

Informed Consent for Pelvic Reconstruction: Does Having a Support Person Matter?¹

Background

Informed consent for surgery is an ethically vital component of patient care. This typically occurs in our practice during the preoperative appointment. During this visit, the surgeon discusses the medical condition being treated, treatment options and alternatives, and surgical options with the patient. The surgery plan is discussed and decided upon. The risks and benefits of surgery, the typical recovery course, and possible complications are also reviewed. This conversation is a critical component of the medical decision-making process involving ethical principles of respect for patient autonomy and beneficence.

Patients’ recall of risks and complications associated with procedures tend to be low, particularly in older patients.¹ Hallock *et al.* found that patient knowledge of informed consent was significantly associated with patient satisfaction.² Due to a desire to improve patient knowledge, several interventions have been created to improve patient knowledge including interactive multimedia, written information, and audio-visual aids.³ Research is continuing to be done to improve the medical informed consent process.

Most patients that are scheduled to undergo surgery experience preoperative anxiety, and some experience this more than others.⁴ Anxiety was frequently cited as the worst aspect of the perioperative experience in an observational study from the UK that surveyed more than 16,000 patients postoperatively.⁵ This anxiety or fear is likely due to the unknown. In our practice, we recommend that patients bring a family member or close friend to their pre-operative appointment to help with patient anxiety, comprehension, and informed decision-making. However, there are few data in the literature to support this recommendation. We hypothesize that having a family member or close friend present will decrease patient anxiety and improve patient satisfaction and recall regarding the risks/benefits/alternatives of surgery.

Study Objectives

The primary objective is to assess the impact of having a support person present during the patient’s preoperative visit on patient anxiety regarding informed consent for surgery. The secondary objective is to assess the impact of a support person on patient satisfaction, self-assessment of understanding, knowledge, time spent with patient, and pre- and post-operative phone calls.

Hypotheses

H₀: For women with a support person present during their preoperative visit, there is no difference in the patient-reported anxiety regarding informed consent for surgery compared with women without a support person present.

H_A: For women with a support person present during their preoperative visit, there is a difference in the patient-reported anxiety regarding informed consent for surgery compared with women without a support person present.

Research Questions

The research questions to be answered as a part of this study are:

- (1) Does having a support person present at the pre-operative visit affect anxiety, satisfaction, preparedness and knowledge regarding their surgery?
- (2) Does having a support person present impact utilization of clinic resources including time spent with physicians, preoperative phone calls, and postoperative phone calls?

Study Design and Methods

This study will be a prospective cohort study. All women scheduled to undergo vaginal pelvic reconstructive surgery will be recruited from the Urogynecology clinics of the Hartford Hospital Medical Group at the time of their pre-operative appointment. Patients who qualify for inclusion and consent to participate will be enrolled in the study. The subjects will be consented by the principal investigator, the patient’s treating Urogynecology physician, or one of the FPMRS division’s nurses, all of whom are CITI-trained and have completed IRB-required consent training course.

Participants will be assigned to one of two arms:

- (1) the “support person present” arm, or

(2) the “patient present only” arm.

Randomization is not practical, as it would be unethical to advise a patient not to bring a support person to the appointment if she so chose. Thus, the study will be conducted as a real-world trial, and assigning the groups based on whether or not a support person is present in the room during the patient’s appointment with her physician. The patient will consent to participate; the support person (when applicable) will not. The support person will not provide information, nor will any questions about the support person be asked of the participant. Thus, no inclusion/exclusion criteria are applicable for the support person.

There will be four data collection times, shown schematically in Table 1, below:

- (a) After enrollment into the study and prior to meeting with the medical assistant and physician, subjects will fill out background information and several questionnaires: Generalized Anxiety Disorder 7-item (GAD-7), a 3-item Short Literacy Survey, and the STAI-6.
- (b) At the end of their visit, subjects will fill out the STAI-6, Satisfaction with Decision Scale for Pelvic Floor Disorders (SDS-PFD), a knowledge questionnaire, and the Preoperative Preparedness Questionnaire.
- (c) 2-3 days prior to their scheduled surgery, each subject will be called at the telephone number she indicated during the research consent process. The STAI-6, SDS-PFD, the knowledge questionnaire, and the Preoperative Preparedness Questionnaire will be administered over the phone.
- (d) At the 3-5 week postoperative visit, subjects will be asked the Postoperative Symptom and Satisfaction Questionnaire.

Additional demographic information upon enrollment will be collected via chart review. Phone calls pertaining to pre-operative education will be obtained from chart review at the 3-5-week post-operative visit. The time spent with the patient by the physician during the pre-operative appointment will be recorded by the medical assistant.

The attending surgeon will not be informed of patient’s enrollment status to limit study impact on the attending surgeon’s standard consent format.

Table 1: contact/data collection times

| Survey/data* | Prior to Pre-Operative Appointment | After Pre-Operative Appointment | Phone Call 2-3 days Prior to Surgery | Post Op Appointments at 3-5 weeks |
|--|------------------------------------|---------------------------------|--------------------------------------|-----------------------------------|
| Demographics | x | | | |
| GAD-7 | x | | | |
| 3-Item Short Literacy Survey | x | | | |
| STAI-6 | x | x | x | |
| SDS-PFD | | x | x | |
| Knowledge Questionnaire | | x | x | |
| Preoperative Preparedness Questionnaire | | x | x | |
| Postoperative Symptom and Satisfaction Questionnaire | | | | x |
| Patient Global Impression of Improvement Questionnaire | | | | x |

*detailed descriptions are included in the **Data Collection/Use** section

Human Subjects

Inclusion Criteria - all patients

- female
- ≥ 18 years old and ≤ 89 years old
- scheduled to undergo a 23-hr observation or inpatient surgery for pelvic organ prolapse
- able to understand English
- able/willing to sign informed consent document

Exclusion Criteria – all patients

- male
- < 18 years old or ≥ 90 years old
- surgery canceled
- inability to provide consent
- resident of a long-term care facility or utilization of a home health service (aid, nursing, occupational or physical therapy)
- scheduled for outpatient surgery
- non-English speaking
- unable/unwilling to sign informed consent document

Patient Present Only

Inclusion Criterion

- Patient attending appointment with the physician by herself

Support Person Present Only

Inclusion Criterion

- Patient attending appointment with the physician with a support person present in the room

Risks/Benefits to Patients

Potential risks

This is a minimal-risk study. The only research element, and therefore introduction of potential risk(s) beyond standard-of-care treatment, comprises administration of several surveys and data collection. Thus, the potential risks and ways to mitigate them include:

- Inconvenience of having to take the time to complete the surveys in person and over the phone. These are expected to take no more than 15 minutes per visit or phone call, and the participants will be told during the research informed consent process that they can take a break or refuse to answer anything if they wish.
- Accidental disclosure of protected health information (PHI). Strict protection of all patient data, including PHI, will be adhered to, as discussed below in the **Data Storage/Security** section.

Potential benefits

There are no direct benefits to patients. This is not a treatment study, as patients would be receiving the same medical care and surgical procedures if they were not in the study. The potential benefit of this study is to science/medicine, as discussed in the **Significance to HH and its Patients** section.

Data Collection/Use

Data will be collected from questionnaires and from review of the electronic medical record (EPIC) of enrolled patients. This information will be entered into REDCap for future analysis. The surveys/instruments to be used are shown below:

Generalized Anxiety Disorder 7-item (GAD-7): This questionnaire is a 7-item questionnaire that is used to screen for generalized anxiety disorder. The GAD-7 has good reliability, and construct, factorial and procedural validity. Test-retest reliability is good (intraclass correlation = 0.83).⁶

Brief Health Literacy Screen: This is a 3-item, 5-point-scale questionnaire that takes about one minute to complete. Its validity and reliability have been established in the literature in comparison to the longer S-THFLA and REALM questionnaires.^{7,8}

State-Trait Anxiety Inventory-6: To measure state anxiety we used a validated 6-question short-form of the STAI state scale (STAI-6), which yields a score between 20 (least anxious) and 80 (most anxious).^{9,10} Scores range from 20 to 80 with higher scores indicating more severe anxiety. An individual is considered highly anxious with a score of over 44.¹¹ It has been shown to be internally consistent, reliable, and valid.¹⁰

Satisfaction with Decision Scale for Pelvic Floor Disorders (SDS-PFD): The SDS-PFD is a 6-item questionnaire with items scored from 1 to 5. The questionnaire takes approximately three minutes to complete. The SDS-PFD has reported internal consistency (Cronbach's $\alpha=0.95$) and reproducibility (ICC=0.80-0.90).¹²

Knowledge Questionnaire: This is a created a 14-item questionnaire. This survey was created by a Urogynecology fellow. The survey was reviewed and edited by four Urogynecology attendings, two Urogynecology fellows, APRN, and our nurse team. The questionnaire was piloted among our Urogynecology staff. The Flesch-Kincaid readability score is 50.1.

Patient Preparedness Questionnaire: This questionnaire is an 11-item questionnaire. Although there are no fully validated patient preparedness scales, this scale has been previously reported in a population of women undergoing SUI and/or pelvic organ prolapse surgery.^{13,14}

Postoperative Symptom and Satisfaction Questionnaire: This questionnaire is a 7-item questionnaire. This questionnaire has been previously reported in a population of women undergoing SUI and/or pelvic organ prolapse surgery.¹³

Patient Global Impression of Improvement (PGI-I) Questionnaire: This is a validated 1-item questionnaire to measure global improvement.

Data to be collected (including surveys above) are the following

Primary outcome variables

- STAI-6
- SDS-PFD
- Knowledge questionnaire
- Preoperative preparedness questionnaire
- Postoperative preparedness questionnaire
- PGI-I
- Time spent with physician
- Preoperative phone calls
- Postoperative phone calls

Secondary outcome variables

Patient demographic and medical/surgical history

- Age
- Gravidity and parity
- Race
- BMI
- Ethnicity
- Marital status
- Insurance status
- Education level
- Employment status
- History of employment in health care field
- History of family/friend undergoing similar procedure
- History of prolapse surgery
- History of hysterectomy
- Prolapse Stage
- Presence of Urgency Incontinence

- Presence of Stress Urinary Incontinence
- GAD-7
- Brief Health Literacy Screen
- Charlson Comorbidity Index (CCI)
- Pelvic floor dysfunction surveys previously completed by patient

Data Storage and Security

Data will be entered into REDCap which is a secure, web-based application designed to support data capture for research studies. Data will be downloaded from REDCap into secure password-protected Excel document that will be housed on a secure Hartford Hospital network. Data will be entered into a secure password-protected Excel document that will be housed on a secure Hartford Hospital network. Only investigators named on the study will have access to the data. Data will be shared only via secure HHC e-mail, and will be disseminated in aggregate to avoid potential breach of confidentiality. Because of the potential for storing protected health information (PHI), data will be maintained as described above for six years.

Power Analysis/Sample Size Estimate

The study is powered to detect a 20% relative difference in scores on the STAI-6 between the two arms. Sample sizes of 35 in each arm (a total sample of 70) would afford 80% power to detect an absolute difference of 6.8 between the null hypothesis that the means are 37.6 in each arm and the alternative hypothesis that the mean of the companion arm is 30.8, with estimated standard deviations of 10.9 and 8.9, resp., using a significance level of 0.05 with a two-sided t-test. A sample of 35 in each arm also would allow for a minimum of 80% power to detect a difference in the SDS-PFD between arms of 0.5 points, assuming a 20% common standard deviation.

To achieve the evaluable sample of 70, allowing for a 5% attrition/loss-to-follow-up rate that we anticipate will be equal in each arm, we will plan to recruit 74 subjects, 37 per arm.

Data Analyses/Statistics:

Statistical Analyses will comprise descriptive and inferential statistics. Descriptive statistics will be generated for each arm and for the sample overall. After evaluating data for normality, they will include means and standard deviations for normally distributed, continuous data (*e.g.*, age, BMI); medians and interquartile ranges for non-normal, continuous data (*e.g.*, LoS, CCI), and frequencies, using percentages, for categorical data (*e.g.*, ethnicity, marital status).

Inferential statistics will be used to compare outcomes between arms. For normally distributed, continuous data, a Student’s t-test will be used. For non-normally distributed, continuous data, a Mann-Whitney U test will be used. For categorical data, a Pearson chi square will be used unless the data set up as a 2x2 comparison, in which case a Fisher’s exact test will be used.

If differences in the primary outcome(s) is/are seen, a linear regression model may be constructed to account for any variable(s) that may be confounding the findings. The model would be constructed as a forward, conditional model and evaluate factors shown to be different upon univariate testing (as above). Although the sample is small and may not be powered adequately to detect more than three or four variables, any variables included in the model that do show a significant influence may be explored in future research.

All analyses will be conducted using SPSS v. 21 (IBM, Armonk, NY 2013) with an *a priori* alpha level of 0.05 such that all results yielding $p < 0.05$ will be deemed statistically significant. This study does not meet the definition of a clinical trial; thus, no NCT registration will be sought.

Significance to HH and its Patients

This study will increase our knowledge regarding the benefits of having a support person present at preoperative appointments for patients undergoing vaginal reconstructive surgery.

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