

RESPONSIVENESS OF THE PELVIC FLOOR DISTRESS INVENTORY (PFDI) AND PELVIC FLOOR IMPACT QUESTIONNAIRE (PFIQ) IN WOMEN UNDERGOING SURGICAL AND NON-SURGICAL TREATMENT FOR PELVIC ORGAN PROLAPSE

Hypothesis / aims of study

The Pelvic Floor Distress Inventory (PFDI) and Pelvic Floor Impact Questionnaire (PFIQ) are two valid and reliable condition-specific quality of life questionnaires for women with pelvic floor disorders.[1] The objective of this study was to evaluate the responsiveness (i.e. ability to capture clinically important change) of the PFDI and PFIQ in women with pelvic organ prolapse (POP) undergoing surgical and non-surgical management.

Study design, materials and methods

The PFDI has 46 items and serves the role of both a symptom inventory and measure of the degree of bother or distress caused by the broad array of pelvic floor symptoms. The PFIQ measures the degree to which bladder, bowel or vaginal symptoms affect the daily activities, relationships and emotions of patients with pelvic floor disorders. Both instruments have bladder, colorectal and prolapse scales.

The responsiveness of the PFDI and PFIQ were assessed in two independent populations: 1) 42 women with \geq stage 2 POP enrolled in an ongoing multi-center randomized trial comparing two different pessaries (Pessary group) and 2) 64 women with stage \geq stage 3 POP who underwent vaginal reconstructive surgery (Surgery group). All subjects completed the PFDI and PFIQ at baseline and again either 3 months (Pessary group) or 6 months (Surgery group) after initiation of treatment. The Pessary group also completed a visual analog scale (VAS) evaluating their satisfaction with the pessary. Responsiveness was assessed with standardized response mean (SRM), effect size (ES) and the paired t-test. For both SRM and ES, a value of 0.5-0.7 is considered moderate responsiveness, $>.80$ to 1.0 is considered good and >1.0 is considered excellent.[2]

Results

In the Pessary group, there was a significant improvement in the prolapse and urinary scales of the PFDI, with each demonstrating moderate responsiveness (prolapse: SRM .69, ES .68; urinary: SRM .57, ES: .49, $p<.001$ for each). The colorectal scale of the PFDI and each of the 3 scales of the PFIQ demonstrated no significant change in scores with pessary use. The change in score of the prolapse and urinary scales of the PFDI and the PFIQ had significant positive correlation with satisfaction with the pessary (PFDI: $r = .61$ & $.66$, $p<.001$; PFIQ: $r = .40$ & $.54$, $p \leq .04$). In the surgery group, there was a significant improvement in the prolapse, urinary, and colorectal scales of both the PFDI and PFIQ ($p<.01$ for each). The prolapse and urinary scales of the PFDI demonstrated excellent responsiveness with SRM and ES ≥ 1.20 for the prolapse scale and ≥ 1.03 for the urinary scale. The colorectal scale of the PFDI and each of the 3 scales of the PFIQ demonstrated moderate responsiveness (SRM .60-.70 and ES .55-.61) after surgery. Six percent (4/64) of subjects in the surgery group developed recurrent prolapse beyond the hymen by 6 months after surgery. Those who developed recurrence had significantly less improvement in the prolapse scales of both the PFDI and PFIQ. After controlling for preoperative prolapse stage and baseline QOL scores, subjects in the surgery group had significantly greater improvement in each of the scales of the PFDI and the prolapse and urinary scales of the PFIQ than did the pessary group.

Interpretation of results

Responsiveness, or sensitivity to change, is the ability of an instrument to detect a small, but clinically important change. It is an important psychometric property for any measure intended to assess an intervention. In this study, the PFDI and PFIQ demonstrated moderate to excellent responsiveness in women undergoing both surgical and non-surgical treatment for pelvic organ prolapse. The PFDI appears to be more responsive than the PFIQ in this population. Results of this study suggest that vaginal reconstructive surgery may result in greater improvement in condition-specific quality of life than pessary use in women with advanced POP, although a clinical trial is necessary to answer this question definitively.

Concluding message

The PFDI and PFIQ, two valid and reliable quality of life instruments for women with pelvic floor disorders, are responsive to change in women undergoing both surgical and non-surgical treatment for pelvic organ prolapse

References:

1. Psychometric evaluation of 2 comprehensive condition-specific quality of life instruments for women with pelvic floor disorders. *Am J Obstet Gynecol* 2001;185:1388-95.
2. Defining clinically meaningful change in health-related quality of life. *J Clin Epidemiol* 2003; 56:395-407.