

LESSONS LEARNED FROM A PATIENT BURDEN SURVEY FOLLOWING A LARGE RANDOMIZED CONTROLLED TRIAL FOR THE SURGICAL MANAGEMENT OF STRESS URINARY CONTINENCE IN WOMEN

Hypothesis / aims of study

At completion of a large randomized controlled trial requiring extensive pre- and post- study testing and several follow-up visits, study staff were interested in understanding the burden or bothersomeness of study procedures/measures for planning future studies. Therefore, a survey was conducted at the completion of the study at 2 years to examine acceptance of outcome measures, rating of clinic visits and access to physician, and motivation to participate in the study.

Study design, materials and methods

A total of 655 women were recruited and randomly assigned to receive either the Burch colposuspension or fascial retropubic sling to treat stress urinary incontinence. Methods and results have been previously reported (1, 2). Study patients received the questionnaire after completing their 24 month visit. Surveys were returned in a self-addressed stamped envelope to the data coordinating center. The degree of bother for each of 7 study procedures was ranked as 1= no bother, 2= minimal bother, 3=moderate bother and 4= major bother. This was followed by questions to identify the least bothersome and the most bothersome study procedures/measures. The degree of bother (range 1-4 as above) for each of 8 study-related factors (e.g., travel cost, number of questionnaires) was also queried, again followed by questions to identify the least bothersome and the most bothersome. Next, the patient was queried about 8 possible motivations to participate in the study, ranking each from 1 =strongly agree to 5=strongly disagree. Finally, patients were asked to describe the best part of participating in the study (free text) and if they would you do it again (yes / no).

Results

A total of 338 study participants (52% of total enrolled) returned the questionnaire. Of all study procedures, urodynamic testing was the most bothersome, followed by the 24 hour pad test and Q-tip test (Table 1). Self-administered questionnaires were the least bothersome. In terms of study visit factors (Table 2), travel time and parking availability were the most bothersome issues whereas wait time to see the study physician, travel cost, visit length and insurance co-pay were well accepted. Number of forms to fill out also was rated as quite bothersome. The main reasons to participate in the study were to help others, obtain better knowledge about the condition, and being guided by a committed team of investigators and study coordinators dedicated to provide the best care (Table 3). Finally, almost all patients (96%) reported that they would participate again.

Table 1 Bothersomeness of study procedures.

| Study Procedure | Moderate/Major Bother % | Most Bother % | Least Bother % |
|---------------------|-------------------------------|-----------------------------|----------------------|
| Urodynamic Studies | 29 | 51 | 2 |
| 24 h Pad test | 12 | 12 | 18 |
| Q-tip test | 17 | 9 | 3 |
| Stress test | 19 | 8 | 2 |
| 3 day Diary | 11 | 8 | 22 |
| Self Questionnaires | 12 | 4 | 37 |

Table 2. Bothersomeness of study visit factors.

| Visit Factor | Moderate/ Bother % | Major Most Bother % | Least Bother % |
|--------------------------------|--------------------------|--------------------------------------|----------------------|
| Travel time | 20 | 25 | 9 |
| Number of forms to fill out | 13 | 23 | 5 |
| Parking availability | 14 | 15 | 16 |
| Visit length | 10 | 11 | 7 |
| Insurance co-pay | 7 | 7 | 8 |
| Wait time | 4 | 6 | 40 |
| Travel cost | 9 | 6 | 5 |
| Parking cost | 8 | 6 | 11 |

Table 3. Motivation for study participation.

| Motivation | Strongly agree, or agree (n) | Percent |
|--------------------------|---|---------|
| Helping others | 316 | 96 |
| Best care | 315 | 95 |
| Caring research team | 298 | 91 |
| Privacy protection | 265 | 81 |
| Personal health learning | | |

| | | |
|--------------------|-----|----|
| | 227 | 70 |
| Personal attention | 219 | 67 |
| Access to care | 115 | 35 |
| Incentive | 71 | 23 |

Interpretation of results

Patients' main areas of motivation to participate in this study were to "help others", receive the "best care" and benefit from a "caring research team". We learned several important lessons, including the need to avoid urodynamic testing, to limit patient visits because of travel time and parking issues, and to minimize the number of forms to fill out.

Concluding message

In a large multicenter surgical study, urodynamic testing was the most bothersome procedure for the majority of participants. These survey findings may influence the design of future multi-center study protocols. It helped to better understand critical patient factors that may contribute to study participation and retention.

References

1. Albo ME, Richter HE, Brubaker L, et al. Burch Colposuspension versus Fascial Sling to Reduce Urinary Stress Incontinence. *Engl J Med* 2007;356:2143-55
2. Tennstedt S. Design of the Stress Incontinence Surgical Treatment Efficacy Trial (SISTER). *Urology* 2005;66:1213-7

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| <i>Specify source of funding or grant</i> | NIH U01DK60395-01, |
| <i>Is this a clinical trial?</i> | No |
| <i>What were the subjects in the study?</i> | HUMAN |
| <i>Was this study approved by an ethics committee?</i> | Yes |
| <i>Specify Name of Ethics Committee</i> | IRB at each of nine centers involved in study |
| <i>Was the Declaration of Helsinki followed?</i> | Yes |
| <i>Was informed consent obtained from the patients?</i> | Yes |