

VALIDATION OF THE PATIENT GLOBAL IMPRESSION OF CHANGE (PGIC) IN A PATIENT POPULATION FOLLOWING VAGINAL PROLAPSE REPAIR WITH MESH

Hypothesis / aims of study

The Patient Global Impression of Change (PGIC) is a single-item, self-report question initially validated in a sample of women with urinary incontinence or pelvic organ prolapse.^[1] The aim of this study was to evaluate the concurrent and known group validity of the PGIC among women undergoing vaginal prolapse repair augmented with mesh and a vaginal support device (VSD).

Study design, materials and methods

A prospective multi-center, single arm study of surgical pelvic organ prolapse (POP) repair augmented with mesh and supported by a VSD was conducted. 136 women with symptomatic stage II or III POP were recruited from clinical sites in the United States, United Kingdom, Australia and Germany and were treated using polypropylene mesh implants and a VSD (GYNECARE Proxima™ Pelvic Floor Repair System, Ethicon, Somerville, NJ, US). Data from baseline and 12-month follow-up visits were used to evaluate the validity of the PGIC. The PGIC is a single item with 5 Likert-type response options: “Compared with how you were doing before your recent pelvic floor operation, would you say that you are: much better, a little better, about the same, a little worse or much worse?”. In addition to the PGIC, each participant also completed the Pelvic Floor Distress Inventory (PFDI-20) and Pelvic Floor Impact Questionnaire (PFIQ-7).^[2] The PFDI-20 and PFIQ-7 both produce a summary score as well as 3 subscale scores for symptoms and health-related quality of life (HRQL) impact, respectively, related to the following three concepts areas: prolapse, bowel/colorectal-anal and urinary. For both questionnaires the subscale scores range from 0 to 100 and the Summary scores are obtained by adding the 3 subscale scores and range from 0 to 300. For all scales, higher scores indicate increased bother. Clinical characteristics including measures of anatomy via ICS POP-Q staging were obtained in all patients. The concurrent validity of the PGIC was assessed with Spearman’s correlations with the PFDI-20, PFIQ-7 and the POP-Q. General linear models were used to examine known-groups validity using the PGIC responses to discriminate among PFDI-20 and PFIQ-7 change scores and change in POP-Q stage.

Results

The mean age of the women was 64.3 ± 10.5 years, mean BMI was 28.4 ± 5.0 and most were Caucasian (96.3%). At baseline 73 (53.7%) women were POP-Q stage II, and 63 (46.3%) women were Stage III. The majority of the operations were combined (52.9%) mesh repairs, followed by posterior (24.3%) and anterior compartment (22.8%). Most women (70.6%) underwent concomitant surgery such as vaginal hysterectomy, mid-urethral sling, or perineal repair. At 12-months, most women reported that they were either “much better” (73.3%) or “a little better” (15.3%) on the PGIC with few women reporting that they were “about the same” (7.6%), “a little worse” (0.8%), or “much worse” (3.1%). Concurrent validity was demonstrated at 12-months, the PGIC was strongly correlated with the PFDI-20 summary score and subscales (r range = 0.31 to 0.48, all $p < 0.001$) and moderately correlated with the PFIQ-7 summary score and subscales (r range = 0.25 to 0.42, all $p < 0.01$). The PGIC had small and insignificant correlations with the POP-Q at 12 months ($r = 0.11$, NS). Improvements in POP-Q stage were generally noted by patients as improvements in the PGIC; 89% of patients with an improved POP-Q at 12 months noted an improvement in the PGIC as well. The PGIC response of “much better” significantly discriminated from “no change/worse” on the PFDI-20 summary and POPDI-6 and UDI-6 subscales scores at 12-months (Figure 1). Significant discrimination was also present between “a little better” versus “much better” for all PFDI-20 scales. The PFIQ-7 was less sensitive to the PGIC responses with significant differences noted between the “much better” versus “no change/worse” response options in the PFIQ-7 Summary Score and the UIQ-7 and the POPIQ-7 subscales at 12-months (Figure 2).

Interpretation of results

The correlations of the PGIC with the PFDI-20, PFIQ-7, and POP-Q are as hypothesized – higher correlations with subjective measures, lower correlations with clinical measures demonstrating concurrent validity. Importantly, 89% of women who perceived success on the PGIC also improved in POP-Q stage, however this improvement was not necessarily incremental – so women who improved by 2 stages did not necessarily report “much better” which contributed to the low correlation. The clear trend of greatest improvement in the “much better” PGIC group among all subscales demonstrates known-group validity. The score differentiation of the PFDI-20 and PFIQ-7 among the PGIC responses highlights the sensitivity of the PGIC in discriminating other patient reported outcome (PRO) responses and its usefulness as a subjective measure of patient perceived success 12 months following pelvic floor operations.

Concluding message

The validation of the PGIC in this population is a useful patient reported outcome (PRO) tool for clinicians to assess patient outcomes in POP surgery from the patient perspective and allows clinicians to gain a better understanding of the changes that women experience after POP surgery.

Figure 1. Discriminant Validity of the PGIC with the PFDI-20

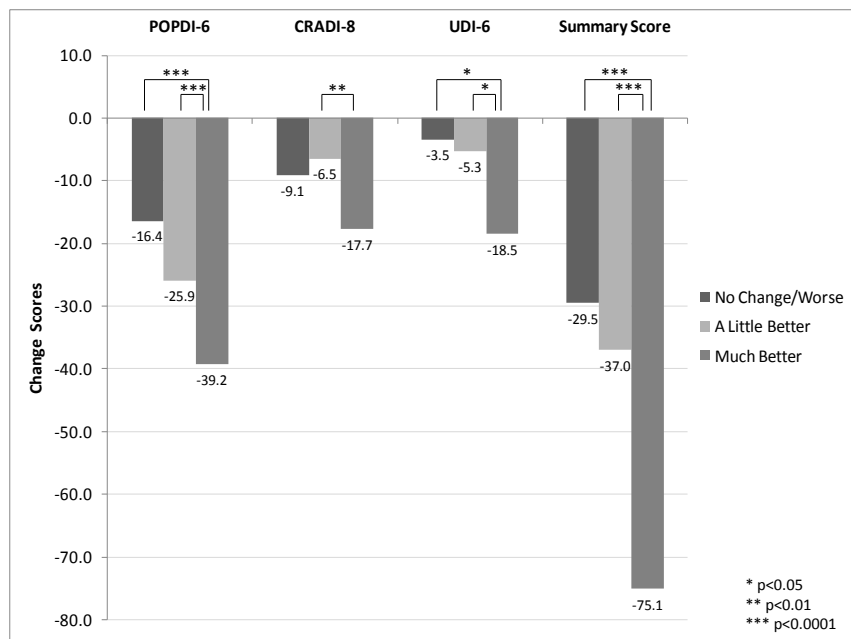
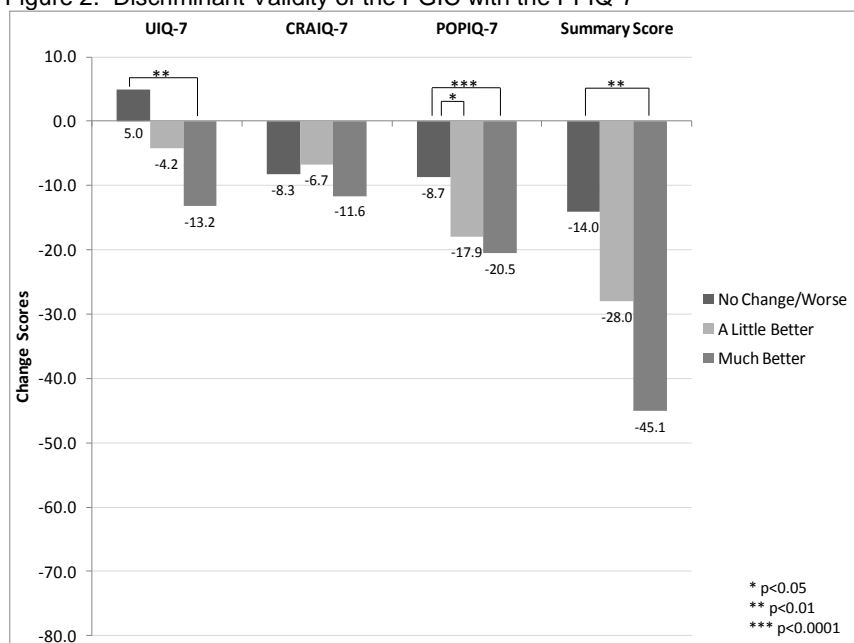


Figure 2. Discriminant Validity of the PGIC with the PFIQ-7



References

1. Wren PA, Janz NK, Brubaker L, Fitzgerald MP, Weber AM, LaPorte FB, Wei JT (2005). Reliability of health-related quality-of-life measures 1 year after surgical procedures for pelvic floor disorders. Am J Obstet Gynecol 192(3): 780-788.
2. Barber MD, Walters MD, Bump RC (2005). Short forms of two condition-specific quality-of-life questionnaires for women with pelvic floor disorders (PFDI-20 and PFIQ-7). Am J Obstet Gynecol 193(1): 103-113.

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Specify Name of Ethics Committee	Multiple IRB's
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes