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THE MINIMUM CLINICALLY IMPORTANT DIFFERENCE IN INCONTINENCE QUALITY OF LIFE QUESTIONNAIRE (I-QOL) TOTAL AND SUBSCALE SCORES IN WOMEN WITH STRESS URINARY INCONTINENCE (SUI)

Hypothesis / aims of study

Health related quality-of-life instruments translate a patient's evaluation of the impact of a disease on daily life, for example on physical and social functioning, into a score that represents a continuous variable. When using this score to quantify improvements in a disease state with treatment, it is important to evaluate both the statistical significance and the clinical relevance of an observed improvement. The aim of this study was to set two important clinical relevance reference points for the I-QOL questionnaire total and subscale scores in women with SUI: the within-treatment minimal clinically important difference (MCID) and the between-treatment MCID. The within-treatment MCID is defined as the I-QOL score increase with treatment at which patients first recognize that they are improved. For a treatment effect to be relevant, it should exceed the within-treatment MCID. The between-treatment MCID is the difference between the I-QOL score increase at which patients first perceive that they are improved and the increase at which they perceive they are unchanged. For one treatment's effect to be considered relevantly different from another treatment's effect, the difference in effects should exceed this between-treatment MCID threshold.

Study design, materials and methods

The analysis included 1133 US women with predominant SUI enrolled in two randomized, placebo-controlled studies [1,2]. Subjects were randomized to receive placebo (n=425) or one of three doses of duloxetine (n=708) for 12 weeks. Real-time urinary diaries were completed along with two validated patient-reported outcome instruments: the Patient Global Impression of Improvement scale (PGI-I – with seven ratings, see table 1) [3] and the I-QOL [4,5] questionnaire. The I-QOL yields a total and three subscale scores [4]. The within and between-treatment MCIDs were obtained by anchoring the I-QOL scores to the PGI-I rating, regardless of treatment assignment. The within-treatment MCID was derived as the mean I-QOL score for the group of women that rated their improvement with treatment as "a little better" on their last PGI-I. The between-treatment MCID was derived as the difference in mean I-QOL scores between the group of women that recorded a "no change" rating and the group that recorded "a little better" rating on their last visit PGI-I. Placebo and duloxetine 80 mg/day treatment differences in I-QOL scores were analyzed for statistical significance using an ANCOVA model. The number of patients needed to treat in order to gain one additional responder with duloxetine compared with placebo was calculated using the ratio $1 \div (p2-p1)$ where p1 and p2 are the proportions of subjects who exceeded the within-treatment MCID in placebo and duloxetine groups, respectively [6].

Results

Table 1 presents the I-QOL score data by PGI-I category. The within and between-treatment MCIDs for the total I-QOL score are 6.3 and 2.5, respectively. The total and subscale scores have almost identical MCIDs. Treatment with duloxetine 80 mg significantly improved I-QOL total and all subscale scores compared with placebo (Table 2). In all instances the duloxetine-placebo treatment differences exceeded the between-treatment MCIDs (4.1 for total and 3.6 to 4.5 for subscale) and duloxetine treatment exceeded the within-treatment MCIDs (10.5 for total and 9.4 to 12.1 for subscale). The number of patients needed to treat (NNT) to gain an additional I-QOL responder was 6.8, which compares favorably with NNT values reported in the literature for other treatments.

Table 1. Changes in I-QOL total and subscale scores from baseline to endpoint by PGI-I categories at endpoint

PGI-I Category	n	Mean changes			
		I-QOL Total	Avoidance	Psychosocial	Embarrassment
Very Much Better	134	19.1	20.8	14.2	25.3
Much Better	230	13.2	14.0	11.3	15.5
A Little Better	277	6.3	6.7	5.6	6.8
No Change	389	3.8	4.2	3.3	4.2
A Little Worse	47	-0.1	0.1	-0.8	1.0
Much Worse	12	-5.9	-5.8	-4.9	-7.9
Very Much Worse	2	-13.1	0	-22.2	-17.5
Within-treatment MCID		6.3	6.7	5.6	6.8
Between-treatment MCID		2.5	2.5	2.3	2.6

Table 2. I-QOL results with treatment

	Placebo (n = 425)		Duloxetine (n = 433)		
	Baseline mean (sd)	Change mean (sd)	Baseline mean (sd)	Change mean (sd)	p-value
I-QOL Total Score	66.6 (17.9)	6.4 (12.6)	65.4 (19.6)	10.5 (14.0)	<.001
Avoidance	65.8 (18.7)	7.2 (13.9)	64.5 (19.8)	10.8 (15.0)	.001
Psychosocial	75.7 (18.8)	4.9 (12.9)	74.5 (21.1)	9.4 (14.8)	<.001
Embarrassment	51.6 (23.3)	8.1 (17.6)	50.5 (24.4)	12.1 (18.4)	.003

Interpretation of results

Treatment population differences in I-QOL scores should be greater than the between-treatment MCIDs for statistically significant differences to be considered clinically meaningful. Our findings suggest that treatment differences for I-QOL scores between duloxetine and placebo and increases in I-QOL scores from baseline with duloxetine exceed the between and within-treatment MCID, respectively.

Concluding message

Based on the data in this study, 2.5 points could be considered a reasonable guide for the I-QOL total score between-treatment MCID and 6.3 points for the within-treatment MCID.

References

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