Original article

What is the correlation between Pelvic Organ Prolapse and Quality of Life? Clinical validation of the Pelvic Organ Prolapse Quantification Index (POP-Q-I)

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Abstract: INTRODUCTION: This study sought to assess the correlation between the Pelvic Organ Prolapse Index (POP-Q-I)[10] and the Prolapse Quality of Life Questionnaire (P-QOL). SUBJECTS AND METHODS: Seventy-one consecutive patients were examined by a member of the urogynecology faculty blinded to P-QOL. Pearson's test was used to assess the correlation between the average POP-Q-I and P-QOL scores. Patients were then divided in four groups by prolapse intensity to assess the dose-response correlation. RESULTS: Significant, but low correlation was found for each point, the overall POP-Q-I and global POP-Q-I (table 2). After dividing the sample, we observed a significant dose-response correlation for both Overall (p=.005) and Global (p=.008) POPQ-I (table 4). CONCLUSION: These results clinically validate the POPQ-I and suggest that comparing anatomical outcomes alone is not enough when comparing different treatments, meaning assessment of clinical success should take into account patient expectations and post-intervention quality of life.

Keywords: Pelvic Organ Prolapse; Classification; POP-Q; POP-Q-I; Quality of Life.

INTRODUCTION

Standardization of pelvic organ prolapse (POP) classification has been a major issue in the literature during recent decades[1-9]. Much of these efforts were based on the need for a uniform method to assess anatomical outcomes in POP research. Taking part on these efforts, we have proposed the Pelvic Organ Prolapse Quantification Index (POP-Q-I)[2], which quantifies the prolapse as a standardized continuous variable, in which 0 means completely absent prolapse, while 1 reflects complete vaginal eversion. This standardized quantification makes anatomical outcomes variables statistically more powerful and optimizes research. The POP-Q-I was validated at our center in a blinded prospective randomized study, showing good inter-observer correlation[9].

The clear utility of accurately measuring anatomic results, however, neglects a potentially critical element of clinical success: patient expectations and quality of life. The objective of this study was to assess the correlation between the POP-Q-I and quality of life (QOL), in order to clinically validate the former.

SUBJECTS AND METHODS

The study was prospective, randomized and blinded. Seventy-one consecutive patients presenting to the outpatient urogynecology clinic of Santa Casa of São Paulo were included, after reading, agreeing and signing an informed consent, approved by the local ethics committee. Sample size was calculated on Minitab 15.1.1.1 (Minitab Inc.), considering an estimated correlation coefficient of .35, 80% power (β=.20) and significance level of 5% (α=.05).

Patients with the following complaints were included: a sense of something coming or falling out of their vagina; the ability to feel a bulge coming out of their vagina; urinary incontinence; fecal or anal incontinence; pelvic fullness or pressure particularly when upright; having to push up on the perineum or digitate the vagina in order to urinate or defecate. All subjects that could not provide informed consent, subjects under age 18 years, pregnant or within 6 months post partum at the time of the exam, subjects who could not tolerate a second pelvic exam at one clinic visit, and those who could not perform a Valsalva or deep cough were excluded.

Before the POP examination, a validated portuguese version of the "Prolapse Quality of Life" (P-QOL)[10] questionnaire was applied by a member of the Urogynecology staff. The questionnaire consists of 43 questions with responses ranging from ''none/not at all'', through ''slightly/a little'' and ''moderately'' to ''a lot''. Therefore, a four point (0-3) scoring system for each item was used for severity measurement of urogenital prolapse symptoms.

After answering the questionnaire, women were examined by a member of the urogynecology staff, blinded to the QOL result. All patients were examined in lithotomy, performing Valsalva or cough when the examiner considered the pressure achieved by Valsalva to be insufficient for a valid examination. POP-Q points Aa, Ab, C, Bp and Ap were measured. Point D was used only for the identification of patients with cervical hyperplasia. Genital hiatus (GH), perineal body (PB) and total vaginal length are not taken into account for the POP-Q-I, since it is not possible to estimate normal and maximum values for these measures. Measures were made with a wooden rule, following the directions of the POP-Q[4] and, for each point, two values were gathered (Fig. 1): Value1, the actual distance the point was from its original site; and Value2, an estimation of how far the point would go in case of total vaginal eversion.

Data were recorded on a form specially designed for this study and entered in Excel for Mac:2008 (Microsoft Corp.). We used Excel to calculate the POP-Q-I for both examiners at each point (Aa, Ba, C, Bp, and Ap) by dividing Value1/Value2; this score ranges from 0 (no prolapse) to 1 (total eversion of the given point). We calculated an overall score (maximum prolapse score for any point) and a global score (average of the five points).

In addition to P-QOL domain analysis, a standardized QOL index (QOL-I) ranging between 0 and 1 was calculated by dividing the observed score by the maximum possible overall score (including all dominions). Scores closer to 1 represent greater impairment of QOL.

POPQ-I results were first compared to the P-QOL results

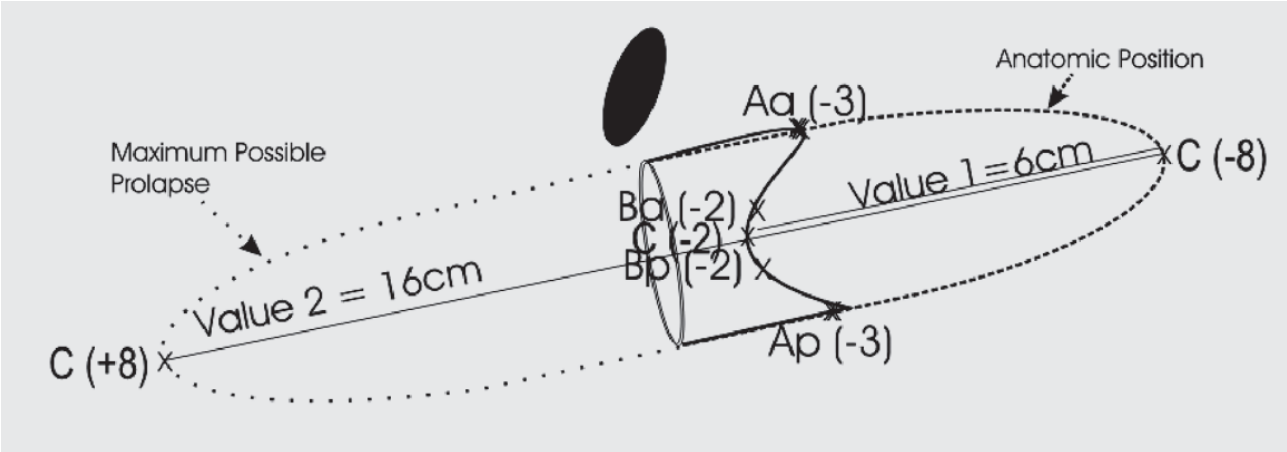

Fig. 1. – POP-Q-I is the result of the division of Value 1 (the actual distance the point was from it's original site) by Value 2 (an estimation of how far the point would go in case of total vaginal eversion).

by Pearson's correlation. In subsequent analyses, patients were grouped in an ordinal fashion according to Overall and Global POPQ-I (group I POPQ-I from 0 to .25; group II from .251 to .5; group III from .51 to .75; and group III >.75) in order to assess the dose-response relationship.

Data were analysed on SPSS for Macintosh version 16 (SPSS Inc.).

RESULTS

Seventy-one women were included in the study. Their demographics, mean POPQ-I scores and mean standardized P-QOL scores are displayed in Table 1. Pearson's correlation between QOL-I scores and the POP-Q-I for all points are displayed in Table 2. Significant, although weak correlation was observed for all points, except for point Ap.

"*r*" is the number of standard deviations that P-QOL score increases for every standard-deviation increase on POPQ-I. This means, for example, that for every 0.294 increase on POPQ-I, a 0.065 increase on P-QOL standardized score was observed (i.e.: for each POPQ-I SD increase, P-QOL increases R times P-QOL SD).

"*r* square" means the amount of the QOL-I score that is determined by the prolapse. In our example Overall POPQ-I prolapse is responsible for 10.7% of P-QOL score.

The correlation between the POP-Q-I and the domains of the P-QOL is shown on table 3. Note that although most of the domains scores showed statistically significant correlation with both Overall and Global POP-Q-I, only the domains that relate to prolapse intensity (i.e Prolapse Impact and Severity) showed moderate correlation with the POP-Q-I, while more subjective domains correlated poorly (i.e. $r<.40$) or did not correlate at all ($p>.05$).

When grouping patients in an ordinal fashion (group I POPQ-I from 0 to .25; group II from .251 to .5; group III from .51 to .75; and group III >.75) a dose-response correlation between POPQ-I and QOL-I was observed. For each 0.25 increase on POPQ-I, there was a 0.06 increase on QOL-I, both for the overall (p=0.0059) and for the global (p=0.008) indexes (Table 3).

Table 1. – Sample (n=71) demographics, mean POPQ-Index for each POP-Q point, mean Overall (maximum) and Global (mean) POPQ-I, mean P-QOL standardized score.

	Mean	*Range*	*SD*
Age	57.86	(34-82)	12.621
BMI	26.78	(20.08-33.6)	3.333
Parity	3.30	(0-14)	2.637
Aa	0.457	(0-1)	0.311
Ba	0.349	(0-1)	0.297
C	0.261	(0-1)	0.311
Bp	0.233	(0-1)	0.290
Ap	0.255	(0-1)	0.285
Global POPQ-I	0.311	(0-1)	0.259
Overall POPQ-I	0.479	(0-1)	0.294
QOL-I	0.303	(0-0.715)	0.200

Table 2. – Pearson's Correlation: POP-Q-I vs. QOL-I

Point	*R (95% Confidence Interval)*	*R square*	*P*
Aa	0.266 (0.022-0.320)	0.071	0.025
Ba	0.249 (0.011-0.325)	0.062	0.036
C	0.258 (0.016-0.315)	0.066	0.030
Bp	0.283 (0.036-0.354)	0.080	0.017
Ap	0.201 (-0.024-0.306)	0.040	0.093
Overall	0.327 (0.068-0.377)	0.107	0.005
Global	0.290 (0.047-0.402)	0.084	0.014

DISCUSSION

The correlation between intensity of prolapse and quality of life is an active area of current research, as success of prolapse treatment has classically been considered anatomical cure and complication rates. In our results, we found an unexpectedly low correlation between prolapse intensity and QOL scores, suggesting that larger prolapses do not consistently correlate with a larger perceived problem. Elkadry et al.[11] have assessed patients' goals for pelvic reconstructive surgery and observed that "Patient characteristics and the number of pelvic floor diagnoses do not seem to influence goal selection". This means that it is not pelvic floor dysfunction itself that bothers the woman, but the lifestyle hindrances it causes. Those authors have also observed that objective cure of prolapse or incontinence does not predict satisfaction or goal achievement.[11] Ellerkman et al[12] found that "although there were weak to moderate correlations with respect to several symptoms that are typically thought to be compartment specific, it was not possible to deter-

Table 3. – Pearson's Correlation: P-QOL domains scores vs. POP-Q-I

	Global POP-Q-I			*Overall POP-Q-I*		
Domain	***r***	***r square***	***P***	***r***	***r square***	***P***
General Health Perception	.082	.007	.495	.27	.001	.825
Prolapse Impact	.462	.213	<.001	.473	.224	<.001
Role Limitations	.25	.062	.036	.226	.051	.058
Physical Limitations	.365	.133	.002	.347	.120	.003
Social Limitations	.331	.110	.005	.312	.097	.008
Personal Relationships	.100	.010	.407	.058	.003	.632
Emotions	.290	.084	.011	.305	.093	.010
Sleep/Energy	.209	.044	.081	232	.054	.052
Severity	.494	.244	<.001	.547	.299	<001

mine a specific stage of prolapse at which these symptoms became more pronounced". Other authors[13-14] have reached the same conclusion and failed to find a point at which vaginal descensus becomes clearly symptomatic. Those results also agree with Petros'[15] pictorial algorithm for diagnosis and management of pelvic floor dysfunction, which bases surgical treatment mainly on the symptoms, instead of physical examination findings, as, according to this author, the intensity of symptom is individual and not related to the intensity of prolapse.

This study addresses the above issue by assessing the linear correlation between the amount of prolapse and the intensity of its impact on womens' QOL. Thus, there are two main differences between this and the above cited studies: the first is the continuous outcome variable, as stated; and the second is the fact that only symptomatic women were included, regardless of presenting or not any prolapse. These methodological differences grant a strict assessment of prolapse intensity and its impact on women's QOL, instead of evaluating presence of symptoms on groups with and without prolapse. This may be the reason for the difference between ours and other studies results, [10-15-16] since these have addressed the mean symptom score difference between groups with and without pelvic organ prolapse. In our study, on the other hand, Pearson's Correlation reflects the correlation between the QOL and POP-Q-I scores for each individual patient. This statistical difference highlights the actual impact of prolapse on QOL on each single patient and highlights its individually variable nature. This explains why the correlation is so low, although mean P-QOL and POP-Q-I are so close, as shown in Table 1.

On the other hand, when we split the sample in two groups, a significant difference appeared. The translation of these statistical findings is the following: groups with more advanced prolapse tend to show higher median P-QOL scores; but this is only a general, average, tendency which does not represent the truth when every single woman is evaluated apart from her group. This evaluation was one the aims of our study. Moreover, the significant dose-response correlation observed here clinically validates the POPQ-I, which had already demonstrated good inter-observer agreement.[10] Other authors have failed to identify this correlation with the traditional POP-Q stages, but found it when analyzing data in a more continuous fashion, based on the position of the leading prolapse edge.[15] These observations suggest that prolapse intensity should probably be better quantified by a continuous variable, instead of an ordinal categorical one, such as POP-Q stages, as we have stated elsewhere.[2]

Table 4. – Dose-response analysis of "dummy variables" between grouped POPQ-I and QOL-I. For each 0.25 increase on POPQ-I, there was a 0.06 increase on P-QOL score, both for the overall and for the global indexes.

Reference	***Quartile I to II (p**)***	***Quartile I to III (p**)***	***Quartile I to IV (p**)***	***p****
Overall	0.05 (.44)	0.096 (.15)	0.185 (.009)	.005
Global	0.11 (.04)	0.14 (.11)	0.17 (.03)	.008

*Dose response analysis
**"Dummy variable" analysis

In our analyses, we found POP intensity to be responsible for about 10% of the P-QOL score in symptomatic women. Statistically thinking, when it concerns a multifactorial outcome such as quality of life, a variable to which this amount of impact can be attributed is actually a very important one. On the other hand, clinically thinking, we can deduce that 90% of the impact on QOL is not correlated with the prolapse intensity. Even on domains designed to evaluate the direct prolapse impact on quality of life, the "r square" analysis never reached 30%.

The hindrances of this study include its cross-sectional design, which does not address the variability of symptoms as described by Sung et al.[20] This is due to the low educational level of the study population, which makes it very difficult to use diaries or self-administered questionnaires. Symptoms evaluation is then only possible by interviews at the time of consultation. Despite these limitations, our observations objectively demonstrate what other authors[11,12,17-21] have been stating: surgical outcomes must be based on patients expectations and symptomatic relief, and not only on anatomical outcomes. Based on the empirical observation that physician and patient surgical expectations are often mismatched, Brubaker & Shull[19] have proposed the "EGGS for patient-centered outcomes", in which "E" stands for patients' expectations, "G" stands for goal setting, another "G" for goal achievement, and "S" for satisfaction. This seems a reasonable proposition, since pelvic floor disorders are not life-threatening and the surgical objective should, thus be focused on patients' symptoms and the resolution of lifestyle hindrances. Our results reinforce the above proposition, as well as the recommendation for validated questionnaires for symptomatic assessment in POP research.[21]

Summarizing, our results clinically validate the POP-Q-I by means of a dose response correlation that, to our knowledge, has not yet been demonstrated for traditional POP-Q stages. The data shown here also suggest that assessing anatomical outcomes is not enough as these are responsible for only

10% of patient satisfaction. Thus basing success and failure on anatomical outcomes alone may lead researchers and urogynecologists to neglect the main goal of treating pelvic floor dysfunction: to fulfill women's expectations and give back quality of life.

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