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Title: Health-related Quality of Life and Female Urinary Incontinence -  
Evaluation of Measurement and Predictive factors in Specialized Health Care

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#### Abstract

The purpose of this study was to validate two disease-specific health-related quality of life (HRQoL) instruments: Urinary Incontinence Severity Score (UISS) and specific Visual Analogue Scale (VAS), to establish predictors of HRQoL impairment and to assess the effect of incontinence treatment on the HRQoL and its modifying factors in women referred to a specialized health care unit for symptomatic urinary incontinence. According to the predefined inclusion criteria, 123 consecutive women were eligible for the study. Eighty-two incontinent patients (mean age 52, range 28-80) were recruited for the study that included baseline investigation and re-evaluation 13 months (range 6-21) after treatment. Twenty-nine control women, who had urinary incontinence, but were not bothered by it, completed the HRQoL measurements. Patients underwent clinical and urodynamic evaluation, frequency/volume chart, 48h pad-test, estimated the degree of bother from urinary incontinence (UI) using VAS and completed two HRQoL instruments: disease-specific UISS and generic 15D. The psychiatrists evaluated the women's depression and anxiety using a structured interview of the Hamilton Depression Scale and the Hamilton Anxiety Scale. Physical activity was measured by a self-report questionnaire and an electronic motion sensor (Caltrac accelerometer) worn by the women for one week. Patients were classified on the basis of history and urodynamic evaluation into two diagnostic groups: stress urinary incontinence (SUI) (n=57) and idiopathic urge incontinence with or without stress incontinence UII(\*SUI) (n=25). Validation of the HRQoL instruments was done by standard psychometric methods. Internal consistency (Cronbach's alpha 0.85) and content validity of UISS was good. Both measures UISS and VAS were reproducible; Spearman rank correlation between test-retest was 0.88 and 0.85, respectively. The control women's UISS and VAS scores were significantly lower than patient's scores ( $p<0.001$ ), which proves good discriminant validity. UISS and VAS proved to be extremely responsive to treatment for UI women. The generic 15D performed well and appears to be sensitive in detecting change in HRQoL due to treatment of urinary incontinent women. Compared to age-matched female general population, the HRQoL of urinary incontinent women was significantly poorer (mean 0.914 versus 0.836,  $p<0.001$ ). Urge or mixed incontinence impairs HRQoL more than stress incontinence (mean 0.789 versus 0.857,  $p=0.002$ ). The correlation between pad test and VAS, and UISS at baseline was:  $r=0.47$  ( $p<0.001$ ) and  $r=0.25$  ( $p<0.05$ ) respectively. The UISS and 15D scores correlated poorly with urodynamic and frequency/volume chart findings. Major depression occurred in 44.0 % of women with UII(\*SUI) incontinence and in 17.5 % women with SUI [(OR 3.69), 95 % CI 1.30 -10.49]. In addition co-morbid major depression correlated with reduced incontinence-specific HRQoL. Incontinent patients were as physically active as the normal population which suggests that exercise habits may

influence treatment seeking behaviour. Even after successful treatment, exercise habits were not changed. Significant improvement was found in women's HRQoL measured by all three HRQoL instruments after treatment. Among patients with SUI the total score of the 15D was about the same as in the age-matched general female population, but among those with UUI(\*SUI) although improved significantly, did not achieve the HRQoL level of women with SUI at baseline. Poor level of HRQoL at baseline, greater decrease in urine leakage, SUI diagnosis and lower depression scores after treatment predicted greater for the better change in HRQoL scores. Among women with SUI, the surgical treatment predicted better improvement in HRQoL than conservative treatment. The UISS, VAS and 15D proved to be sound HRQoL instruments for the evaluation of the effectiveness of urinary incontinence interventions. Severity of urinary incontinence measured objectively correlate poorly with HRQoL. The treatment of women with SUI had a greater impact on HRQoL improvement than treatment of urge or mixed incontinence. In specialized health care, the effectiveness of surgical treatment on incontinence-specific HRQoL was greater than conservative treatment. Co-morbid depression not only predicted greater impairment of incontinence-specific HRQoL but the high rate of major depression among women with UUI suggests an association between these two conditions.