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Informed Consent for Sacrocolpopexy: Is Counseling Effective in Achieving Patient Comprehension?

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Abstract

Objectives—The purpose of the informed consent process is to reinforce a patient's understanding of her condition and treatment alternatives and to thoroughly review the chosen procedure with its risks and benefits. We aimed to evaluate how well women who consented to undergo sacrocolpopexy understood their planned procedure.

Study Design—We prospectively studied women who had undergone detailed informed consent in preparation for laparoscopic or robotic sacrocolpopexy. A 15-item questionnaire was developed and administered before surgery to assess the patients' comprehension of preoperative counseling.

Results—Fifty women were enrolled. The mean knowledge score was 69.7%. Sixty-four percent of the patients did not recall that they could have a prolapse repair without mesh, 44% did not understand the location of mesh attachment, and 34% believed there was no risk of recurrent prolapse. Women who completed the questionnaire within 3 weeks of signing the surgical consent had a higher mean score (78.5%) than women for whom 3 or more weeks elapsed (66.3%; $P=0.02$).

Conclusion—Despite detailed preoperative discussion, women had deficiencies in their understanding of sacrocolpopexy. New methods to improve patient education and comprehension should be considered.

Keywords

Comprehension; informed consent; prolapse; sacrocolpopexy

Preoperative education and discussion is a crucial part of the surgeon-patient relationship. This process, which includes obtaining written consent from the patient to perform surgery,

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aims to ensure that the patient has an accurate understanding of her condition, the treatment alternatives, the course of recovery, and appropriate comprehension of the risks, benefits, and potential complications of the planned operative procedure.¹

Procedures in urogynecology are most often elective and aim to improve quality of life in an otherwise healthy patient. Adequate preoperative counseling and education is essential for patients to have realistic expectations of surgical success. However, the pelvis is an anatomically complex area of the body that is difficult for many patients to understand. Traditional methods to educate patients include verbal information that is augmented by written material, but retention of information discussed has been shown to be variable at best and generally poor.^{2–10} Audio and video-based presentation methods also have been used, sometimes with better results.^{11–16}

Although methods to optimize the process of preoperative learning and comprehension have been proposed in the surgical literature,^{11–16} scarce data exist on directly attempting to assess the level of consent-related comprehension in patients undergoing gynecologic surgery.^{17,18} The purpose of this study was to determine if patients undergoing sacrocolpopexy or supracervical hysterectomy and sacrocervicopexy have appropriate understanding of the procedure, risks, benefits, and alternatives after undergoing our usual consent process.

MATERIALS AND METHODS

After institutional review board approval, we conducted a prospective study of women planning to undergo laparoscopic or robotic sacrocolpopexy with or without hysterectomy. Participants were recruited from a regional urogynecologic referral practice in a community teaching hospital. Women were eligible if they were older than 18 years and had already signed an informed consent in English for sacrocolpopexy with any one of the 4 fellowship-trained urogynecologists in the practice. Women having alternative types of apical prolapse repairs, including vaginal procedures, hysteropexy, or paravaginal repair, were excluded. Women were also excluded if they were non-English speaking, required interpreter assistance, or had cognitive impairment. In our institution, the informed consent process includes a detailed description of the sacrocolpopexy procedure, alternative management options, and postoperative recovery expectations. All surgeons use the same hospital-approved consent form. The risks and benefits are reviewed with particular attention to mesh-related complications. Visual aids, diagrams, and models are used according to surgeon's preference; actual surgical or animated videos are not used. The duration of this discussion is typically 25 to 40 minutes and is tailored to patients' needs and concerns. To evaluate the level of comprehension of the standard preoperative counseling process, participants were given a questionnaire at the conclusion of a separate preoperative visit with a nurse approximately 1 week before surgery.

The 2-page questionnaire consisted of 3 components: a demographic section, a self-assessment of whether the participant felt prepared for surgery, and a participant knowledge assessment. The participant knowledge assessment was developed as a brief tool that could evaluate patients' knowledge of the procedure, risks, benefits, and alternatives. We solicited a list of important concepts pertaining to preoperative counseling from the 4 attending urogynecologists and 3 fellows in our practice. We also consulted with 4 nurses who typically perform the preoperative visits. In doing this, we gained feedback on typical questions patients ask or items that often need clarification. These items were condensed into the 15-item knowledge assessment; the true-or-false format was chosen for simplicity of administration. A "not sure" answer choice was added to further differentiate among patient level of knowledge and to reduce patient guessing. The survey was pilot tested with office

administrative personnel to determine appropriate wording and assess for items creating confusion. The language of the questionnaire was further simplified based on this feedback to be suitable for patient assessment. All surgeons were aware that the study was occurring but were not instructed to change their consent process in any fashion. Surgeons did not know whether their patients would eventually participate in the study; the informed consent discussion and counseling took place before participants were offered study enrollment, and a signed consent was part of the eligibility criteria. Furthermore, the surgeons did not receive feedback about their patients' performance on the questionnaire while the study was being conducted.

The questionnaire was scored based on the proportion of correctly answered questions; answers were considered incorrect if the response was either incorrect or "not sure". Charts were reviewed for relevant demographic information, surgical history, and dates of office visits and phone calls.

All patients were given a set of explanations to the questionnaire at the conclusion of the survey. If time allowed, the nurse reviewed the questionnaire answers with the patient at the end of the preoperative visit. Contact information was provided so that participants could telephone the study staff in case questions arose at a later date.

Data are presented as proportion with 95% confidence interval, median (interquartile range) or mean $\pm$ SD. Results were compared using the appropriate parametric or nonparametric test. $P < 0.05$ was considered statistically significant, and all tests were two sided. All analyses were done using SAS 9.3 (SAS institute Inc, Cary, NC). We did not perform an a priori sample size calculation; this was a sample of convenience based on the goal of completing the study within 1 year.

RESULTS

From February 2011 through January of 2012, 92 eligible women presented for their preoperative visit at our institution. Thirty-nine women (42.3%) were not enrolled owing to clinical time constraints, usually because women had to present to their preoperative anesthesia appointment shortly after their appointment in our practice. Three women (3.3%) declined study participation. The remaining 50 women (54.3%) completed the study.

Of the 50 women who participated, 47 women (94.0%) were white and 27 women (54.0%) completed college or postgraduate education. The median age was 60.4 years (interquartile range, 51.9–65.0 years). Thirty-two women (64.0%) were employed, seven (21.9%) of whom worked in health care. Most women (66.0%) reported obtaining outside information about their pelvic floor condition. Of these, 57.6% obtained information from the internet, 72.7% had discussions with another health care provider, and 27.3% had discussions with their family or friends. Most (62.0%) of the women had prior pelvic surgery, with 30.0% of them having had a previous hysterectomy and 22.0% having had a prior prolapse repair. Demographic characteristics and surgical history are displayed in Table 1. Nearly all participants (94.0%) strongly agreed or agreed that they felt prepared for their surgery. Importantly, women strongly agreed or agreed that they understood the purpose (98.0%), risks (92.0%), benefits (98.0%), and alternatives (86.0%) of the planned procedure. Most of the women (70.0%) agreed or strongly agreed that their anxiety was relieved by the consent process. Furthermore, most of the women (94.0%) strongly agreed or agreed that their physicians and nurses spent enough time preparing them for the upcoming procedure.

Most of the participants (94.0%) were scheduled to undergo surgery with a laparoscopic approach, whereas a small number (6.0%) consented to a planned robotic approach. No patients consented to open prolapse repair. Thirty-four participants (68.0%) planned to

undergo supracervical hysterectomy with sacrocervicopexy, 14 participants (28.0%) planned to undergo sacrocolpopexy alone, and 2 participants (4.0%) planned to undergo total hysterectomy with sacrocolpopexy. Almost half (48.0%) planned to undergo a concomitant suburethral sling procedure at the time of prolapse repair.

Including the preoperative visit, women had a median of 4.0 (4.0–5.0) documented office visits and 0.0 (0.0–0.0) phone calls before their procedure. Typically, the office visits consisted of an initial consultation with a physician, urodynamic testing with a nurse, a follow-up appointment with the physician to review testing results and signing of consent, and another visit with a nurse to review preoperative instructions. The median time between signing the consent and completing the questionnaire was 5.9 weeks (2.7–8.9 weeks). The median time from questionnaire to surgery was 7 days (7.0–9.0 days).

On the questionnaire, the mean knowledge score was 69.7% (95% confidence interval, 64.9%–74.5%; range, 28.6%–100.0%). Women who completed the survey within 3 weeks of signing the surgical consent had a higher mean score (78.5%) than women for whom 3 or more weeks elapsed (66.3%, $P=0.02$). Most (68.0%) of the women incorrectly believed they might experience postoperative back pain due to the mesh location, 46.0% incorrectly believed there was no risk of an intraoperative blood transfusion, 34.0% incorrectly believed there was no risk of recurrent prolapse, and 64.0% did not understand that they could have a prolapse repair without mesh. More than one third (44.0%) of the women could not correctly identify the location of distal mesh attachment.

Other items of the questionnaire were better understood. Virtually all (98.0%) of the women were able to correctly identify if they were planning to have a sling procedure at the time of their prolapse repair, 90% understood that the mesh was attached to a ligament on the sacrum, and 80.0% understood there was a risk of bleeding and infection with surgery.

There were no significant differences in score relative to education, age, number of office visits or prior pelvic surgery (all $P>0.12$). Table 2 shows the proportion of correct and incorrect responses for each knowledge item on the questionnaire.

During the study period, the number of procedures per surgeon ranged from 7 to 24. To evaluate whether the level of patients' knowledge was surgeon dependent, we compared the mean participant knowledge scores among surgeons. The mean scores did not differ among surgeons ($P=0.40$). The median time between surgical consent and consent date was somewhat longer for surgeon 1 ($P=0.04$). Table 3 stratifies participant knowledge scores by surgeon.

COMMENT

Surgical treatments for pelvic floor disorders are complex and often difficult to comprehend. First, a patient must understand the 3-dimensional anatomy of the pelvic floor; the reproductive organs and urinary system must be understood in relation to bony, vascular, and muscular landmarks. She must grasp how her anatomy is different from “normal”. Discussions about pelvic floor disorders typically use terminology that is unfamiliar to most women and is sometimes redundant. Whereas physicians use “rectocele” or “posterior compartment defect” interchangeably, patients may not realize that both terms refer to the same problem. The patient knows that she has a bulge but may not understand the categorization into apical, anterior, and posterior compartments. Patients also may use colloquial terms that confuse pelvic floor disorders. Terms such as “tying up [my] bladder” or “bladder lift” can refer to multiple types of procedures but fail to distinguish between treatments for prolapse versus incontinence. This problem is not unique to pelvic reconstructive surgery; it exists in other aspects of medical care.

These challenges provided the motivation to examine and improve the level of consent-related comprehension in our practice. Our goal in this study was to better understand our usual consent process and to determine the level of consent-related comprehension with our current methods, before assessing any type of intervention. Our findings suggest that most patients have deficiencies in their understanding of sacrocolpopexy. The evaluation tool that we developed was specifically designed to assess understanding of this surgical procedure and demonstrates that on average, patients comprehend only 70.0% of the information tested during the preoperative counseling process. Scores did not vary by surgeon, but this may be due to a relatively small sample size and unequal numbers of procedures among surgeons.

In our practice, surgeons place great importance on individualized preoperative counseling. It was assumed that multiple office visits created ample opportunity for patient preoperative education. When patients present for their initial visit, their diagnosis of prolapse is reviewed in detail along with all treatment options, and if a patient is a candidate, the surgical procedure of sacrocolpopexy is typically introduced. Women who were interested in surgical options returned after urodynamic testing for a dedicated counseling and consent discussion. At this visit, they usually sign the consent form. One week before surgery, at the preoperative visit with the nurse, patients are again prompted to ask any remaining questions about their upcoming surgery. Despite this process, many women did not understand basic elements of the consent and procedure. Many had major misconceptions about sacrocolpopexy, including being unaware that there was a risk of blood transfusion and not understanding that there were alternatives to mesh-based prolapse repairs. The patients often did not understand the location of the mesh attachment to the vagina or cervix, although most participants had a prior hysterectomy or prolapse repair. Interestingly, the patients were consistent in their understanding of certain items, including understanding that there is a difference between a suburethral sling and sacrocolpopexy and recalling the proximal mesh attachment site. This suggests both gaps in understanding about specific anatomical issues and difficulty remembering the general risks of any surgical procedure. It is possible that patients selectively hear information, are overwhelmed by details, or simply do not desire to know all the specific details of their upcoming procedure. Patients, like all people, tend to forget certain details over time, and this is demonstrated by the fact that time from consent adversely affected recall.

Interestingly, women overestimate their understanding of the risks and benefits of the sacrocolpopexy. Most felt they had spent enough time with their surgeon and that they fully understood the procedure they planned to undergo. Based on this study, women seem to be satisfied with communication with their surgeons and do not feel that they were inadequately counseled. This may be due to confidence in, or comfort with, their surgeon as well as feeling that sufficient time was spent with them. Patient satisfaction with the consent process is important, and women seem to be satisfied with the process based on information from this study.¹⁹

Strengths of this study include the prospective design and questionnaire administration by an impartial observer. All patients were seen at the preoperative visit by the same nurse, who always prompted patients to ask questions and provided a similar educational experience. Furthermore, all women were enrolled at 1 week before surgery, a time period at which their comprehension of the procedure should have been optimal, with all questions answered. This cohort of patients was well educated and were all planning to undergo the same type of minimally invasive apical support procedure. The evaluation tool was tailored to the procedure and developed by physician investigators who perform the procedure routinely. The surgeons were not asked to change their usual consent process for the study and did not receive interim feedback on their patients' performance on the questionnaire. Therefore, the

surgeons' true consent practice was studied, and no surgeon adjusted his or her style or content based on information from the study while it was being conducted.

Limitations of this study include a single-center experience of a relatively small number of patients and an evaluation of only one type of procedure. Another limitation of our study was that the consent discussion was the usual practice and there was no standardization of the informed consent discussion or use of other-than-usual aids among the surgeons involved in this study. However, our objective was to assess patient knowledge following a typical consent process; we did not aim to evaluate the effectiveness of an intervention. Specific aspects or interventions in the consent process may be an area of future study.

The choice to enroll patients at the preoperative visit, after all counseling had been performed and the consent had been signed, created several constraints. First, we were not able to measure the duration of the consent discussion, nor was the consent discussion documented or recorded to ensure that each questionnaire item was reviewed in 100% of counseling sessions. Although recording this information would have been interesting, it was not feasible given our study design and logistic constraints. There are multiple points before surgery when patients interact with nursing staff, fellows, and attending surgeons and potentially acquire additional information. We attempted to quantify patient encounters with our office by counting documented office visits and phone conversations.

The lack of a standardized or recorded consent process also brings up the potential variation that the 4 surgeons may have in their consent content or style that may have affected patients' comprehension. However, we believe that these differences are less than might be expected given that two of our surgeons trained under the other 2 surgeons, and all surgeons use the same hospital-approved consent form. We believed this would translate into a similar consent discussion. In addition, during the creation of the questionnaire, all surgeons viewed the questionnaire and indicated that the items were fair and covered during their consent process.

Another potential weakness of our study was that the questionnaire was newly developed by the authors and has not been validated. Although this is a concern, we view our work to be an initial investigation into an area where no validated questionnaires have yet been developed. The language in the survey was designed to be simple but was not tested or targeted to a specific education level. Answers that were indicated as "not sure" were counted as incorrect. We made the decision to consider "not sure" as an incorrect response because if a patient is unsure of the information, then we question whether they are able to make an informed decision. They would also be unable to describe to a future provider what they had done or know what to expect.

Other weaknesses of our study are that we only examined patients' comprehension at a single time point before surgery and that we did not assess comprehension postoperatively. Postoperative recovery and complications may affect recall, and this was not addressed by our current study design. We acknowledge these limitations but are confident that the survey reading level was appropriate for our well-educated population. The reading level of the survey was similar to the reading level of the standard consent form, which all patients signed in English without the aid of an interpreter. However, we recognize that other physicians may have more ethnically diverse patient populations who are non-native speakers of English. In this case, the survey may not be at an appropriate level and the results may not apply. We would hypothesize that in this type of patient population, the questionnaire scores may have been lower. Despite these limitations, we believe that the knowledge assessed in this study is basic knowledge that all patients should have in making

an informed decision before surgery. Therefore, we believe our results are still important to the informed consent process.

This study provides an initial investigation into the challenge of obtaining informed consent in the field of pelvic reconstructive surgery. Although patients may have different opinions and expectations as to what “informed” means, surgeons are obliged to fully disclose information and emphasize important aspects of a proposed procedure. Surgeons strive to ensure that patients comprehend various treatment options, as well as their associated risks and benefits, to better enable patients to be a more effective partner in the surgical decision-making process. It is clear that new methods to improve patients’ education and understanding of key points should be developed and implemented. Future directions for research may involve development of consent discussion aids, such as videos or online tools, as well as validation of a questionnaire to assess preoperative and postoperative knowledge. We hope our study will provide preliminary data for further work in this area and potentially identify areas for improvement of the surgical consent process.

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TABLE 1

Patients' Characteristics

Characteristic	All Participants n=50
Age, median (IQR)	60.4 (51.9–65.0)
Gravida, median (IQR)	2.5 (2.0–4.0)
Parity, median (IQR)	2.0 (2.0–3.0)
BMI, median (IQR)	25.1 (23.6–29.8)
Race/ethnicity, n (%)	
White	47 (94.0)
Black or African American	1 (2.0)
Asian or Pacific Islander	1 (2.0)
Hispanic or Latino	1 (2.0)
Education, n (%)	
Junior high school	2 (4.0)
High school	8 (16.0)
Some college	13 (26.0)
College	12 (24.0)
Professional/Graduate	15 (30.0)
Currently employed, n (%)	
Yes	32 (64.0)
No	17 (34.0)
Missing	1 (2.0)
Employed in health care, n (%)	
Yes	7 (21.9)
No	25 (78.1)
Prolapse stage, median (IQR)	3.0 (2.0–3.0)
Prior prolapse repair, n (%)	
Yes	11 (22.0)
No	39 (78.0)
Prior hysterectomy, n (%)	
Yes	15 (30.0)
No	35 (70.0)

IQR, interquartile range.

TABLE 2**Results of Knowledge Assessment by Response**

Knowledge Questions	Incorrect Response (%)	Correct Response (%)
1. Have you signed an informed consent for your surgery?	10.0	90.0
2. Are you scheduled to have a sling procedure for stress incontinence at the same time as your prolapse repair?	2.0	98.0
Purpose		
3. The purpose of my prolapse surgery is to treat my urgency/frequency symptoms.	36.0	64.0
Alternatives		
4. Instead of surgery, I could choose to have a pessary (a device placed in the vagina to help with pelvic organ prolapse).	20.0	80.0
5. Instead of mesh, I could choose to have prolapse repair without any sort of mesh.	64.0	36.0
Procedure		
6. In this procedure, one end of the mesh is attached to a ligament on the sacrum/backbone.	10.0	90.0
7. Another end of the mesh is attached to the vagina or cervix.	44.0	56.0
Risks		
8. I am likely to have back pain after this procedure due to the location of the mesh.	68.0	32.0
9. After surgery, there is a risk of mesh exposure (mesh or stitches) coming through the vagina.	44.0	56.0
10. There is no risk of infection or bleeding with this procedure.	20.0	80.0
11. The bowel, urinary tract, blood vessels or nerves may be injured during this procedure, leading to further surgery.	32.0	68.0
12. I may require a blood transfusion due to bleeding at the time of surgery.	46.0	54.0
Other		
13. I may need to be discharged home with a urinary catheter.	14.0	86.0
14. There is a chance my prolapse will come back after this procedure.	34.0	66.0
15. The mesh is permanent.	16.0	84.0

TABLE 3

Knowledge Score and Time Between Surgical Consent and Survey by Surgeon

Surgeon	Surgical Cases n (%)	Time Between Signing Consent and Survey, Weeks, Median (IQR)	Score, Mean $\pm$ SD
Surgeon 1	24 (48.0)	7.4 (3.0–14.9)	68.8 $\pm$ 19.2
Surgeon 2	9 (18.0)	5.1 (3.0–7.9)	63.0 $\pm$ 14.2
Surgeon 3	7 (14.0)	1.1 (0.0–5.9)	76.1 $\pm$ 15.7
Surgeon 4	10 (20.0)	6.3 (2.9–8.4)	73.5 $\pm$ 12.9
All surgeons	50 (100)	5.9 (2.7–8.9)	69.7 $\pm$ 16.8

SD, standard deviation.