The Minimum Important Differences for the Urinary Scales of the Pelvic Floor Distress Inventory and Pelvic Floor Impact Questionnaire

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Objective: To determine the minimum important difference (MID) for the urinary scales of the Pelvic Floor Distress Inventory (PFDI) and Pelvic Floor Impact Questionnaire (PFIQ)

Methods: 444 subjects enrolled in a multi--center randomized trial comparing behavioral therapy to an incontinence pessary for stress urinary incontinence completed baseline and 3 month follow-up visits. Eligibility criteria included: age $\geq$18 years, stress-predominant urinary incontinence, >2 stress incontinence episodes on a 7-day bladder diary, and patient desire for non-surgical treatment. At baseline and 3 month follow-up, subjects completed the 7-day diary, the Incontinence Severity Index (ISI), PFDI, and PFIQ. The Patients Global Impression of Improvement (PGI-I) was completed at the 3-month visit. The MID of the Urinary Distress Inventory (UDI),the UDI-stress subscale of the PFDI, and the Urinary Impact Questionnaire (UIQ) of the PFIQ were assessed using anchor- and distribution-based approaches. Higher scores on these measures indicate more distress/impact. Anchors included the PGI-I, ISI, and incontinence episodes on the bladder dairy. Distribution-based measures included effect size and standard error of measurement. Treatment assignment remained blinded and was not assessed in these analyses.

Results: Mean (SD) changes from baseline to 3 months after treatment in UDI, UDI-stress and UIQ scores were -33(39), -19 (22), and -33(44) points, respectively. The MID based on the PGI-I (difference in scores between subjects who indicated they were "better" vs. those who responded "about the same") was -6.4, -4.6 and -6.5 for the UDI, UDI-stress and UIQ, respectively. MID determined by the other anchor-based methods (ISI and bladder diary) were greater than those for the PGI-I and similar to the distribution-based findings. (Table)

Conclusion: The MID of the urinary scales of the PFDI and PFIQ are smaller from a patient's perspective than when objective criteria are used. While differences in scores of the UDI, UDI-stress and UIQ greater than 11, 7.5, and 16 points respectively should be considered clinically important, incontinent women may be able to perceive smaller differences. The impact of these smaller differences on quality of life improvement requires further study.

MID of UDI, UDI-Stress and UIQ using Anchor- and Distribution-Based Methods.

		Change from baseline to 3 months after treatment in		
Anchor-based methods	Criteria	UDI	UDI-Stress	UIQ
PGI-I, patient global impression of improvement	Difference in scores between patients reporting "Better" and those reporting "About the Same"	-6.4	-4.6	-6.5
Change in UIE, urinary incontinence episodes	Difference in scores between patients with > 25% improvement and those with no change*	-22	-16	-17
Incontinence Severity Index	Difference in scores between patients with one level of improvement on ISI and those with no change	-11	-7.5	-16
		Baseline		
Distribution-based methods		UDI	UDI-Stress	UIQ
Effect size	0.5 SD (standard deviation)	-20.3	-18.2	-19.4
Standard error of Measurement (SEM)	1 SEM	-15.6	-24.4	-7.9

* no change defined as $\pm$25% change from baseline to 3 months in UIE