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Quantification of Vaginal Support: Are Continuous Summary Scores Better than POPQ Stage?

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Abstract

Objectives—This analysis compared 3 continuous variables as summary support loss scores with POPQ ordinal stages.

Study Design—We used pooled baseline data from 1141 subjects in 3 randomized trials (CARE, n=322; OPUS, n = 380; ATLAS, n =439) to test 3 support loss measures. The relative responsiveness was assessed using the standardized response mean of 2-year outcome data from the CARE trial.

Results—Each support loss measure was strongly correlated with POPQ ordinal staging; the single most distal POPQ point had the strongest correlation. Improvements in anatomic support were weakly correlated with improvements in POPDI ($r = .17-.24$, $p < .01$ for each) but not with changes in POPIQ for all measures of support loss or POPQ stage.

Conclusions—While continuous, single number summary measures compared favorably to ordinal POPQ staging system, the single most distal POPQ point may be preferable to POPQ ordinal stages to summarize or compare group data.

Keywords

Pelvic organ prolapse; prolapse; pelvic surgery; outcome measures; quantification of prolapse

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Introduction

A recent U.S. national population-based survey reported that approximately 3% of adult women have symptomatic pelvic organ prolapse (POP) ¹. As the population of the United States ages, the number of women with POP will increase with projections from 3.3 million in 2010 to 4.9 million in 2050 ². In 1995, the International Continence Society developed the Pelvic Organ Prolapse Quantification (POPQ) system in order to standardize the anatomic assessment of POP ³. This system, which has been shown to be consistent across examiners, has been adopted worldwide and allowed a common language for clinicians and investigators.

The POPQ, ordinal staging system in which POP is categorized as Stage 0, 1, 2, 3 or 4, quantifies the anatomic descent of the vaginal wall relative to the hymenal ring. The staging system was arbitrarily derived and there is growing sentiment that the POPQ staging system may not optimally differentiate clinically important subgroups. For example, stage 2 prolapse (leading edge within 1 cm proximal or distal to the hymen) is known to include patients who range from asymptomatic to symptomatic, yet the POPQ system does not allow for any differentiation between these groups within stage. Stage 3 is even less anatomically specific as it spans numerous centimeters beyond the points designated as Stage 2. In addition, a patient may change POPQ stage with less than one centimeter of change in vaginal topography. A system which uses a continuous variable to stage prolapse might allow clinicians and investigators to more effectively correlate anatomy with symptoms and to more easily compare results of one type of surgical treatment to another.

The objective of this analysis was to compare several single numerical summary scores that are continuous variables with the established ordinal staging system. Pertinent POPQ points were used to develop equations which give numerical values to specific degrees of prolapse, thereby creating a continuum of degrees of prolapse. Using available prospectively collected data, we assessed the utility of these single continuous measures to describe pelvic organ support loss. Finally, we correlated these support loss measures with symptoms and condition specific quality of life scores, and assessed the utility of these measures in evaluating anatomical outcomes after surgery.

Materials and Methods

We analyzed pooled baseline data from 1141 subjects in 3 randomized trials, CARE, OPUS, and ATLAS, conducted by the Pelvic Floor Disorders Network, (PFDN), an NIH sponsored multi-center network. These clinical trials used standardized tools including the POPQ, the Pelvic Floor Distress Inventory (PFDI) and the Pelvic Floor Impact Questionnaire (PFIQ) ⁴. The CARE study enrolled women planning sacrocolpopexy for stage 2-4 prolapse without symptoms of stress incontinence and completed follow-up in 2005 ^{5, 6}; the OPUS study enrolled stress continent women with anterior vaginal prolapse undergoing vaginal surgery and is ongoing ⁷; and the ATLAS study enrolled women with stress incontinence and stage 0-2 vaginal support and completed follow-up in 2008 ⁸. Each clinical site and the data coordinating center received institutional review board approval for these studies, and all subjects provided written informed consent.

The POPQ measurements Aa, Ba, Ap, Bp and C have positive values when the prolapse extends beyond the hymen and negative when the particular points remain proximal to the hymen. We created three composite measures of support loss (SL) as summary measures, SL3 (includes TVL, C, Ba and Bp), SL5 (includes TVL, C, Aa, Ba, Ap and Bp), and SLmax (includes location of single most distal point) (Figure 1).

When there is perfect support, POPQ points Aa, Ba, Ap and Bp equal minus 3; thus, the support loss formulas add 3 to each of these values so that, in a situation of perfect support, the resulting

measurement of support loss would equal zero. In regard to C (cervix or vaginal cuff), we added this value to total vaginal length (TVL); in a situation of perfect support, the negative C would be similar to TVL and result in a value near zero. We note that in women with a cervix *in situ*, perfect support may mean that negative C is not the same as TVL since the cervix is anterior and distal to the TVL measurement in the cul-de-sac. Figure 1 contains the equations for the three definitions tested in this analysis.

Each support loss measure was correlated with several measures of pelvic symptoms and severity, as well as condition-specific life impact: the Pelvic Organ Prolapse Quantification (POPQ) system stage^{3, 9}, total scores for responses to the Pelvic Organ Prolapse Distress Inventory (POPDI) and the Pelvic Organ Prolapse Impact Questionnaire (POPIQ), and responses to questions 4 (“usually have a sensation of bulging or protrusion”) and 5 (“usually have a bulge or something falling out seen/felt”) of the Pelvic Floor Distress Inventory (PFDI)⁴. Pearson correlation coefficients and associated p-values are reported. The relationships between POPQ stage with the support loss measures, POPIQ and POPDI were assessed using one-way ANOVA.

In order to assess the utility of these support loss measures to describe long-term anatomical outcomes, only two-year CARE data¹⁰ were used (as the ATLAS and OPUS studies only assessed one year outcomes). The change in each support loss measure, as well as POPQ stage from baseline to 24 months, was calculated. The relative responsiveness of each measure was evaluated using the standardized response mean (SRM). SRM, a commonly used statistic of responsiveness, is defined as the mean change in score over a time period divided by the standard deviation of individuals' changes in scores¹¹. A higher SRM (in absolute value) is indicates better responsiveness. A value of 0.5 is a cutoff for moderate responsiveness, 0.8 good responsiveness, and 1.0 excellent responsiveness¹¹. Pearson correlation coefficients were calculated for the change from baseline to 24 months in support measures and POPQ stage with corresponding changes in POPDI and POPIQ.

All reported p-values were based on the two-sided statistical tests and intended to be interpreted from a hypothesis-generating framework. The analyses were performed in SAS 9.1.3 for Windows (SAS Inc., Cary, NC).

Results

One thousand one hundred and forty-one subjects who enrolled in one of the three trials considered in this analysis and completed at least baseline POPQ data collection are the subject of this report (CARE trial, n=322; OPUS trial, n = 380; ATLAS trial, n =439). Subject characteristics for this pooled group, as well as for each individual study, are shown in Table 1. Consistent with the inclusion criteria for the studies evaluated, those enrolled in the CARE and OPUS trials had stage 2-4 prolapse while those enrolled in the ATLAS trial had stage 0 - 2 vaginal support. Overall, the distribution of POPQ stage for the pooled group was 4.3% stage 0, 17.9% stage 1, 29.4% stage 2, 40.5% stage 3 and 7.9% stage 4. 66% of subjects complained of vaginal bulging as indicated by an affirmative response to PFDI question number 4 or 5 and 48% of subjects indicated that they were bothered by these symptoms moderately or quite a bit.

For the pooled group, the mean±SD Support Loss 5 (SL5) was 18.1±12.6 (range 0 to 60), the SL3 was 13.2±10.1 (range: 0 to 48), and the SLmax was 1.5± 3.0 (range: -3 to 12) at their baseline evaluation. The relationship between each support loss measure and POPQ stage is shown in Table 2. Each support loss measure demonstrated a strong correlation with the POPQ ordinal staging with the strongest correlation seen with SLmax (SLmax, r=.93, SL5, r = .87; SL3, r=0.85, p<.001 for each). Each support loss measure demonstrated statistically significant

but weak correlations with POPDI and POPIQ scores similar to that of POPQ stage (Table 3). Moderate correlations were noted between each support loss measure and the presence and degree of bother caused by vaginal bulging symptoms (PFDI questions 4 and 5) ($r = 0.51-0.69$, $p < .01$ for each) which was also similar to that of POPQ stage ($r = .62$ and $.69$, $p < .001$).

The change in anatomic support in the CARE population two years after abdominal sacrocolpopexy is displayed in Table 4 using the three continuous support loss measures and POPQ stage. Each measure demonstrated excellent responsiveness with SRMs ranging from 1.89 to 2.25 with SLmax demonstrating the greatest responsiveness. However, improvements in anatomic support correlated only weakly with improvements in POPDI ($r = 0.17-0.24$, $p < .01$ for each) and did not correlate with changes in POPIQ for all measures of support loss or with POPQ stage (Table 4).

Discussion

In this study, we explored other ways, besides POPQ stage, of describing the POPQ examination results with a single summary score. When it was introduced in 1996, the POPQ system represented a significant advance for pelvic floor disorders research by providing clinicians and investigators with a quantitative and reliable tool to measure outcomes³. Each point in the POPQ system describes a specific part of vaginal support and at this time we recommend no changes in how these data are collected. However, in clinical research a summary score is helpful to compare treatments or groups of patients. Currently, POPQ stage is most frequently used to summarize the six POPQ points. This ordinal 0 through 4 staging system included in the original POPQ report was arbitrarily derived and the numerical measure intervals between the stages are ordinal. Since 1996, evidence has accumulated that Stage 2 prolapse (± 1 cm from the hymen) includes both symptomatic and asymptomatic women and normal and abnormal women¹²⁻¹⁶. In addition, Stage 3 prolapse encompasses a wide range, from prolapse >1 cm below the hymen to nearly complete vaginal prolapse. Finally, the arbitrary and non-linear nature of the ordinal staging system does not allow easy statistical comparisons between groups.

We found that a single numerical variable that is continuously expressed compares similarly to the ordinal POPQ staging system in measuring prolapse symptoms and bother, and prolapse related quality of life. The three different summary scores correlated well with prolapse symptoms, bother, and prolapse quality of life, and all were responsive to change. The SLmax score (also known as maximum vaginal descent) is the easiest to understand and does not require any calculations, and we therefore recommend it for most prolapse outcome studies in which characterization with a continuous score is desired. In our sample of over 1,000 women, the distribution of this measure was slightly right skewed. A desirable feature of a single summary measure would be the ability to be able to report with means and standard deviations with parametric statistical analysis so that results are easily imaged by the reader, improving transparency of surgical outcome reporting. Unlike the relative POP-Q-Index proposed by Lemos et al, in which a POP-Q index (the actual position score of one POP-Q point minus its anatomic (optimal) position score) is divided by the maximum possible POP-Q-Index for that point to create a continuous value expressed as a proportion, the SLmax score provides a summary of the entire vaginal support system, but requires no math or conversion factors¹⁷.

Our data and other studies indicate the SLmax score is clinically relevant, as it correlates well with a woman's perception of seeing or feeling a bulge (questions 4 and 5 on the PFDI)¹²⁻¹⁶. The weak correlation between the POPIQ and POPDI (~ 0.25) and the various summary scores reflects the fact that degree of prolapse correlates poorly with quality of life, which is more likely to be impaired due to pelvic floor symptoms that may or may not be related to the prolapse itself.

Given its ability to provide an easily understood measure of maximum vaginal descent and its high responsiveness, SLmax may serve as a good primary outcome in studies evaluating prolapse treatment. We do not, however, recommend that SLmax be the sole anatomic descriptor of prolapse. If the aim of a surgical procedure is to restore support to a specific compartment, it is logical to provide descriptive statistics for the pre- and post-operative status of that compartment. We recommend including SLmax, rather than or in addition to POPQ stage, and also providing results for all anatomic outcomes relevant to the procedure or treatment performed (generally measures of anterior, posterior and apical support).

Our study is strengthened by including a diverse group of 1141 women with a full range of prolapse stages. However, our data on responsiveness of the summary scores is limited to the CARE data, because the OPUS anatomic outcomes after surgery have not been completed and the ATLAS patients were not treated for prolapse.

In conclusion, we report some new continuous measures that closely correlate with POPQ stage and symptoms, and have statistical advantages and improved transparency. Our data suggest that reporting SLmax, the single most distal point in the ordinal POPQ system, may be preferable to reporting the POPQ ordinal stages when a single summary statistic is desired.

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Figure One. Equations for Three Summary Scores for Support Loss

$SL3 = (TVL + C) + (Ba + 3) + (Bp + 3)$; and $SLmax =$ location of single most distal point.

Zero is the theoretical lower limit of $SL5$ and $SL3$ and -3 is the limit for $SLmax$, and represent perfect support. Higher values of SL measures represent greater support loss.

Table 1
Baseline Patient Characteristics by Study and for Combined Population

	CARE Trial	OPUS Trial	ATLAS Trial	Total
N	322	380	439	1141
Age, Years	Mean (SD)	60.9 (10.2)	63.7 (10.0)	49.8 (11.9)
BMI, kg/m ²	Mean (SD)	27.1 (4.5)	28.1 (5.5)	29.5 (6.8)
Cesarean Deliveries	Median	0	0	0
	Min - Max	0 - 5	0 - 4	0 - 5
Vaginal Deliveries	Median	3	3	2
	Min - Max	0 - 11	0 - 12	0 - 12
Race				
White	299/322 (92.9)	331/380 (87.1)	374/439 (85.2)	1004/1141 (88.0)
Black	17/322 (5.3)	24/380 (6.3)	44/439 (10.0)	85/1141 (7.4)
Other	6/322 (1.8)	25/380 (6.6)	21/439 (4.8)	52/1141 (4.6)
Ethnicity				
Hispanic	9/322 (2.8)	52/380 (13.7)	32/439 (7.3)	93/1048 (8.2)
Prior Hysterectomy	228/271 (84.1)	143/378 (37.8)	108/437 (24.7)	479/1086 (44.1)
Prior UI Surgery	22/322 (6.8)	12/379 (3.2)	27/438 (6.2)	61/1139 (5.4)
Prior POP Surgery	126/322 (39.1)	53/379 (14.0)	15/439 (3.4)	194/1140 (17.0)
Prolapse Stage				
0	0 (0)	0 (0)	49/439 (11.2)	49/1141 (4.3)
1	0 (0)	0 (0)	204/439 (46.5)	204/1141 (17.9)
2	44/322 (13.7)	106/380 (27.9)	186/439 (42.4)	336/1141 (29.4)
3	218/322 (67.7)	244/380 (64.2)	0 (0)	462/1141 (40.5)
4	60/322 (18.6)	30/380 (7.9)	0 (0)	90/1141 (7.9)
PFDI question 4 – “Do you usually have a sensation of bulging or protrusion from the vaginal area?”				
No	28/315 (8.9)	43/346 (12.4)	346/424 (81.6)	417/1085 (38.4)
Yes, how much does it bother you?				
Not at all	10/315 (3.2)	11/364 (3.2)	6/424 (1.4)	27/1085 (2.5)
Somewhat	56/315 (17.8)	67/346 (19.4)	51/424 (12.0)	174/1085 (16.0)

	CARE Trial	OPUS Trial	ATLAS Trial	Total
Moderate	45/315 (14.3)	66/346 (19.1)	12/424 (2.8)	123/1085 (11.3)
Quite a bit	176/315 (55.9)	159/346 (46.0)	9/424 (2.1)	344/1085 (31.7)
PFDI question 5 – “Do you usually have a bulge that can be seen or felt in the vaginal area?”				
No	23/315 (7.3)	36/346 (10.4)	388/428 (90.6)	447/1089 (41.0)
Yes, how much does it bother you?				
Not at all	8/315 (2.5)	13/346 (3.8)	7/428 (1.6)	28/1089 (2.6)
Somewhat	48/315 (15.2)	63/346 (18.2)	19/428 (4.4)	130/1089 (11.9)
Moderate	53/315 (16.8)	58/346 (16.8)	7/428 (1.6)	118/1089 (10.8)
Quite a bit	183/315 (58.1)	176/346 (50.9)	7/428 (1.6)	366/1089 (33.6)
POPDI*	Mean (SD)	59.8 (62.6)	49.9 (48.2)	69.8 (63.8)
	Min - Max	0 - 300	0 - 214.3	0 - 300
POPIQ*	Mean (SD)	50.9 (61.6)	17.5 (42.7)	40.5 (63.3)
	Min - Max	0 - 371.5	0 - 278.8	0 - 371.5
SL5#	Mean (SD)	23.4 (10.0)	6.71 (4.00)	18.10 (12.60)
	Min - Max	7 - 60	0 - 21.5	0 - 60
SL3#	Mean (SD)	17.09 (8.30)	4.54 (2.61)	13.24 (10.06)
	Min - Max	4 - 48	0 - 14	0, 48
SLMAX #	Mean (SD)	2.88 (2.17)	-1.46 (1.00)	1.50 (3.05)
	Min - Max	-1 to 12	-1 to 10	-3 to 12

Data Presented as n/N (%) unless otherwise noted.

BMI, body mass index

* POPDI, Pelvic Organ Prolapse Distress Inventory (range 0-300); POPIQ, Pelvic Organ Prolapse Impact Questionnaire (range 0-400); higher scores indicate greater symptoms distress/life impact.

SL5 (Support Loss5) = (TVL + C) + (Aa + 3) + (Ap + 3) + (Ba + 3) + (Bp + 3); SL3 = (TVL + C) + (Ba + 3) + (Bp + 3); SLmax = location of single most distal point. Zero is the theoretical lower limit of SL5 and SL3 and -3 is the limit for SLmax, and represent perfect support. Higher values of SL measures represent greater support loss.

Table 2
Support Loss Outcomes by POPQ Stage

POPQ Stage	N	SL5	SL3	SLMAX
0	49	1.47 ±0.97 (0 to 4)	1.47±0.97 (0 to 4)	-3.00±** (-3 to -3)
1	204	4.78 ±1.88 (1 to 12.5)	3.40±1.52 (1 to 9.5)	-1.99 ± 0.25 (-3 to -1.5)
2	336	12.27 ± 4.15 (4 to 24)	8.21±3.20 (2 to 19)	-0.05 ± 0.78 (-1 to 1)
3	462	25.24 ± 7.75 (10.5 to 50.5)	18.62±6.79 (5.5 to 41.5)	3.52 ± 1.43 (1.5 to 8)
4	90	42.52 ±9.68 (16 to 60)	33.13±8.35 (9 to 48)	7.31 ±1.68 (3 to 12)
P value			<.001	<.001
R ²			0.73	0.87
R			0.85	0.93

SL5, SL3, SLMax data presented as mean ± standard deviation (range)

** standard deviation undefined

Table 3
Correlation between Baseline Support Loss Outcomes and Pelvic Organ Prolapse Distress Inventory and Impact Questionnaire

N=1,141	POPDI	POPIQ	PFDI Question 4	PFDI Question 5
SL5	0.25*	0.24*	0.57*	0.64*
SL3	0.24*	0.24*	0.55*	0.62*
SLmax	0.26*	0.25*	0.62*	0.69*
POPQ Stage	0.24*	0.24*	0.62*	0.69*

*
 p<0.01

Table 4
Change in Support Loss Measures 2 years after surgery in the CARE Trial

	Baseline N=322	24 Month N=250	Change from Baseline N=250	SRM	Correlation of change from baseline and change in POPDI (r)	Correlation with change from baseline and change in POPIQ (r)
SL5						
Mean (SD)	27.4 (11.3)	4.4 (3.3)	-22.7 (10.8)*	2.10	0.24*	0.10
Range	7 to 60	0 to 15	-53 to 0			
SL3						
Mean (SD)	20.6 (9.7)	2.6 (2.0)	-17.6 (9.3)	1.89	0.20*	0.09
Range	4 to 48	0 to 11	-42 to 0			
SLmax						
Mean (SD)	3.9 (2.4)	-1.5 (1.2)	-5.4 (2.4)*	2.25	0.22*	0.08
Range	-1 to 12	-3 to 3	-13 to 0			
POPQ Stage						
Mean (SD)	3.0 (0.6)	1.3 (0.8)	-1.8 (0.9)*	2.00	0.17*	0.01
Range	2 to 4	0 to 3	-4 to 0			

* p<0.01

POPDI, Pelvic Organ Prolapse Distress Inventory; POPIQ, Pelvic Organ Prolapse Impact Questionnaire
SRM, standardized response mean; values greater than 1 indicate excellent responsiveness.