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Mostafa A[1], Hassafa Z[1], Abdel-Fattah M[1]
1. *university of Aberdeen*

CAN THE PATIENT GLOBAL IMPRESSION OF IMPROVEMENT QUESTIONNAIRE PREDICT THE RESULTS OF LONG QUALITY OF LIFE AND SEXUAL FUNCTION QUESTIONNAIRES?

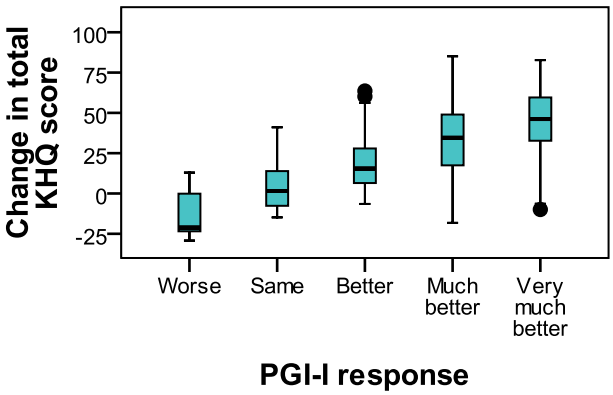
Hypothesis/ Aims of study:
To assess the correlation between the Patient Global Impression of Improvement (PGI-I) and post-operative changes in the Kings Health Quality of Life Questionnaire (KHQ) and Pelvic Organ Prolapse/Urinary Incontinence Sexual Function- Short Form questionnaire (PISQ-12), following surgical treatment in women with stress urinary incontinence (SUI).

Study design, materials and methods:
299 women underwent Transobturator tension free vaginal tapes as a sole procedure for treatment of SUI in the period between April 2005 & April 2007 and have completed 12 moth follow-up. All women completed pre-operative KHQ and PISQ-12 among other assessments. The KHQ is a validated disease-specific tool for assessment of the impact of UI on women's quality of life (QoL); it consists of nine domains assessing different aspects such as general health, impact on sleep/ personal relations. The improvement in women's QoL after certain treatment is calculated as the difference between the post- pre treatment score in each domain and in the total score. The PISQ-12 is a validated short form for PISQ. It is also a validated disease-specific tool for assessing the impact of treatment for UI and/or prolapse on women's sexual function. The short form is only validated for the total score rather than per domain analysis. The PGI-I is a validated generic tool for assessment of the over-all improvement or deterioration that the patient may experience following the treatment. It is a simple 7-point scale from "Very Much improved" to "Very Much Worse" that usually takes less than one minute to complete.
Postoperatively 292 women (97.7%) completed the PGI-I questionnaire, 299 (100%) and 199 (65%) women completed a valid KHQ and PISQ-12 respectively. 100 women (35%) did not complete the PISQ-12 pre or postoperatively for a variety of reasons or had more than 2 missing items and therefore invalidate the questionnaire.
Women were classified into 5 groups based on their responses to this questionnaire: "a= Very Much Improved", "b= Much Improved", "c= Improved", "d= same" and "e= worse". Spearman's correlation coefficient was used to evaluate the degree of association between PGI-I responses at follow-up and the changes in total KHQ score and total PISQ-12 score. Kruskal-Wallis tests were performed to compare the PGI-I groups in terms of the change in total KHQ score, the change in each KHQ domain, and the change in total PISQ-12 score. Missing values were excluded from the analysis, which was performed using SPSS Version 17.

Results:
292 women attended the follow-up appointment, completed the PGI-I questionnaire, and are included in this analysis. All 292 (100%) of these women completed the KHQ at baseline and follow-up, but only 199 (68%) completed the PISQ-12 at both time points. The mean (standard deviation) age was 52.3 (10.2) years, and a median (IQR] body mass index was 28 (25, 31) kg/m^2. None of these women responded to the PGI-I by describing the impact of surgery as "much worse" or "very much worse", so the women were classified into five groups, ranging from "worse" to "very much better".
There was a significant positive correlation between PGI-I response and the change in the total KHQ score (Spearman's correlation coefficient = 0.48, P < 0.001) Figure 1. The change in the total KHQ score became larger and positive as the PGI-I response became more positive. Most women who described their condition on PGI-I as "worse" had a reduction in their total KHQ score (deterioration in QoL), while the majority of women who answered "very much better" had a large increase in their total KHQ score (improvement in QoL). Overall, there was a statistically significant difference between the PGI-I groups with respects to the change in total KHQ score (P < 0.001). A similar pattern was seen when the change in the individual domains of the KHQ was compared across the PGI-I groups, apart from the general health domain, where there was no significant difference between the five groups (P = 0.282) Table 1.
There was a statistically significant, but weak positive correlation between PGI-response and the change in the total PISQ-12 score (Spearman's correlation coefficient = 0.17, P = 0.019) Figure 2. Similarly, there was a statistically significant difference between the PGI-response groups in terms of the change in the total PISQ-12 score (P = 0.016) Table 2. Those women who had replied their condition was "worse" or the "same" on the PGI-I questionnaire at follow-up, were less likely to have an increase in their total PISQ-12 score (an improvement in sexual function) compared to the women in the other three PGI-I response groups.

Figure 1: Strong Positive Correlation between PGI-I Response and the Change in the Total KHQ

Figure 2: Weak Positive Correlation between PGI-I Response and the Change in the Total PISQ1-2



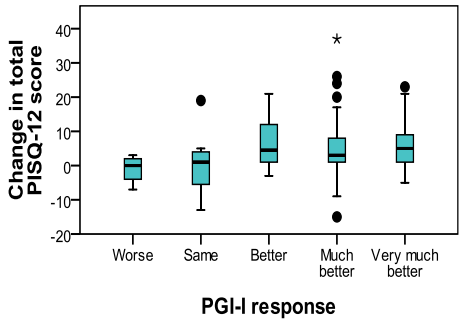


Table 1: Changes in the individual domains & Total KHQ compared across the PGI-I groups

Change in KHQ score (Baseline – follow-up)*	PGI-I response median (lower quartile, upper quartile)					
Domain	Very much better n=126	Much better n=106	Better n=35	Same n=18	Worse n=7	P-value
General Health	0 (0, 25)	0 (0, 0)	0 (0, 25)	0 (-31, 0)	0 (-25, 0)	0.282
Incontinence Impact	100 (67, 100)	50 (0, 100)	33 (0, 67)	33 (0, 67)	0 (0, 0)	< 0.001
Role Limitation	67 (33, 83)	50 (17, 83)	17 (0, 50)	0 (-4, 38)	0 (-33, 0)	< 0.001
Physical Limitation	58 (33, 83)	50 (17, 67)	17 (17, 67)	0 (-17, 33)	-17 (-33, 0)	< 0.001
Social Limitation	33 (11,67)	27 (11, 47)	11 (0, 44)	6 (-11, 33)	-22 (-44, 0)	< 0.001
Personal Relations	1 (0, 46)	12 (0, 33)	2 (0, 50)	0 (-33, 24)	-4(-67, 0)	< 0.014
Emotions	44 (22, 78)	39 (22, 67)	17 (0, 56)	0 (-22, 22)	-11 (-44, 0)	< 0.001
Sleep Energy	33 (17, 50)	17 (0, 33)	0 (0, 33)	0 (-4, 17)	-17 (-33, -17)	< 0.001
Severity Measures	58 (42, 75)	42 (17, 67)	25 (0, 42)	0 (-8, 29)	0 (-17, 0)	< 0.001
Mean Score	46 (32, 60)	35 (17, 49)	15 (6, 28)	2 (-8, 10)	-21 (-25, 3)	< 0.001

Table 2: Changes in the Total PISQ-12 compared across the PGI-I groups

PGI-I responses	Changes in PISQ-12 median (IQR)
Very Much Better (n=83)	5 (1,9)
Much Better (n=70)	3 (1,8)
Better (n=22)	5 (1,12)
Same (n=12)	1 (-6,4)
Worse (n=4)	0 (-6,3)
p-value	0.016

Interpretation of results:

The PGI-I is a reliable & validated generic tool in assessment of the overall impact of an intervention. This study has shown strong positive correlation between the PGI-I and the changes in the KHQ total scores after surgery for stress incontinence: patients reporting “Very Much improved or Much improved” which are usually used as measure of success reported a mean change in KHQ of 46 & 35 points (Range (17 – 60 points) with clear demarcation from those reporting “no change and/or worse condition” (mean 2 & -21; Range -25 – 10). These findings indicate that PGI-I can be a useful short tool in assessment of overall QoL changes following surgery for SUI, especially in busy clinical settings. However if more detailed information are required then the KHQ or other detailed disease specific QoL questionnaires can be used. The study showed weak correlation, though significant, between PGI-I and PISQ-12 scores indicating less ability of PGI-I in detecting impact of SUI surgery on women’s sexual function.

Concluding message:

The PGI-I strongly correlate with changes in KHQ scores following surgery for SUI. It can be used to predict impact on overall QoL changes in busy clinical settings.

Specify source of funding or grant	**The study has funded by a grant from the Henry Smith Charity.** **Address:** **6th floor** **65Leadenhall Street,** **London** **EC3A 2AD** **Regestered Charity Number: 230102.**
Is this a clinical trial?	**Yes**

Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**www.clinicaltrials.gov**
Is this a Randomised Controlled Trial (RCT)?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**West of Scotland Research Ethics Committee** **Address: 1st floor Tennent Institute 38ChrchStreet Glasgow G11 6NT**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**