GYNECOLOGY

Patient satisfaction and informed consent for surgery

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BACKGROUND: Informed consent is a process that necessitates time and effort. Underlying this investment is the belief that informing patients about the surgery promotes patient satisfaction with the decision for surgery and potentially satisfaction more broadly.

OBJECTIVE: The objective of the study was to investigate the extent to which preoperative satisfaction with a decision to pursue surgery is associated with understanding after an informed consent discussion.

STUDY DESIGN: We performed an observational study of adult women seeking surgical treatment for pelvic floor disorders. Study participants were recruited after routine preoperative counseling by board-certified or board-eligible urogynecologists. In our practice, the preoperative informed consent process typically includes a discussion of the indications, risks, benefits, alternatives, and chance of success of the procedures. Participants completed a 35 question survey preoperatively at one setting. The primary outcome, satisfaction with decision, was measured with a validated 6 item Satisfaction with Decision Scale-Pelvic Floor Disorder. Participants were classified as highly satisfied if they indicated the highest level of satisfaction for all items. The primary exposure was patient knowledge of the planned surgery, measured using a newly adapted 20 item Informed Consent Questionnaire including 15 yes/no questions and 5 free-text questions. Additionally, the survey included a validated 3 item tool for health literacy, a single-item anxiety measure, and demographic data. Analyses were performed with a χ^2 test, a Student *t* test, and a multivariable logistic regression using the binary outcome variable, highly satisfied or not highly satisfied.

RESULTS: A total of 150 participants were enrolled, with a mean age of 57.5 years. The majority were non-Hispanic (97.3%) or white (87.3%), with at least some college education (51.0%). The median number of days between the informed consent discussion and the survey was 35. The mean total Satisfaction with Decision score was 27.9 (SD, 2.6; range, 19–30), indicating overall high satisfaction with the decision. A patient's preoperative satisfaction with her decision was strongly associated with increased knowledge of the planned surgery, as measured on the Informed Consent Questionnaire ($P = .003$). The mean score for the highly satisfied group was 17.8 (n = 70; SD, 3.6; range, 6–20) and for the not highly satisfied group was 16.1 (n = 77; SD, 2.8; range, 9–20). There were no significant differences between the highly satisfied and not highly satisfied groups with respect to age, race, education level, anxiety score, or health literacy. The odds of being highly satisfied increased for every 1 point increase in the Informed Consent Questionnaire score (odds ratio, 1.28; 95% confidence interval, 1.06–1.32; $P = .003$). The association between decisional satisfaction and knowledge persisted after controlling for demographic and clinical variables including education level, health literacy, race/ethnicity, age, surgeon years since completing fellowship, diagnosis, surgery category, number of visits in the past 6 months, and number of days between informed consent discussion and survey.

CONCLUSION: This study found that patient knowledge and understanding of surgery are important components of a patient's satisfaction with her decision to proceed with pelvic floor surgery. By measuring patient understanding after informed consent discussions, clinicians may be able to better manage preoperative expectations, increase patient satisfaction, and improve the informed consent process.

Key words: health literacy, informed consent, patient satisfaction, pelvic floor disorders, risk

Informed consent involves information disclosure, recommendation of a plan of care, patient understanding, voluntary decision making, and authorization to proceed with the plan of care.[1,2] Informed consent discussions are individualized not only with regard to the patients' surgical condition and goals but also their varying information needs, health literacy,[3] and anxiety.[4] Thus, informed consent is a process that necessitates time and effort.

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Underlying this investment is the belief that educating and informing patients about the surgery and its alternatives promotes patient satisfaction with the decision for surgery and potentially satisfaction more broadly.[5-7] However, it is not known to what extent a patient's understanding of the surgical plan has an impact on his or her satisfaction with the decision to proceed with surgery.

The primary objective of this study was to explore the relationship between patients' knowledge about informed consent and decisional satisfaction. The primary hypothesis was that knowledge about informed consent is significantly higher among women who are highly satisfied with their decision. The second objective was to investigate whether higher health literacy and lower anxiety increased knowledge about informed consent and improved decisional satisfaction.

Materials and Methods

We performed a prospective study of adult female urogynecology patients planning surgery for pelvic floor disorders. This study was approved by the Johns Hopkins Institutional Review Board. Because the research question pertained to those being counseled regarding surgical informed consent, participation was limited to women planning surgery.

Patients were recruited from 2 tertiary urogynecology practices from July 2015 through June 2016. Potential participants were identified upon review of the operating room schedule. Inclusion criteria were female sex, age 18 years or older, and counseling regarding surgical management options for pelvic floor

disorders. Exclusion criteria were non-English speaking, known cognitive impairment, and surgery in the previous 6 months.

Study participants were recruited preoperatively after routine preoperative counseling by board-certified or board-eligible urogynecologists. In our practice, the routine preoperative informed consent process typically includes a discussion of the indications, risks, benefits, alternatives, and chance of success of the procedures. The individual discussions were not standardized, timed, or recorded. Study participants provided informed consent prior to completing a preoperative 35 question survey in person, online, or via telephone based on their preference. The survey was completed preoperatively at one setting.

The primary outcome, satisfaction with decision, was measured with a validated 6 item Satisfaction with Decision Scale—Pelvic Floor Disorder (SDS-PFD). The SDS-PFD is composed of 6 individual items graded from 1 to 5, with higher scores indicating higher satisfaction.[5] Participants were classified as highly satisfied if they indicated the highest possible level of satisfaction for all items.

The primary exposure was patient knowledge of the planned surgery. Patient understanding of pelvic floor surgery has been measured in prior research for specific surgical procedures, including sacrocolpopexy[8] and mid-urethral sling.[9] However, these instruments focus on the details of a specific surgery and are not broadly applicable.

To have a tool that could apply more generally to surgeries for pelvic floor disorders, understanding and knowledge were measured using an adapted 20 item Informed Consent Questionnaire (ICQ-20).[10] Participants received a point for an affirmative answer to each of 15 yes/no questions and a point for a correct answer to each of 5 free-text questions. Two authors (J.L.H. and V.L.H.) scored the 5 free-text answers separately; reliability was found to be excellent (kappa = 0.93−1.00).

Health literacy was assessed using a 3 item tool validated by Chew et al.[11] Anxiety was assessed with a single-item question with a Likert scale.[12] Additionally, participants provided demographic information such as age, race, ethnicity, and education level. Chart review was performed to collect clinical characteristics such as diagnosis, planned surgical procedure, and date of preoperative counseling.

Univariate descriptive statistics for the study sample were reported as mean with SD for continuous variables and frequency with percentage for categorical variables. Bivariate associations comparing groups of highly satisfied with not highly satisfied were tested using Pearson χ^2 and Fisher exact tests for categorical variables and Student t tests for continuous variables.

To determine whether satisfaction was associated with any variable and to assess how much variance was accounted for by the explanatory variables, we tested our central hypothesis using multivariable logistic regression with the binary variable, highly satisfied or not highly satisfied, as the outcome variable. The multivariable models were created by first including the main independent variable (ICQ-20 score) and then adding the variables representing demographic and clinical characteristics individually and in blocks (such as race and ethnicity, education and literacy, etc). The most parsimonious final model was selected based on deviance fit statistics.

For all analyses, the probability value of $P < .05$ was considered statistically significant. All analyses were performed with STATA statistical software (StataCorp 2015, version 14 SE, College Station, TX).

We performed a priori power calculations to inform recruitment targets based on published data.[10,13] Assuming an alpha of 0.05 and power of 0.8, a sample size between 140 and 218 would allow us to detect mean score differences between 1.6 and 2 points on the ICQ-20, with Cohen's d effect sizes between 0.4 and 0.5.[14]

Results

During the 12 month period, of 346 eligible patients planning surgery, a total of 233 women were approached and 150 participants were enrolled (64.4%). The difference between eligible and approached was due to availability limitations of the study team members and was not based on patients' demographic or clinical characteristics.

Compared with the 83 women who declined to participate, the 150 participants were not different with regard to age ($P = .52$); no other demographic data were collected for those who were not enrolled in the study. Of the 83 women who did not agree to participate, 38 (45.8%) could not be contacted despite multiple attempts, 30 (36.1%) did not complete the survey, and 15 (18.1%) declined.

The 150 enrolled participants had a mean age of 57.5 years (SD, 14.2; range, 22−89). The majority were non-Hispanic (97.3%), white (87.3%), with at least some college education (51.0%). The median number of days between the informed consent discussion and the survey was 35. The most common surgical indication was pelvic organ prolapse (32.0%), followed by coexisting prolapse and stress urinary incontinence (23.3%). The most commonly scheduled procedure was vaginal reconstructive surgery with native tissue repair of pelvic organ prolapse (36.0%).

Table 1 summarizes participant decisional satisfaction. Most participants agreed or strongly agreed with each of the 6 statements of the SDS-PFD; no participant strongly disagreed with any single statement. The mean total SDS-PFD score was 27.9 (SD, 2.6; range, 19−30), indicating overall high satisfaction with the decision. Seventy-one women (47.7%) were highly satisfied with their decision regarding surgery, meaning the participant strongly agreed with all 6 statements of the SDS-PFD. There were no significant differences between the highly satisfied and not highly satisfied groups with respect to age, ethnicity, race, education level, method of survey administration, surgeon, surgery type, surgical indication, number of visits in the previous 6 months, time between informed consent discussion and survey, health literacy, or anxiety score (Table 2).

Overall, the participants were knowledgeable about the planned surgery. The mean knowledge score was 16.9 (SD, 3.3; range, 6−20). Forty-two women