminating, working, social participation, mental functioning, pain/ache, depression, distress and perceived health. The score is on a 0-1 scale (0=death, 1=best HRQOL)(2). The UISS questionnaire consists of 10 questions designed to quantify the amount of leakage and the degree to which UI affects aspects of women's daily lives scored 0-2 and yielding a total score between 0 and 20. The women were asked to describe the subjective burden of incontinence on a 100 mm VAS scale which ranged from 0," not bothered" to 10 "severely bothered".
For the UISS and VAS reproducibility assessment women were asked to complete questionnaires again 1 week later. After accurate diagnosis was established, all patients were given conservative or operative treatment according to severity and type of urinary incontinence.
66 patients were re-evaluated 13 months (range 6-21) after the initial examination and initiation of the treatment plan. The patients were classified on the basis of pad test as improved (decreased leakage), stable (no change) or deteriorated (increased leakage). Responsiveness was measured by Guyatt's statistic that is the ratio of the mean change score for each group divided by the standard deviation for the stable group. A statistic of 1.00 or greater (or-1 or less when improvement is denoted by a negative change score) is considered indicative of a measure highly responsive to change.

Results
Internal consistency of UISS measured by Cronbach's alpha was high 0.85. Test-retest correlation for UISS was 0.88 (Spearman rank correlation coefficient $p<0.001$) and for VAS 0.85 ($p<0.001$). There were no differences between UISS, VAS and 15D scores for patients with different diagnoses of UI. The control women's UISS, 15D and VAS scores were significantly lower than patient's scores ($p<0.001$, Mann-Whitney *U* test) which proves good discriminant validity of these measures. The correlation between the scores of the UISS and VAS was strong: at baseline $r=0.73$; after treatment $r=0.85$. UISS and VAS correlations with the total score of the 15D was moderate: $r = -0.45$($p<0.001$) and $r = -0.23$ ($p=0.016$) in the baseline and $r = -0.50$ ($p<0.001$) and $r = -40$ ($p=0.001$) in the follow-up.
The correlation between pad test and UISS, VAS and 15D at baseline was: 0.59(Spearman rank correlation coefficient $p<0.001$), 0.67 ($p<0.001$) and 0.29 ($p=0.004$) respectively. 49 patients were improved after treatment, 12 patients had no change and in 5 patients had deteriorated. The UISS, VAS and 15D in the improved group had responsiveness (Guyatt's) statistics: 1.48, 1.74 and –0.80 respectively. The changes in pad test correlated moderately well with those in the VAS ($r=0.50$ $p<0.001$Spearman) and with those in the UISS ($r=0.30$ $p=0.040$). For the changes in the eliminating dimension of the 15D the correlation was –0.29 ($p=0.035$) but there was no correlation for changes in the total 15D score.

Conclusions
Both UISS and VAS proved to be valid, reproducible and responsive to treatment for UI women. The functionality of the generic 15D was good but it demonstrated less sensitivity to changes following therapeutic intervention than UISS and VAS.

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Title (type in CAPITAL LETTERS, leave one blank line before the text):

DOES CYSTOMETRY AGREE WITH THE EFFECT OF URINARY SYMPTOMS ON QUALITY OF LIFE?

Aims

To investigate whether cystometry findings agree with the symptoms experienced by women diagnosed as having Genuine Stress Incontinence (GSI) or detrusor instability (DI) when compared tothe effect those symptoms have on women's quality of life.

Methods

Results of objective and subjective investigations were examined for 50 consecutive women diagnosed as having GSI and 50 diagnosed as having DI.

Objective Assessment.

Videocystourethrography was performed using contrast medium at a flow rate of 100mls/s. Detrusor instability was diagnosed if a detrusor pressure rise greater than 15cmH_2O occurred, associated with a sensation of urgency, while the woman was attempting to inhibit micturition. Standard cystometric values were recorded. Severity of GSI was graded according to the number of coughs required to produce leakage. An ICS one hour pad test, was also performed on women diagnosed as having GSI.

Subjective Assessment

A seven day frequency volume chart was completed by women prior to attending for VCU. All women had completed a validated condition specific quality of life (QoL) questionnaire before VCU.

Pearson's correlation coefficient was used to examine relationships between the variables. SPSS v8 software was used for statistical analysis.

Results

GSI group: The severity of GSI as graded during VCU or on pad testing agreed closely with the effect of symptoms on women's reported quality of life. This is as expected as the more severe the GSI the greater the effect it would be expected to have on lifestyle.

DI group: - for clarity not all cystometric parameters are shown. Statistically significant results are shown in bold type.

Correlation of QoL scores with cystometry findings and voiding diaries.

	Cystometric Parameters.		Voiding Diaries	
QoL Domain	First desire to void Significance	Max pDet Significance.	Daytime frequency Significance.	Nocturnal frequency Significance
Incontinence impact	0.310	0.242	0.065	0.388
	0.84	0.174	0.73	0.034
Role limitation	0.199	0.072	0.080	0.532
	0.292	0.700	0.679	0.004
Social limitation	0.093	0.031	0.044	0.394
	0.619	0.867	0.81	0.035
Sleep/Energy	0.373	0.308	0.031	0.483
	0.036	0.081	0.86	0.007
Severity measures	0.132	0.034	0.062	0.473
	0.48	0.85	0.745	0.010