Defining success following sling surgery: association of satisfaction with patient reported outcomes

David E. Rapp, MD, Nancy J. Neil, PhD, Kathleen C. Kobashi, MD
The Continence Center at Virginia Mason Medical Center, Seattle, Washington, USA

RAPP DE, NEIL NJ, KOBASHI KC. Defining success following sling surgery: association of satisfaction with patient reported outcomes. The Canadian Journal of Urology. 2010;17(1):4995-5001.

Aims: *The assessment of incontinence therapies is complicated by the variety of patient reported outcomes (PRO) measures used in research protocol. Patient satisfaction may be one of the most relevant albeit complex PRO measures and is a function of many related variables. We sought to assess the relationship between patient satisfaction and other PRO.*

Methods: *A retrospective review of patients undergoing SPARC (n = 314) and autologous rectus pubovaginal sling (PVS) (n = 127) was performed, with 204 (SPARC) and 67 (PVS) patients completing questionnaire surveillance and minimum 12 month follow up. Outcomes were assessed using validated incontinence questionnaires (UDI-6, IIQ-7) supplemented with additional items addressing subjective improvement. Comparisons were made between patients reporting a willingness to recommend and repeat surgical intervention (combined variable, satisfaction surrogate) and achievement of defined endpoints in the remaining outcome measures.*

Results: *A large difference in outcomes was seen depending on PRO measure analyzed. Dry was the strictest measure used (33%, SPARC; 39%, PVS; p = NS), while ≥ 50% improvement was reported with the greatest frequency (75%, SPARC; 73%, PVS; p = NS). With the exception of pad use, a statistically significant association between all PRO measures and the willingness to recommend/repeat surgery was identified.*

Conclusions: *Our data demonstrate an association between a variety of PRO measures and patient reported satisfaction. Based on this finding, the development of a simplified and standardized PRO instrument, one that maintains an accurate reflection of patient satisfaction and is less cumbersome for the patient may be possible.*

Key Words: patient satisfaction, outcomes, sling

Introduction

A variety of instruments are used to assess outcomes following the medical or surgical treatment of urinary incontinence (UI). Historically, focus has been placed on objective markers that provide defined information regarding a biologic response to treatment, including bladder diary variables and urodynamic parameters.[1] Despite their utility, these instruments fail to define the impact that incontinence has on patients' daily lives or the patient perceived benefit of intervention.[1] Accordingly, more focus has recently been placed on the inclusion of patient reported outcomes (PRO) in related research. The importance of these instruments is highlighted by data demonstrating the failure of objective symptom improvement to correlate with subjective benefit following incontinence therapies.[2,3]

Many instruments have been developed to assess PRO in the treatment of overactive bladder and incontinence.[4] Taken together, these instruments assess a wide range of concepts (including symptomotology, physical function, psychological well being, and role activities) in a variety of ways. While these tools are important in providing clinicians with a global understanding of the impact a treatment has on a patient,[5] the lack of consistency among them complicates the process of incorporating both objective and subjective outcome measures into a common instrument, interpreting the resultant data, and defining a successful result.

Accepted for publication September 2009

Address correspondence to Dr. David E. Rapp, Virginia Mason Medical Center, 1100 9th Avenue, C-7 URO, Seattle, WA 98111 USA

Arguably the most important and complex construct within the framework of subjective outcomes is that of patient satisfaction. Because it is a function of many variables, patient satisfaction often demonstrates a complex relationship with other outcome measures. Certainly, satisfaction is related to objective treatment outcome and patient expectation for treatment benefit.[6] However, satisfaction may also be shaped by variables separate from the treatment outcome itself, such as patient age and gender (fixed characteristics) or nursing care and physician patient interaction (variable experiences).[6] Despite the many factors influencing patient satisfaction, it can be argued that satisfaction is the single most important subjective outcome as a satisfied patient generally indicates a successful result irrespective of remaining outcome measures.

We sought to evaluate the relationship between patient satisfaction and other commonly used PRO measures following the surgical treatment of incontinence. Specifically, we hypothesized that some outcome measures may demonstrate greater levels of statistical association with patient satisfaction, thereby supporting the use of these measures in current assessment instruments. For the purpose of this analysis, patient willingness to recommend and repeat the surgical management was used as a surrogate for patient satisfaction. Comparisons were then made between this measure and remaining outcome measures. Analyses were performed separately for cohorts of patients undergoing autologous rectus fascial pubovaginal sling (PVS) and SPARC mid-urethral sling placement in the treatment of stress urinary incontinence.

Materials and methods

A retrospective review of patients undergoing SPARC (American Medical Systems, Minnetonka, MN) and PVS placement was performed using the prospectively collected Continence Center database at Virginia Mason Medical Center. Surgical procedures were performed by one of two surgeons. The surgical technique for SPARC placement is previously described.[7] PVS placement was performed using standard technique, as described by Blaivas.[8] PRO were assessed using a mailed questionnaire comprised of separate subjective outcome measures as described below. Virginia Mason Medical Center IRB approval was obtained for the study protocol.

Outcome measures

Patient outcomes were assessed using a variety of selected PRO measures as detailed in Table 1. The specific outcomes selected for this analysis included frequency of incontinence episodes, daily pad use, patient perceived symptom improvement, patient satisfaction, likelihood of recommending the surgery to a friend, likelihood of electing surgery again if they had the opportunity to choose again, and the Urogenital Distress Inventory (UDI-6) and Incontinence Impact Questionnaire (IIQ-7) short form questionnaire scores.

Incontinence frequency and daily pad use were assessed as described in Table 1. Patient perceived improvement and satisfaction were separate questions assessed using a graded Likert scale. Likelihood of recommending or repeating surgical intervention were phrased as dichotomous (yes/no) questions. Both the

TABLE 1. **Selected outcomes measures from incontinence questionnaire**

1. Do you leak when you cough, sneeze, or perform physical activities?
a. never, b. < 1/week, c. once/day, d. always, e. not sure

2. Protection required during the day?
a. no pads, b. 1-3 liners, c. 1-3 medium pads/day, d. 1-3 large pads/day, e. > 3 pads/day or diapers

3. How much improved is your urinary leakage now compared to before the surgery?
100% better, 90%, 80%, 70%, 60%, 50%, 40%, 30%, 20%, 10% better, the same, worse

4. Overall, how satisfied are your with the results of your sling surgery?
0 (not satisfied), 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 (very satisfied)

5. Knowing what you know now, would you have the sling surgery again?
a. yes, b. no, c. not sure

6. Would you recommend the sling surgery to a friend?
a. yes, b. no, c. not sure

UDI-6 and IIQ-7 are empirically validated instruments assessing urinary symptom distress and life impact as described by Ubersax and colleagues.[9]

Statistical analyses

To assess the relationship between patient satisfaction and other outcome measures, we compared patients reporting a willingness to recommend and repeat surgical intervention (combined variable) with achievement of defined endpoints in the remaining outcome measures. Patient willingness to recommend/repeat surgical intervention (yes/no) was used as the dependent variable. Non-parametric tests of association (chi square) were performed on all variables; in the case of Likert scales, two alternative thresholds of success (percent improvement, ≥ 50% and ≥ 70%; satisfaction, ≥ 5 and ≥ 7) were used, owing to the use of similar thresholds in published literature.[7,10] Similarly, three score thresholds were selected for analysis of both UDI-6 (≤ 6, 7-12, ≥ 13) and IIQ-7 (≤ 7, 8-14, ≥ 15) scores. Analyses were performed separately for each sling type. Fisher's Exact correction was employed for analyses with any cell size less than 10. Additionally, we used Z-test for proportions to compare levels of outcome attainment in SPARC versus PVS cohorts. Student's t-test was used to compare mean UDI-6 and IIQ-7 questionnaire scores in SPARC versus PVS cohorts. Each analysis was structured as a two-tailed test at the $\alpha = .05$ level.

Results

A total of 314 and 127 female patients underwent SPARC and PVS placement between June 2001 and March 2007, respectively, with 259 (82%) and 74 (58%) completing required questionnaire surveillance. Of these, 204 (SPARC) and 67 (PVS) patients achieved 12 month minimum follow up and were included in data analysis. Mean patient age in the SPARC cohort was 63 years (range 23-91); mean age in the PVS cohort was 68 years (range 40-93). Mean follow up among SPARC patients was 32 months (range 12-52) and 36 months (range 14-56) in the PVS cohorts.

TABLE 2. **Outcomes following sling placement**

Outcome	**SPARC (n = 204) (patients (%))**	**PVS (n = 67) (patients (%))**	**p value**
Incontinence frequency			
Dry (no leakage)	67 (33)	26 (39)	ns
< 1 episode/week	75 (37)	22 (33)	ns
Pad use (daily)			
No pads	114 (56)	35 (52)	ns
1-3 liners	63 (31)	18 (27)	ns
> 3 liners or any med/large pads	27 (13)	14 (21)	ns
% Improvement*			
100	72 (35)	28 (42)	ns
≥ 70	139 (68)	46 (69)	ns
≥ 50	152 (75)	49 (73)	ns
Satisfaction*			
10	76 (37)	23 (34)	ns
≥ 7	134 (66)	43 (64)	ns
≥ 5	150 (74)	46 (69)	ns
Recommend			
Yes	151 (74)	44 (66)	ns
Repeat			
Yes	154 (75)	46 (69)	ns
UDI-6 (mean (SD))	4.6 (3.8)	5.1 (4.6)	ns
IIQ-7 (mean (SD))	2.4 (5.3)	3.0 (4.6)	ns

*Figures represent patients achieving listed outcome or superior outcome; data presented is limited to outcome thresholds shown.
ns = non significant (p > 0.05)

Outcomes following SPARC and PVS placement are detailed in Table 2. Results showed wide differences in sling "success" rates depending on the outcome measure used. The complete absence of incontinence episodes ("dry") was the strictest outcome measure used, with 33% and 39% of patients achieving this outcome in the SPARC and PVS cohorts, respectively. Conversely, improvements ≥ 50% were associated with the greatest percentage of patients achieving this response in both sling types (75%, SPARC; 73%, PVS). These data are previously reported.[11] UDI-6 and IIQ-7 questionnaire scores showed similar results between the sling cohorts. Statistical analysis revealed no significant differences in the proportion of SPARC and PVS patients achieving a positive outcome in each of the measures used.

Our primary analysis focused on the relationships between patients' willingness to recommend/repeat surgical intervention and the remaining outcome measures. These results are presented in Table 3. A statistically significant association between most PRO measures and the willingness to recommend/repeat surgical intervention was identified, including various degrees of post-surgical incontinence frequency and all selected thresholds of the improvement and satisfaction Likert scales. In contrast, mixed results were seen in the analysis of pad use versus willingness to recommend/repeat. While a statistically significant association was demonstrated for the absence of pad use, a similar association was not observed for patients reporting the continued use of liners for protection. Finally, a statistically significant association between assessed UDI-6/IIQ-7 score thresholds was identified. As expected, the finding of UDI-6/IIQ-7 scores in the highest score threshold (worse outcome) was statistically associated with an unwillingness to recommend/repeat.

TABLE 3. **Results of chi square analyses: patient reported outcomes versus likelihood of recommend/repeat**

	Recommend/Repeat (yes)*	
PRO measure	**SPARC (n = 204) (p value)**	**PVS (n = 67) (p value)**
Incontinence frequency		
Dry (no leakage)	< 0.0001	0.02
< 1 episode/week	< 0.0001	0.0002
Pad use (daily)		
No pads	< 0.0001	0.01
1-3 liners	0.013	0.57
% Improvement*		
100	< 0.0001	< 0.0001
≥ 70	< 0.0001	< 0.0001
≥ 50	< 0.0001	< 0.0002
Satisfaction*		
10	< 0.0001	0.0004
≥ 7	< 0.0001	< 0.0001
≥ 5	< 0.0001	< 0.0001
UDI-6		
≤ 6	< 0.0001	< 0.0001
7-12	< 0.0001	0.02
≥ 13†	0.0025	0.06
IIQ-7		
≤ 7	< 0.0001	0.0015
8-14	0.0043	0.0041
≥ 15†	0.0025	0.08

*Analysis performed for patients reporting 'yes' to both "would recommend" and "would repeat" surgical intervention.
†Association between higher score (worse outcome) and unwillingness to recommend/repeat.
PRO = patient-reported outcome; PVS = pubovaginal sling; UDI = urogenital distress inventory; IIQ = incontinence impact questionnaire

Discussion

In an effort to improve outcomes reporting, the International Consultation on Incontinence of 2002 forwarded recommendations regarding clinical outcomes reporting in incontinence therapies.[12] The guidelines call for the use of both clinician and patient based observational symptom instruments to provide both objective and subjective information regarding patient response. These recommendations have been paralleled by a great number of varied PRO instruments used in incontinence research. Despite the importance of such tools, this variation yields inconsistencies in data reporting, limiting the ability of the urologic community to perform uniform data analyses and forward evidence-based recommendations regarding optimal treatment modalities.[13] Such difficulties are evident in an attempt by the American Urological Association to determine the success of interventions for UI, in which inconsistencies in results reporting limited the panel's ability to identify a common representation of outcomes.[14] Accordingly, the resultant guidelines have been criticized for a lack of specific evidence based recommendations, highlighting the need for defined approaches to outcomes reporting.[13] Indeed, these issues have led to academic support for the initiation of common assessment tools to be used by academicians studying UI therapy outcomes.[15]

Attempting to identify the optimal type and number of outcome measures for use in a common instrument remains difficult. Certainly, the interpretation of objective response is more straightforward and, therefore, defining success based on these parameters is attractive to the clinician. However, as patient perceived responses do not always correlate with objective improvement, assessment of treatment benefit using PRO instruments is important.[3] Unfortunately, whereas a finite number of objective measures for UI exist, a far greater number of PRO instruments have been introduced and make the process of identifying the optimal instrument difficult. Further, the inclusion of multiple PRO questionnaires in study protocol becomes cumbersome for the patient and may limit patient response.

Based on this background, we maintain that there would be value not only in identifying optimal PRO instruments, but also standardizing and focusing those instruments on only those measures demonstrated to be most closely associated with positive/negative patient outcomes. While patient satisfaction may be one of the most relevant variables and may represent the best measure of subjective success, other PRO measures may have relevance as well. For these reasons, it becomes important to assess the relationship between satisfaction an additional PRO measures in an attempt to identify those measures most reflective of patient benefit. Our investigation sought to assess this relationship.

This study reveals several important findings. Foremost, significant associations were identified between nearly all PRO measures analyzed and likelihood of recommending/repeating ("recommend/repeat"). Such findings indicate that each measure may provide an accurate reflection of patient satisfaction when assessing outcomes following sling surgery. Concurrently, these data complicate the task of simplifying PRO instruments by failing to identify specific measures that most accurately reflect positive satisfaction. Nonetheless, our results suggest that it may be possible to use a more limited number of PRO measures as they may reflect similar data.

In further analyzing the specific PRO measures, several additional findings were notable. First, significant associations were seen in evaluating the relationship between both dry and rare (< 1 episode/week) incontinence frequencies and recommend/repeat. This finding may suggest that patients are indeed satisfied when complete absence of leakage is not achieved.

In contrast to these positive associations, analysis of daily pad use demonstrated mixed results. Whereas the absence of pad use exhibited a strong association with recommend/repeat, the use of 1-3 liners did not demonstrate an association in the PVS cohort. Given the associations demonstrated for incontinence frequency measures, these data may suggest that pad use is an inferior measure of patient satisfaction. Certainly, the difficulty in interpreting pad use results is well known. As some patients may use pads primarily for protection whereas others do so for significant leakage, pad use does not necessarily represent the degree of associated leakage. Such discrepancy is the basis for the development of the pad test in order to allow for more objective assessment of this variable. Previous investigation demonstrated that improvements in incontinence episodes did not parallel reductions in daily pad use following UI treatment, further supporting that pad use may be a less optimal measure for PRO instruments.[16]

Strong associations were also seen when comparing all analyzed thresholds selected for the improvement and satisfaction Likert scales. The use of such scales is common to PRO instruments in incontinence research, although the threshold used to define success remains controversial. These data may support that complete improvement is not mandatory for patient satisfaction and, further, that the use of any of these thresholds may be

an appropriate measure of success. However, in the PVS cohort we note the lower percentage of patients reporting a likelihood of recommending/repeating as compared to that achieving improvement levels of 50%.

Finally, strong associations were identified for the lowest and intermediate score thresholds of the UDI-6/IIQ-7 scores. While these data suggest that lower and intermediate questionnaire scores may be associated with patient satisfaction, we also believe that these results underscore the difficulty in interpreting UDI/IIQ scores by failing to discriminate between score totals. Despite their common use in reported incontinence investigation, a paucity of data exists to truly define normal/abnormal values for both questionnaires in large population-based study and to further define disease severity based on score levels. Normative values for the UDI-6 are presented based on a community-based analysis of patients receiving nonurologic primary care.[17] Nonetheless, further research is necessary to provide an evidence based score key by which the urological community may interpret these commonly used instruments.

Despite assessing identical PRO, some minor variation was seen in the results of the chi square analysis between sling types. The etiology of this discrepancy is unclear to us. However, this finding would underscore the complexity of developing PRO instruments that are effective at assessing outcomes for different treatments of a common disease type.

Certain study limitations should be addressed. Foremost, we acknowledge the limitation to using likelihood of recommending/repeating as a surrogate for satisfaction. Nonetheless, in order to analyze the association between satisfaction and additional measures, we felt that it was important to attempt to characterize satisfaction in a dichotomous fashion. Our PRO instrument has been in use since 1999 and directly solicits satisfaction degree using a Likert scale as opposed to a "yes/no" question item. For this reason, a surrogate was used as detailed. Nonetheless, an association between the Likert satisfaction scale and recommend/repeat was demonstrated, which may support the use of this measure as a surrogate. Importantly, the inclusion of two sling cohorts was not intended as a direct comparison of outcomes. Results detailing outcomes in patients undergoing SPARC are previously reported.[7] As a direct comparison, this study would be characterized by methodologic limitations, including a retrospective nature, cohort differences, a single site, and limited follow up numbers. However, in contrast, the inclusion of two cohorts was reported to specifically assess whether the relationship between PROs and satisfaction was maintained in two different surgical populations.

Conclusion

The sheer variety of PRO measures complicates the process of developing a common instrument for use within the urologic community, and the resultant process of interpreting the data and defining a successful result of treatment. Patient satisfaction may be one of the most relevant, albeit complex, PRO measures and represents an important endpoint in understanding subjective success following incontinence therapies. This analysis demonstrates an association between a variety of PRO measures and patient reported satisfaction. Results of our study suggest that it may be possible to develop a simplified PRO instrument for use in related research. This simplification is an integral part of the development of a commonly accepted PRO instrument that can not only assess the outcomes of incontinence therapies, but do so in a way that is not cumbersome for the patient and facilitates data analysis and interpretation across studies. □

References

1. Brubaker L, Chapple C, Coyne KS, Kopp Z. Patient-reported outcomes in overactive bladder: importance for determining clinical effectiveness of treatment. *Urology* 2007;68(Suppl 2A): 3-8.
2. Burgio KL, Locher JL, Roth DL, Goode PS. Psychological improvements associated with behavioral and drug treatment of urge incontinence in older women. *J Gerontol B Psychol Sci Soc Sci* 2001;56(1):46-51.
3. Franco AV, Lee F, Fynes MM. Is there an alternative to pad tests? Correlation of subjective variables of severity of urinary loss to the 1-h pad test in women with stress urinary incontinence. *BJU Int* 2008;102(5):586-590.
4. Coyne KS, Tubaro A, Brubaker L, Bavendam T. Development and validation of patient-reported outcomes measures for overactive bladder: a review of concepts. *Urology* 2006;68(Suppl 2A):9-16.
5. Fitzpatrick R, Davey C, Buxton MJ, Jones DR. Evaluating patient-based outcome measures for use in clinical trials. *Health Technol Assess* 1998;2(14):1-73.
6. Marschall-Kehrel D, Roberts RG, Brubaker L. Patient-reported outcomes in overactive bladder: the influence of perception of condition and expectation for treatment benefit. *Urology* 2006; 68(Suppl 2A):29-37.
7. Nazemi T, Yamada B, Govier FE, Kuznetsov DD, Kodama K, Kobashi KC. Minimum 24-month followup of the SPARC sling for the treatment of stress urinary incontinence. *J Urol* 2008; 179(2):596-599.
8. Blaivas JG, Jacobs BZ. Pubovaginal fascial sling for the treatment of complicated stress urinary incontinence. *J Urol* 1991;145(6):1214-1218.
9. Uebersax JS, Wyman JF, Shumaker SA, McClish DK, Fantl JA. Short forms to assess life quality and symptom distress for urinary incontinence in women: the Incontinence Impact Questionnaire and the Urogenital Distress Inventory. *Neurourol Urodyn* 1995;14(2):131-139.

10. Rodriguez LA, Bukkapatnam R, Shah SM, Raz S. Transvaginal paravaginal repair of high-grade cystocele and lateral defects with concomitant suburethral sling: report of early results, outcomes, and patient satisfaction with a new technique. *Urology* 2005;66(Suppl 5A):57-65.
11. Rapp D, Kobashi K. Outcomes following sling surgery: importance of definition of success. *J Urol* 2008;180(3):998-1002.
12. Payne C, Van Kerrebroeck P, Blaivas J, Herrera H, Chaikin D, Jonas U et al. Research methodology in urinary incontinence. In: Wein A (ed). Incontinence: 2nd International Consultation on Incontinence. Plymouth, UK; Health Publication, 2002;1045-1077.
13. Cole EE, Scarpero HM, Dmochowski RR. The assessment of outcomes used for incontinence interventions in women. In: Staskin D, Cardozo L (eds). Textbook of Female Urology and Urogynecology. Isis Medical, 2005.
14. Leach GE, Dmochowski RR, Appell RA, Blaivas JG, Hadley HR, Luber KM et al. Female stress urinary incontinence clinical guidelines panel. Summary report on the surgical management of female stress urinary incontinence. *J Urol* 1997;158(3 pt 1): 875-879.
15. Zimmern P. Personal communication re: Outcome Measure for Incontinence Treatment (OMIT) Committee, January, 2008.
16. Barkin J, Corcos J, Radomski S, Jammal MP, Miceli PC, Reiz JC et al. A randomized, double-blind, parallel-group comparison of controlled- and immediate-release oxybutynin chloride in urge urinary incontinence. *Clin Ther* 2004;26(7):1026-1036.
17. Svatek R, Roche V, Thornberg J, Zimmern P. Normative values for the American Urological Association Symptom Index (AUA-7) and short form Urogenital Distress Inventory (UDI-6) in patients 65 and older presenting for non-urological care. *Neurourol Urodyn* 2005;24(7):606-610.