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Surgical vs. non-surgical treatment in women with pelvic floor dysfunction: Patient-centered goals at one year

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Abstract

Objective—In women with pelvic floor dysfunction (PFD), we assessed the degree to which treatment (surgical vs. non-surgical) was associated with achievement of patient-centered goals, satisfaction with care, and quality of life.

Study design—Prospective cohort. Between September 2003 and December 2004 we recruited women during their first referral visit for PFD treatment at our outpatient Urogynecology Clinic. At the first visit, women enumerated up to five personal treatment goals, and “anchored” each goal by anticipating best and worst possible outcomes. At 12 month follow-up, women were asked to indicate their level of goal attainment (−2, worst outcome; +2, best outcome). At baseline and follow-up, women completed short forms of the Incontinence Impact Questionnaire (IIQ-7) and Urogenital Distress Inventory (UDI-6) (range 0–100, high scores indicating greater impact or distress). Patients indicated level of treatment satisfaction on a 4 level ordinal scale.

Results—Of the 127 study participants with complete data, 46 (36.2 %) were managed surgically and 81 (63.8%) non surgically. There were no major demographic differences between the two groups in terms of age, race, weight, prior PFD surgery, and vaginal parity. The surgical group was more likely to have received baseline diagnosis of pelvic organ prolapse (80 % vs 60 %, $p = 0.0259$), and be post-menopausal (89 % vs 72 %, $p = 0.0261$). There were no significant differences in the distribution of goal type (symptom relief, activity, self image, general health) by treatment status ($p = 0.1074$). Using logistic regression to adjust for age and baseline diagnosis, surgically managed patients at one year were significantly more likely to report complete primary goal attainment (odds ratio (OR) = 4.42; $p = 0.0154$) and complete treatment satisfaction (OR = 6.12; $p = 0.0109$). For all participants, one-year IIQ-7 and UDI-6 scores were significantly correlated with primary goal attainment scores.

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Condensation: self-described patient treatment goals are similar in surgical and non-surgical patients with pelvic floor dysfunction, but are more likely to be completely achieved in the surgical group one year later

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Conclusions—In this non-randomized, prospective analysis, surgically managed patients with PFD had higher one-year self-described complete goal attainment and satisfaction scores compared with non-surgically managed patients. Goal attainment scores correlated with disease-specific quality of life. Patient-centered outcomes should be incorporated in multi-center prospective research trials for pelvic floor disorders, and incorporated into clinical practice to inform treatment plans.

Keywords

pelvic floor dysfunction; treatment outcomes; patient satisfaction; quality of life; urinary incontinence; pelvic organ prolapse

Introduction

In 2001, the Institute of Medicine cited patient-centeredness among their six aims for improving health care in the 21st century, in addition to the other aims of safety, effectiveness, timeliness, efficiency, and equity. The committee defined patient-centered care as “providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions” (1).

Understanding patient preferences and defining treatment outcomes remains a major challenge for clinicians and researchers in the field of pelvic floor disorders. Historically, treatment outcomes for patients with urinary incontinence, pelvic organ prolapse, and anal incontinence have been defined in procedural, diagnostic, or symptom-based terms. More recently, efforts have focused on treatment dependant patient satisfaction, quality of life (QOL), and goal attainment (2–12).

In two prior investigations, we reported on patient-centered goals for pelvic floor dysfunction (PFD) patients undergoing surgery (11,12). In both short (6–12 weeks) and longer term (1–3 years) follow-up, patient self-reported goal achievement was maintained, and associated with higher quality of life(12). Similar findings were noted by Elkadry et al (9) who described an association between post-operative patient satisfaction and goal attainment at three months. Paradoxically, a lack of association between objective cure and satisfaction was also noted in this study. A one year follow-up assessment by Mahajan et al (10) noted a decrease in patient satisfaction for those women who had symptoms of urge incontinence and less subjective goal attainment.

The primary aim of this investigation was to describe and compare patient-described goals in a prospective cohort of women with PFD managed surgically and non-surgically. Our secondary aims portray the association of goal attainment over time with patient satisfaction and disease-specific quality of life.

Materials and Methods

The study took place at University of Virginia Health System outpatient Urogynecology Clinic, and was approved by the University of Virginia Institutional Review Board. Participants provided informed consent. All patients referred to the first author during 2003–2004 for evaluation and treatment of pelvic floor dysfunction were eligible to participate. All new consultation patients presenting to the first author were eligible to participate. Of 342 new consultation/eligible patients, 143 (41.8%) agreed to participate and provided written consent. Exclusion criteria included: refusal to participate, inability to read or understand English, dementia, or age under 18 years. Prior to their appointment date, participants provided, through questionnaires, a description of their primary presenting complaint and enumerations of symptoms of urinary incontinence (UI), pelvic organ prolapse (POP), and bowel function and

fecal incontinence (FI); information about their general health status (SF-36) and PFD-specific quality of life (UDI-6 and IIQ-7); and listed up to five treatment goals they hoped to achieve through their treatment. Participants provided “anchors” for each goal, describing their perception of the worst possible outcome related to that goal, as well as the best possible outcome. Goals responses were clarified by the study nurse prior to initial physician contact, and the physician remained blinded to patient goals throughout study period.

Follow-up surveys were then sent to participants 6 weeks, 3 months, 6 months, and 1 year after the initial visit. Follow-up surveys included the degree to which each goal had been attained, scaled from the worst possible outcome described by the participant (−2) to the best possible outcome (+2). In addition, each participant completed the PFD-specific quality of life scales (UDI-6 and IIQ-7). Finally, participants indicated their satisfaction with PFD treatment (completely satisfied, very satisfied, satisfied, not satisfied), whether or not they would agree to the same treatment again, and whether they would recommend the same treatment to others. In cases of no response, a second mailing and subsequent telephone contact were made by the study coordinator.

At each clinic visit, treatments were classified as surgical or non-surgical. Treatment options were individualized between each patient and the first author (KLH), who remained blinded to patient goals at all times during the study. Non-surgical interventions included expectant management, behavior modification programs (e.g., timed voiding, physical therapy), pessaries, and medications. At any given visit, women were classified as surgically managed if they had undergone any surgical procedure at or prior to that visit.

Outcome Measures

Women were classified as suffering from urinary incontinence, pelvic organ prolapse, or fecal incontinence based on self-report and initial exam. PFD-specific quality of life was assessed using the short versions of the Urogenital Distress Inventory (UDI-6), a lower urinary tract and prolapse symptom inventory, and the Incontinence Impact Questionnaire (IIQ-7). UDI and IIQ scores were calculated according to published algorithms (13). Because participants were asked to generate their own goals for therapy, and had their own expectations for success, goal attainment scaling was used as a method to measure success on disparate goals using a single metric (14–16). Each participant stated up to five goals, along with the worst possible and best possible subjective or clinical outcome they imagined for each goal. The worst and best outcomes “anchored” a five point scale, with −2 assigned to the worst outcome and +2 to the best. The primary outcome was the attainment “score” of the participant’s primary goal at 12 months. On the initial survey, participants also provided their age, race, educational and marital history, employment status, smoking and exercise habits, previous PFD surgical and medical history, family PFD history, and the number of times they had delivered vaginally.

Statistics

The principal goal of this analysis was to determine whether there were differences between surgically and non-surgically managed patients, either in demographic and clinical characteristics, or in post-treatment quality of life or goal attainment. In addition, we sought to evaluate the association between goal attainment and both quality of life and patient satisfaction. To assess unadjusted differences between surgically and non-surgically managed women, chi-square tests were used for categorical variables, and t-tests (with equal variances either assumed or not assumed, based on tests for homogeneity of variance) for continuous variables. To assess whether clinical management was associated with goal attainment independent of potential confounding factors, logistic regression models were generated, with management entered simultaneously with age and baseline diagnoses of POP, UI, and/or FI. Logistic regression was also used to model the odds of satisfaction (any or complete) at 12

months, adjusting for the aforementioned variables. Similarly, linear regression was used to estimate changes in IIQ and UDI scores at 12 months, adjusting for the same variables as well as baseline IIQ/UDI scores. To determine the extent to which goal attainment was associated with quality of life, Spearman correlation coefficients were calculated between 12-month primary goal attainment scores and both 12-month IIQ and UDI scores.

Results

Patient characteristics are presented in Table I. Of the original 143 participants, 78 withdrew or were lost to follow-up. Aside from a diagnosis of POP and menopausal status, there were no statistically significant baseline differences between the treatment groups.

As in our previous work, we classified goals into domains of 1) symptom relief, 2) activity, 3) self-image including sexual functioning, or 4) general health. Discrepancies for goal classification were resolved by consensus among investigators. Most of the rare discrepancies were due to multiple goal types within one sentence. We chose to classify the first part of a patient's goal in this instance. (For example, "I want to have less leakage and be able to exercise" would be included under symptom relief.) Pre-treatment goal domains did not significantly differ by treatment group. (Figure 1)

Although there was a non-significant difference in overall goal attainment (defined as +1 or +2) between treatment groups ($p = 0.0919$), as depicted in Table 2, surgically-managed patients overall had higher rates of satisfaction at one year compared with non-surgically managed patients ($p = 0.0192$). After adjusting for age and baseline diagnosis, surgically treated patients at one year were 4 times more likely to report complete primary goal attainment (score of +2) than non-surgically treated patients ($p\text{-value} = 0.0154$, Table 3). Similarly, the surgical group was six times more likely to endorse complete satisfaction with treatment than the non-surgically managed group ($p = 0.0109$). Analysis of primary goal attainment and satisfaction by baseline PFD diagnosis (prolapse, urinary incontinence, fecal incontinence) did not reveal any consistently strong or significant results. Those with urinary incontinence were less likely to have attained their goals or be satisfied at 12 months, although these findings were not significant. Those with fecal incontinence were significantly less likely to have completely attained their primary goal ($OR = 0.15$, $p = 0.0244$), with similar but not significant effects observed for satisfaction.

Linear models of 12-month change in IIQ-7 and UDI-6 scores revealed an estimated greater impact in decrease in these scores by 12 months for those who were surgically treated, although these results were not significant (Table 3). As noted in Table 4, for all study participants, goal attainment scores were correlated with 12 month UDI-6 and IIQ-7 scores and with the 12 month change from baseline IIQ-7 score but not with the change in 12 month UDI-6 score.

Comment

This investigation supports prior short-term conclusions about PFD patient-centered treatment goals: symptom relief and activity resumption are the most commonly stated primary patient-centered treatment goals, and goal attainment correlates with PFD-specific quality of life. Although in this investigation we found surgical patients were more likely than non-surgical patients to report greater degrees of primary goal attainment and complete satisfaction at one year post-treatment, it would be premature to conclude that surgery is superior to non-surgical methods.

It is possible that our findings indicate that surgical approaches are superior to non-surgical treatments in achieving the clinical changes that lead to patient-perceived improvements in symptoms and activity. One could also postulate that the greater relative anesthetic and peri-

operative risks of an operative approach implies a greater emotional “investment” on the part of a patient, with a potential for a greater “reward” if the outcome is favorable. Patient treatment preferences are obviously influenced by their clinicians, as noted by Lowenstein et al. (17). In that investigation, patients altered their pre-treatment goals after being counseled by their surgeon, from information-seeking and symptom-type goals to treatment goals. Although we did not assess the impact of physician counseling on patient goal selection/change, the potential for clinicians to either intentionally or inadvertently influence patient treatment choices should be examined in future observational studies. We did not attempt to characterize patient goals as plausible or not. For better or worse, these are the expectations and hopes that patients bring to us, and their judgment of whether treatment is “successful” is based on those expectations. One of the many avenues for this research is to investigate whether pre-treatment discussion of likely or realistic goals is beneficial. Future interventions may be able to improve care by deliberately modifying communication between clinicians and patients.

Our sample size was small, non-randomized, and heterogeneous with respect to both diagnoses and treatment, which clearly tempers our degree of confidence in our conclusions. However, across demographic and other study variables, the two treatment groups at baseline were remarkably similar. In addition, most PFD patients in our clinic carry more than one diagnosis (e.g., POP and UI) which is typical of PFD patients. We recognize the potential for uncontrolled confounding, and we adjusted for what seemed reasonable (i.e., age), but it may be that the surgery group differs from non-surgical group in ways we didn’t assess. In addition, the referral nature of our population may not be generalizable. Pelvic floor disorders tend to have dynamic symptomatology, and these results may change over time.

A more rigorous study design -- randomizing non-surgical and surgical PFD treatment for all conditions -- would be ethically and logistically difficult, at best. Ideally, goals outcome research should be conducted in a multi-centered, prospective randomized setting, among patients who have one PFD condition (e.g., POP alone, or genuine stress urinary incontinence alone), in order to make meaningful evidence-based conclusions stratified by PFD condition, and clarify the provocative nature of our pilot findings.

Another area ripe for additional study would include an assessment of how patient goals differ by socioeconomic, ethnic and geographical background. In contradistinction to the 20% rate of information-seeking goals from Lowenstein’s study in Chicago (17), less than 10% of participants (the majority of whom are from central Virginia) in the current analysis listed an information-seeking type of pre-treatment goal.

Our previous investigations allowed patients to subjectively rate goal achievement over time, but the addition of goal attainment scaling (GAS) in our current study allowed the anchors to be made explicit (i.e. forced pts to state their own ideas of best and worst), and allowed goal attainment over time to be gauged against an unchanging anchor. We believe that this fact, coupled with significant correlation in IIQ-7 and UDI-6 scores, supports the use of GAS as an approach to measuring outcomes in PFD treatment. Nonetheless, we recognize the limitation of using only these two short disease-specific questionnaires. Important domains not measured by the IIQ and UDI (e.g., sexual functioning, colorectal) need to be measured against goal attainment. Comparing goal attainment with other disease-specific PFD quality of life instruments, such as the pelvic floor distress inventory (PFDI) and pelvic floor impact questionnaire (PFIQ) from Barber et al. (18) for example, would further support validation of GAS.

The implications and comparisons of goal attainment, QOL, and satisfaction by treatment group requires additional longitudinal follow-up to see if these trends persist over time. Given the fact that up to one-third of women undergo repeat PFD surgery within a lifetime, short-

term analysis will not capture the reality of potential long term PFD management. Resource limitations precluded our ability to compare these subjective outcome assessments with objective measures. And although we contrasted our sample with the 78 patients who did not complete the study, human subjects considerations precluded us from comparing them on clinical outcomes.

We would advocate the incorporation of patient-centered goals in multi-center research and clinical settings to help frame goals with patients, address what might reasonably be expected of various interventions, track progress, and to motivate patients to achieve their own goals. This position aligns with what has been proposed by the Institute of Medicine:

“The committee recommends expanding the current repertoire of patient-centered measures so as to gain insight based on patients’ experiences, as patients are a valuable part of the interconnected chain of care delivery.... Data that capture measures of health care that matter to patients can be a powerful influence on how care is delivered by providers, purchased by payers, and adhered to by patients.” (19)

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Key definitions for abbreviations

PFD	pelvic floor dysfunction
QOL	quality of life
UI	urinary incontinence
POP	pelvic organ prolapse
FI	fecal incontinence
UDI	urinary distress inventory
IIQ	incontinence impact questionnaire

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Figure 1. Distribution of Primary Goals by Surgery Status

*No significant difference in distribution of goal types by surgery status ($p = 0.1074$)

Table 1
Study frequencies* of interest (overall and by surgery status**)

Variable	Overall	Surgery Status		p-value
		Surgery	No Surgery	
<i>n</i>	143	46	81	
Continuous variables				
Age	58.1 ± 12.4	59.7 ± 10.9	58.1 ± 13.1	0.4686
Height	63.9 ± 2.5	63.7 ± 2.0	64.0 ± 2.2	0.5987
Weight	163.4 ± 35.1	162.7 ± 31.4	162.0 ± 33.5	0.9026
Categorical variables				
Caucasian	136 (96%)	44 (96%)	76 (95%)	0.8685
High school degree or less	46 (34%)	16 (37%)	24 (30%)	0.4157
Currently Employed	75 (53%)	24 (52%)	42 (53%)	0.9719
Smoker	14 (10%)	5 (11%)	4 (5%)	0.2106
Alcohol				0.6473
Does not drink	66 (46%)	22 (48%)	38 (47%)	
Less than 1–2 drinks per day	64 (45%)	22 (48%)	34 (42%)	
1–2 drinks per day or more	12 (8%)	2 (4%)	9 (11%)	
Currently exercises	94 (68%)	29 (64%)	57 (71%)	0.4305
Menopausal	109 (78%)	41 (89%)	57 (72%)	0.0261
Prior PFD surgery	26 (18%)	11 (24%)	12 (15%)	0.1800
Prior hysterectomy	67 (47%)	25 (56%)	33 (41%)	0.1099
Family history of PFD	71 (52%)	21 (50%)	43 (62%)	0.2027
Vaginal parity				0.0296
0 deliveries	8 (6%)	2 (4%)	6 (7%)	
1 delivery	25 (17%)	4 (9%)	18 (22%)	
2 deliveries	50 (35%)	16 (35%)	28 (35%)	
3 + deliveries	60 (42%)	24 (52%)	29 (35%)	
Baseline diagnosis of:				
POP	86 (68%)	37 (80%)	49 (61%)	0.0259
POP Stage:				0.0111
Stage I	2 (2%)	0 (0%)	2 (3%)	

Variable	Surgery Status		p-value
	Surgery	No Surgery	
Stage II	16 (36%)	23 (31%)	
Stage III	15 (34%)	17 (22%)	
Stage IV	4 (9%)	3 (4%)	
UI	26 (57%)	59 (74%)	0.0469
UI Type:			0.4130
UI-Mixed	9 (35%)	14 (23%)	
UI-Urge	8 (31%)	18 (30%)	
Incomplete Empty	5 (19%)	9 (15%)	
UI-Stress	4 (15%)	19 (32%)	
FI	16 (35%)	19 (24%)	0.1975
<i>Withdrew at baseline</i>	--	--	
<i>Total withdrawals</i>	14 (30%)	32 (40%)	0.3066

* Data are reported in terms of frequencies (percentages in parentheses) of the column attribute

** Defined as having surgery during the study

Table 2Results of 12-month outcomes of interest (overall and by surgery status^{**})

Variable	Overall	Surgery Status		p-value [†]
		Surgery	No Surgery	
Primary Goal Attainment Score [*]				0.0919
−2	6 (8%)	3 (10%)	3 (7%)	
−1	8 (10%)	3 (10%)	5 (11%)	
0	13 (17%)	2 (6%)	11 (24%)	
1	26 (34%)	9 (29%)	17 (37%)	
2	24 (32%)	14 (45%)	10 (22%)	
Satisfaction with Treatment [*]				0.0192
Not satisfied	15 (20%)	7 (23%)	8 (18%)	
Satisfied	24 (32%)	2 (6%)	22 (49%)	
Very satisfied	20 (26%)	11 (35%)	9 (20%)	
Completely satisfied	17 (22%)	11 (35%)	6 (13%)	
IIQ-7 Score (Mean ± SD)				
Baseline	36.5 ± 30.0	37.9 ± 34.0	36.6 ± 28.2	0.8249
12 Months	11.9 ± 19.4	9.7 ± 20.2	13.4 ± 19.0	0.4191
Change (12mo – baseline)	−22.4 ± 27.3	−28.4 ± 30.6	−18.8 ± 24.8	0.1449
UDI-6 Score (Mean ± SD)				
Baseline	44.5 ± 24.1	40.8 ± 23.8	46.6 ± 24.2	0.2424
12 Months	25.0 ± 22.3	18.0 ± 20.0	29.8 ± 22.6	0.0212
Change (12mo – baseline)	−17.3 ± 27.3	−20.3 ± 25.3	−15.4 ± 28.5	0.4652

* Data are reported in terms of frequencies (percentages in parentheses) of the column attribute

** Defined as having surgery during the study

† p-values from the Wilcoxon rank sum test (first two variables, exact computation) and the t-test (IIQ-6 and UDI-6 variables) comparing the two surgery groups

Table 3
Twelve-Month Outcomes of Interest: Age-Adjusted Model Results

Model Variable	Logistic Regression Odds Ratio Estimates (95% Confidence Interval, p-value)			Linear Regression Parameter Estimates (p-value)	
	Primary Goal Attainment [*]	Complete Primary Goal Attainment ^{**}	Satisfaction [†]	Change in IIQ-7 Score [‡]	Change in UDI-6 Score [‡]
<i>Surgery (Yes vs. No)</i>	2.57 (0.85, 7.73) p = 0.0942	4.42 (1.33, 14.73) p = 0.0154	0.90 (0.26, 3.14) p = 0.8662	-4.58 p = 0.3263	-8.09 p = 0.1429
<i>Baseline diagnosis of:</i>					
POP	0.83 (0.26, 2.64) p = 0.7499	1.42 (0.38, 5.26) p = 0.6027	1.55 (0.34, 7.03) p = 0.5702	6.14 p = 0.2443	1.70 p = 0.7893
UI	0.50 (0.15, 1.69) p = 0.2620	0.35 (0.10, 1.25) p = 0.1067	2.03 (0.50, 8.21) p = 0.3188	5.12 p = 0.3172	3.37 p = 0.6043
FI	0.29 (0.08, 1.05) p = 0.0593	0.15 (0.03, 0.78) 0.0244	0.71 (0.17, 3.07) p = 0.6486	-2.25 p = 0.6868	-6.37 p = 0.3384

* Primary goal attainment score of 1 or 2

** Primary goal attainment score of 2

† Any level of satisfaction (satisfied, very satisfied, completely satisfied)

‡ Adjusting for baseline value of the IIQ/UDI score as well as age. Model $R^2 = 0.60$ for IIQ-6, model $R^2 = 0.43$ for UDI-6

Table 4
IIQ and UDI Scores vs. Primary Goal Attainment Score at 12 months

Primary Goal Attainment Score	n	IIQ (Mean ± SD)		UDI (Mean ± SD)	
		12-Month Score	Change (12mo-baseline)	12-Month Score	Change (12mo-baseline)
-2	5	11.4 ± 16.0	-17.1 ± 39.6	33.3 ± 23.9	-22.2 ± 31.9
-1	8	18.5 ± 16.0	-10.2 ± 20.2	28.5 ± 25.4	-17.4 ± 25.1
0	12	25.4 ± 23.9	-11.9 ± 12.9	38.9 ± 23.2	-12.5 ± 21.5
1	24	10.5 ± 20.0	-29.6 ± 28.6	27.3 ± 18.2	-14.3 ± 25.4
2	23	5.2 ± 17.2	-26.8 ± 30.9	15.6 ± 22.2	-23.4 ± 34.1
<i>Spearman Correlation Coefficient (p-value)</i>		-0.52 (< 0.0001)	-0.22 (0.0729)	-0.38 (0.0011)	-0.11 (0.3903)