CONSTRUCT VALIDITY OF THE INCONTINENCE SEVERITY INDEX

Hypothesis / aims of study
The Incontinence Severity Index (ISI) is a questionnaire composed of a two-items which assess the frequency (4 levels) and amount (3 levels) of urine leakage. The index value (1-12) is reached by multiplying the two items. The criterion validity of the ISI has been demonstrated by its high correlation with pad-weight tests [1]. We sought to test the construct validity of the ISI by assessing its correlation with a validated patient questionnaire designed to assess symptom severity, the short form of the Urogenital Distress Inventory (UDI-6).

Study design, materials and methods
A cohort of 170 women with a urodynamic diagnosis of stress incontinence who underwent corrective surgery completed the ISI and the UDI-6 both pre- and post-treatment. After entering the data in an SPSS database, we correlated the pre- and post-treatment responses between the ISI and the UDI-6 and its three subscales (Irritative, Obstructive, and Stress Symptoms). We also assessed the sensitivity of the ISI to change by correlating the percent change in score ([pre-treatment – post-treatment]/pre-treatment score) between the two instruments. Given the non-normal distribution of the data, the results were analyzed using a nonparametric test of correlation, the Spearman’s rho.

Results
The index values of the ISI correlated significantly with the pre-treatment (r=0.36, p<0.001) and post-treatment (r=0.78, p<0.001) UDI-6 scores. The percent change from pre- to post-treatment of the ISI was also strongly correlated with that of the UDI-6 (r=0.76, p<0.001). The ISI was highly correlated with two of the UDI subscales, the UDI-Irritative subscale (r=0.68, p<0.001) and the Stress subscale (r=0.84, p<0.001). The ISI was not significantly correlated with the pre-treatment UDI-Obstructive Symptoms subscale (r=0.14, p=0.22), and it was only moderately correlated with this subscale in post-treatment (r=0.25, p=0.003) scores. The ISI was strongly correlated with the other two UDI subscales, however, at almost every time interval. The correlations of the ISI with the UDI-Irritative Symptoms subscale at pre- (r=0.43, p<0.001) and post-treatment (r=0.73, p<0.001) were significant. The highest correlation in our study was seen between the ISI and UDI-Stress subscale in the post-treatment scores (r=0.84, p<0.001).

Interpretation of results
The ISI was highly correlated with the UDI-6 at pre- and post-operative testing. The fact that the percent change in score was also strongly correlated between the ISI and the UDI suggests that the ISI is highly sensitive to the change in symptom severity seen after treatment. The strong correlation seen in with the Stress and Irritative Symptoms subscales provide evidence for the convergent validity of the ISI, while the weaker correlation seen with the Obstructive Symptoms subscale (more a measure of prolapse symptoms than incontinence) speaks to the divergent validity of the ISI.

Concluding message
The ISI is a simple, two-item questionnaire with high construct validity. The existing evidence of its correlation with pad-weight tests coupled with the strong correlation with measures of patient distress seen in this study strengthen the validity and potential value of the ISI as a clinical research tool.