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Lessons from a Patient Experience Survey in a Randomized Surgical Trial of Treatment of Stress Urinary Incontinence in Women

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Abstract

Intorduction and hypothesis—To understand the patient burden of study procedures/ measures at completion of a randomized controlled trial (RCT) requiring extensive testing and follow-up visits.

Methods—A survey sent after completing the 2 year visit of an RCT comparing Burch colposuspension and fascial retropubic sling to treat stress urinary incontinence assessed degree of bother for seven study procedures, eight study-related factors, and possible motivations to participate in the study.

Results—A total of 450 study participants (88%) returned the survey. Urodynamic testing was the most bothersome procedure, followed by 24 hour pad test and Q-tip test. Self-administered questionnaires were the least bothersome. Main reasons to participate in the study were to help others, obtain better knowledge about the condition, and be guided by a committed team of investigators/study coordinators.

Conclusion—At the end of a large multicenter RCT, we learned from a confidential patient survey that the most burdensome activities involved invasive procedures, frequent visits, and multiple forms to fill out.

Keywords

outcome measures; patient survey; stress incontinence

Introduction

The Stress Incontinence Surgical Treatment Efficacy Trial (SISTER) was the first NIH-sponsored multicenter randomized clinical trial to investigate surgical treatment of stress urinary incontinence (SUI) in women. This study was performed by the Urinary Incontinence Treatment Network (UITN)(1) and compared the Burch colposuspension to the pubovaginal sling. SISTER was a landmark study both in its contribution to the literature for randomized surgical trials as well as for its contribution to evidence-based medicine for the treatment of incontinence. The study design and results(2–3) have been published.

Given the paucity of data on patients' experiences in clinical trials, a survey was designed to capture such information from SISTER participants. A literature search for similar data resulted in very few findings(4–6) with the paper by Henzlova et al(6) being the most

similar. In the latter study, participants in a long-term heart failure trial were surveyed with a 10-item questionnaire at the close-out of the study. A 74% response rate was observed. The most common reasons for enrollment were physician recommendation, “to contribute to medical science”, and “to help others”. The majority were satisfied with their experience and would be willing to participate in a future clinical trial. Transportation to and from the clinic and frequent staff changes were mentioned among the negatives.

Committed both to improving a subject’s experience in incontinence research and to conducting future high quality trials, the UITN’s SISTER survey collected data on bothersomeness of study measures, reasons why subjects agreed to participate in the trial, the “best part” of SISTER participation and whether or not subjects would consent to participate based on their study experience. The survey was planned to be completed at the conclusion of the final study visit, i.e. 2-years post surgery.

Methods

Subjects who completed the final SISTER study visit, i.e. 2 years post surgery, were asked to complete a patient experience survey. The survey was given to all participants regardless of their study outcome or level of satisfaction. The trial methods have been published(1). Visit data were collected at baseline, surgery, and 6-weeks, 3-months, 6-months, 1-year, 18-months and 2-years post-operatively(1). The 3- and 18-month visits could be conducted by phone and mail. The most comprehensive visit in terms of both physical measures and questionnaires was the 2-year visit. All study procedures were approved by the institutional review board at each participating clinical center, and written consent was obtained from all women before enrollment. Patients were modestly incentivized for their visit at most participating centers, but did not receive additional compensation to complete this survey.

The patient experience survey was introduced to subjects after all other components of the 2-year visit were complete. The survey was a blinded questionnaire that could be completed either in a private space in the clinic and returned to study staff sealed in an envelope pre-addressed and stamped for mailing to the Data Coordinating Center, or at home and then mailed directly to the Data Coordinating Center in the provided pre-addressed and stamped envelope.

The patient experience survey contained four sections (see Appendix for complete instrument). The first asked “For each procedure listed below, please circle the number that best represents how much of a bother you found the procedure to be.” Response options included “No Bother,” “Minimal Bother,” “Moderate Bother” and “Major Bother.” Procedures listed included the following visit components: Pelvic examination, Stress test, Q-tip test, Voiding Diary, Pad Test, Patient Self-Questionnaires and Urodynamics Testing. The section concluded by asking “Which of the above study measures did you feel to be the most bothersome;” only one response was permitted and subjects were asked to explain their choice in an open-ended fashion. Subjects were asked about the least bothersome procedure in the exact same fashion.

The second survey section used the same four bother response options as the first section, but asked about other study-related matters as follows: wait time to see physician, travel costs, travel time, parking availability, parking costs, length of each visit, insurance co-pay, and number of forms to complete. Because the surgeries performed in this trial met the current standard of care, a patient’s insurance was routinely billed for these procedures and visit co-pay expenses had to be incurred by some participants. Following the same pattern as the first section, subjects were asked to identify the single “most” and “least” bothersome aspect with an open-ended explanation for each choice.

The third survey section focused on reasons why subjects agreed to participate in SISTER. Response options were as follows: “Strongly Agree,” “Agree,” “Neither Agree nor Disagree,” “Disagree” and “Strongly Disagree.” Reasons included perceptions of improved care, compensation for time, increased personal attention, more health education, a feeling of helping others, confidence that study staff would keep information private, personal attention from both study surgeons and nurses, and trust of receipt of the best possible care. This section concluded with an open-ended question about the “best part” of participating in the study.

The fourth and final section contained a single question that asked “If you had known what you know now about the study, would you do it again?” Those answering “No” were asked to explain.

Results

In the SISTER trial, 520 participants completed the 2-year visit out of 665 enrollees [3]. For this patient’s experience questionnaire, we had a high response rate of 88% (450/520). Tables 1, 2 and 3 summarize the respective findings for each of the three survey sections (study procedures, visit factors, motivation to participate in trial). Table 1 indicates a high degree of bother (20–30%) for the invasive testing (urodynamic testing, stress test, and Q-tip test). Three day diary, 24-h pad test, and physical examination had lower percentages of bother of around 10%. Urodynamic studies were considered as most bothersome by nearly 50% of the study participants. In table 2, travel time, parking availability and numbers of forms to complete were highly rated under “moderate/major bother” and “most bother” categories. Cost-related items (insurance co-pay, travel cost, and parking cost) had low bother scores. As displayed in Table 3, the three main domains of motivation to participate in the trial were “helping others”, “best care”, and “caring research team”. In response to the last question, 96% answered yes, indicating she would participate in the study again. Reviewing the free text reasons for the “No” answer in 14/450 participants, there was a mix of issues noted, ranging from still leaking urine (8, “painful” testing (3, “would have liked to choose the surgery type (3), to cost related to time spent and loss of income (6).

Discussion

This patient experience survey was intended to further our understanding of a patient’s experience in an incontinence trial. We asked patients what they considered to be the most and least bothersome procedures and non-procedural factors and what motivated them to enroll and stay in the trial. Several studies have been devoted to the burden of stress urinary incontinence.(7–9) However, to our knowledge, there has been no study reported on the patient experience and burden with intensive testing and repeated visits in patients participating in a randomized clinical trial of surgical treatment for stress urinary incontinence SUI.

This study, and survey instrument, was not designed to provide insight into patient recruitment or patient retention, but to learn from patients about their experience and use this information in the design of future randomized controlled trial (RCT) to improve patient experience.

Previously cited reasons for participation in an RCT include altruistic ideas of helping others with the same health problem, confidence with regard to receiving the best medical care, and having a dedicated physician investigator and research team delivering such care(4, 6). Our results reinforce these observations, as our subjects’ main reasons for participating were to “help others”, receive the “best care” and benefit from a “caring research team.” The

literature is rich with examples of successful recruitment approaches for clinical trials. Trial recruitment plans should aim to incorporate such strategies.

Invasive testing was the most bothersome factor reported by our patients, with 30% reporting moderate or great bother with urodynamic testing, 21% with the stress test and 19% with the Q-tip test. However, a recent pilot study found that many incontinent women preferred to undergo urodynamic testing first rather than have treatment based on symptoms alone (10). Therefore, the critical element is whether the invasiveness of urodynamic testing is warranted to provide pre-operative information that can directly improve patient care or have predictive value on outcome of SUI surgery. This information should be kept in mind when designing RCTs in this field since it could affect patient recruitment and retention if the test needed to be repeated later on in the trial.

The burden of 24-h pad test and voiding diary has been previously cited as primary reasons for loss of patients and poor retention.(11) It is interesting that, in this study, the pad weight test and the diary were listed as “moderate/major” bothersomeness by only 10–11% of patients. One wonders if the nurse coordinator’s direct involvement in helping patients comply with these procedures helped in the overall patient perception of bothersomeness compared to urodynamic testing or other study procedures (Stress test, Q-tip test).

Because pre and post-operative objective and subjective outcome measures with SUI have poor correlation, we used several questionnaires that measure symptom type, bother, and their effect on quality of life. This was a burden reported by our patients with the “number of forms” to be filled out reported as the second most bothersome non-procedural issue, second only to travel time. Interestingly, the several different measures of patient time utilization including travel time, parking availability, number of forms to fill out and visit length were more bothersome than measures of actual costs including insurance costs, travel and parking costs. Compensation to participants was commensurate with burden perceived by the investigators; participants were reimbursed more when they underwent invasive testing such as urodynamic testing. The feedback that we received on burden supports prioritizing physical discomfort, and we recommend that investigators adjust compensation to be commensurate to burden.

Although we present subject bother data, it is important to also call attention to the data regarding satisfaction, i.e. this population was extremely satisfied overall, with 96% stating that they would participate in the study again (2). Such an overwhelmingly positive response is reflective of a few trial-specific qualities. First, urinary incontinence is stigmatizing with many women even reluctant to seek treatment. Patient research interactions are particularly valuable in this situation, as interaction with research staff often provides comfort and reassurance. For many patients, SISTEr was the first time these women met clinicians involved in research and with a focused interest in their specific problems. Further, the UITN provides a patient-oriented quarterly newsletter that includes study results and other pertinent educational topics. Communication and interaction, whether in person or via mechanisms like the study newsletter, may improve retention when integrated as a routine part of an RCT. Kerrison et al (4) concluded that patients want to maintain an ongoing relationship with researchers and should have ongoing opportunities to feel involved in the research.

A strength of this survey is the procedures used to maintain confidentiality of subjects’ response in order to encourage honest and complete reports. Again, the survey was either completed in a private space in the clinic and returned to study staff in a sealed envelope addressed to the DCC or completed in the privacy of one’s own home and mailed directly to the DCC in the provided self-addressed stamped envelope. The very high response rate of

88% is likely attributable to this procedural approach. The survey used in this study was not a validated tool. In fact, because this is a first report in the field of urinary incontinence, such an instrument was not available to us. Because of this limitation, the text of the survey is presented in an Appendix.

Conclusion

Because outcome data is the most critical component of an RCT, maintaining high retention rates is critical to ensuring appropriate statistical power to conduct protocol-planned analyses. We learned several important lessons with respect to the goal of continuous improvement in trial conduct, including carefully considering procedures requiring invasive testing (e.g. urethral catheterization or Q-tip test), minimizing the number of patient visits, and avoiding multiple forms to fill out. Future incontinence trials should be designed with these findings in mind, especially those with an extended follow-up schedule.

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Appendix

For each of the study procedures listed below, please circle the number that best represents how much of a bother you found the procedure to be.

SECTION A

	No bother	Minimal bother	Moderate Bother	Major Bother
Pelvic examination (You were asked to bear down and a nurse or doctor took measurements of the vagina).	1	2	3	4
Stress test (Your bladder was filled through a catheter and you were asked to bear down to see if you leaked any urine).	1	2	3	4
Q-Tip Test (A Q-tip was placed in the urethra and you were asked to bear down).	1	2	3	4
Voiding Diary	1	2	3	4
Pad Test	1	2	3	4
Patient Self-questionnaires	1	2	3	4
Urodynamics testing (Measurements were taken through catheters in your bladder and rectum. Your bladder was filled and you were asked to bear down to see if you leaked any urine)	1	2	3	4

Which of the above study measures did you feel to be the most bothersome? Please choose only one.

Pelvic examination	1
Stress Test	2
Q-Tip Test	3
Voiding Diary	4
Pad Test	5
Patient Self-questionnaires	6
Urodynamics testing	7

Why?

Which of the above study measures did you feel to be the least bothersome? Please choose only one.

Pelvic examination	1
Stress Test	2
Q-Tip Test	3
Voiding Diary	4
Pad Test	5
Patient Self-questionnaires	6
Urodynamics testing	7

Why?

SECTION B

In addition to study procedures, we would like to gather information as to how other study-related matters affect your participation. Please help us by indicating how much of a bother you thought each of the following were for you by circling the number that best represents your response.

	No bother	Minimal bother	Moderate bother	Major bother	Not applicable
Wait time to see study physician	1	2	3	4	-1
Travel costs	1	2	3	4	-1
Travel time	1	2	3	4	-1
Parking availability	1	2	3	4	-1
Parking costs	1	2	3	4	-1
Length of each visit	1	2	3	4	-1
Insurance Co-pay	1	2	3	4	-1
Number of forms to fill out	1	2	3	4	-1

Which of the above study measures did you feel to be the most bothersome? Please choose only one.

Wait time to see study physician	1
Travel costs	2
Travel time	3
Parking availability	4
Parking costs	5
Length of each visit	6
Insurance Co-Pay	7
Number of forms to fill out	8

Why?

Which of the above study measures did you feel to be the least bothersome? Please choose only one.

Wait time to see study physician	1
Travel costs	2
Travel time	3
Parking availability	4
Parking costs	5

Length of each visit	6
Insurance Co-Pay	7
Number of forms to fill out	8

Why?

SECTION C

We are aware that you may also have other reasons that you joined or have continued in the study. For each statement below, please circle the number that best describe how you feel.

I am participating in this study because:	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
	1	2	3	4	5
I can get general medical care I couldn't get otherwise	1	2	3	4	5
I get money or gift certificates for my time during study visits.	1	2	3	4	5
I get personal attention from the study doctors and nurses and the time they spend with me.	1	2	3	4	5
I learn more about how to take care of my health	1	2	3	4	5
I feel like I am helping others.	1	2	3	4	5
I know that study personnel will keep information about me private.	1	2	3	4	5
I feel that the study doctors and nurses really care about me as a person	1	2	3	4	5
I trust that the study doctors and nurses are giving me the best care.	1	2	3	4	5

We are aware that you may also have other reasons that you joined or have continued in the study. For each statement below, please circle the number that best describe how you feel.

What was the best part of participating in the study over the last 2 years?

If you had known what you know now about the study, would you do it again?

Yes	1
No	2

IF NO, please give us a brief explanation

Table 1

Bothersomeness of study procedures.

Study Procedure	Moderate/Major Bother %	Most Bother %	Least Bother %
Urodynamic Studies	30	48	2
24 h Pad test	11	9	18
Q-tip test	19	11	3
Stress test	21	9	2
3 day Diary	10	8	20
Pelvic examination	10	6	14
Questionnaires	3	3	36

The first column reports on the collapse of the two categories (moderate and major) for the bothersomeness of study procedures. The next two columns indicate the patient's response to the procedure ranked as most or least bothersome

Table 2

Bothersomeness of study visit factors.

Visit Factor	Moderate/ Major Bother %	Most Bother %	Least Bother %
Travel time	19	24	7
Number of forms to complete	13	21	5
Parking availability	13	14	13
Visit length	9	10	6
Insurance co-pay	7	6	8
Wait time	3	5	38
Travel cost	10	7	5
Parking cost	7	6	10

The first column reports on the collapse of the two categories (moderate and major) for the bothersomeness of study procedures. The next two columns indicate the patient's response to the procedure ranked as most or least bothersome

Table 3

Motivation for study participation.

Motivation	Strongly agree, agree (N)	Percent (%)
Helping others	415	96
Best care	424	96
Caring research team	394	90
Privacy protection	354	79
Personal health learning	309	69
Personal attention	289	65
Access to Care	158	35
Incentive	104	23