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Patient recall 6 weeks after surgical consent for midurethral sling using mesh

Brook L. McFadden, M.D.[1], **Sarah L. Hammil, M.D.**[1], **Melissa L. Constantine, M.D.**[2], **Megan E. Tarr, M.D.**[3], **Kimberly S. Kenton, M.D.**[3], **Husam T. Abed, M.D.**[4], **Vivian W. Sung, M.D.**[5], and **Rebecca G. Rogers, M.D.**[1]

[1]University of New Mexico Health Sciences Center, Albuquerque, NM

[2]University of Michigan Medical School, Ann Arbor, MI

[3]Loyola University Medical Center, Maywood, IL

[4]Henry Ford Health System, Detroit, MI, USA

[5]Warren Alpert Medical School, Brown University, Providence, RI

Abstract

Introduction and hypothesis—We aimed to determine patient recall of specific surgical risks and benefits discussed during consent for midurethral sling (MUS) surgery immediately after consent and at 6 weeks follow-up. Specifically we sought to determine whether or not women recalled specific risks related to the placement of mesh.

Methods—Surgeons consented patients for MUS in their usual fashion during audio recorded consent sessions. After consent and again at 6 weeks postoperatively, women completed a checklist of risks, benefits, alternatives, and general procedural items covered during consent. In addition, women completed the Decision Regret Scale for Pelvic Floor Disorders (DRS-PFD). Audio files were used to verify specific risks, benefits, alternatives, and procedural items discussed at consent. Recall of specific risks, benefits, and alternatives were correlated with DRS-PFD scores.

Results—Sixty-three women completed checklists immediately post consent and at 6 weeks postoperatively. Six-week recall of benefits, alternatives, and description of the operation did not change. Surgical risk recall as measured by the patient checklist deteriorated from 92 % immediately post consent to 72 % at 6 weeks postoperatively ($p < .001$). Recall of the risk for mesh erosion declined from 91 to 64 % ($p < .001$). Recall that mesh was placed during the MUS procedure declined from 98 to 84 % ($p = .01$). DRS-PFD scores were correlated with poorer surgical risk recall and surgical complications ($r = .31$, $p = .02$).

Conclusions—Recall of MUS surgery risks deteriorated overtime. Specifically, women forgot that mesh was placed or might erode. Further investigations into methods and measures of adequate consent that promote recall of long-term surgical risks are needed.

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Conflicts of interest

None.

Keywords

Informed consent; Mesh; Midurethral sling

Introduction

Surgical consent is performed to aid patients in making informed decisions regarding whether or not to proceed with surgery. The process of informed consent begins at the initial physician-patient encounter. At that time, the surgeon and patient begin a dialogue regarding the patient's medical problems and options for management. During surgical consent, physicians are expected to disclose the risks, benefits, and alternatives of the procedures that the patient is to undergo, as well as specific descriptors of the surgery. The current standard is that the disclosure should not be burdensome to the patient and should include all elements that a "reasonable patient would wish to know" [1]. Traditional full-length midurethral slings (MUS) are the gold standard for the treatment of stress urinary incontinence and are associated with high treatment success and low complication rates [2]. Nonetheless, specific risks of MUS sling surgery have been well documented including risks associated with the use of a permanently implanted mesh, including mesh erosion, pain from mesh placement, and mesh shrinkage. The risks of transvaginally placed mesh were recently highlighted in both the 2008 and 2011 US Food and Drug Administration (FDA) Safety Communications. In these notifications, the FDA recommends that providers ensure that patients understand the postoperative risks and complications associated with the transvaginal placement of mesh and realize that mesh is a permanent implant [3, 4]. The occurrence of long-term risks related to MUS surgery predicts patient dissatisfaction [5] and may result in litigation. Patients who are well informed may be more satisfied with their decision to undergo surgery [6]. We sought to determine what patients recalled from their surgical consent sessions immediately after consent and 6 weeks after MUS surgery and whether or not they recalled specific risks related to the placement of a permanent mesh material.

Materials and methods

This is a planned secondary analysis of a study designed to explore patient understanding of surgical consent for MUS surgery. The aim of this analysis was to describe specific risks, benefits, alternatives, and surgical procedural items that women recalled at their 6-week postoperative visit following MUS surgery. In addition, we sought to determine whether or not women recalled that a permanent mesh was placed and the complications associated with mesh placement, including erosion and removal of the mesh material. During the 2010 study period, four sites across the USA invited urogynecology patients undergoing MUS surgery to participate. All centers were Institutional Review Board (IRB) approved to conduct the study, and all women gave written research consent. Women greater than 18 years of age, able to read and speak English, and planning to undergo MUS surgery for stress urinary incontinence were included. Women with a history of gynecologic malignancy or who had concurrent prolapse or other surgeries were excluded. Baseline characteristics collected included age, ethnicity, race, first language spoken at home, education level, parity,

and history of prior gynecologic or urinary incontinence surgery. Surgical data included MUS type performed, estimated blood loss, presence of intraoperative or postoperative complications, catheter dependence at discharge, and hospitalization duration. We also recorded the time spent in surgical consent counseling.

All women completed a 21-item checklist that listed common risks, benefits, and alternatives as well as specific procedural descriptions of MUS surgery (Table 1). The checklist included two dummy items unrelated to MUS surgery in order to screen responses for reliability. The checklist was generated from a review of the literature, the results of a national survey of gynecologic surgeons we previously conducted [7], and the results of two focus groups, one of gynecologic surgeons and another of gynecologic clinic support staff who routinely observe gynecologic surgical counseling and consent. Checklist items were screened to be read at the 6th grade reading level. Surgeons were asked to counsel and consent women undergoing MUS surgery in their usual fashion. Surgical consent sessions were audio recorded. Immediately following surgical consent, women completed the 21-item surgical checklist, a 3-question health literacy instrument validated by Chew et al. [8], and the Urinary Distress Inventory 6 (UDI-6) [9, 10]. At 6 weeks postoperatively, women again completed the 21-item checklist, the UDI-6, and a validated measure of surgical decision regret—the Decision Regret Scale for Pelvic Floor Disorders (DRS-PFD) [6].

As surgeons were asked to consent in their usual fashion, they were not required to include all checklist items during their consent or use it as a guide during the consent process. It was therefore possible for checklist items to be omitted from the surgical consent. We did not expect women to recall items not actually discussed with them during surgical consent. To ensure that women were not penalized on their recall scores for checklist items omitted, all audio files were reviewed by two study personnel unaware of the study hypotheses. The two reviewers independently completed the same 21-item checklist while listening to the audio file. Discrepancies between the two reviewers were resolved by re-review of the audio file. A third, blinded reviewer was employed if a discrepancy remained. The reviewer's checklist of risks, benefits, alternatives, and descriptors of the surgery actually discussed were compared to patient recall on the 21-item surgical checklist immediately after surgical consent and again at 6 weeks postoperatively. Recall scores were calculated by dividing the number of items correctly recalled by the number of items actually discussed (based on the audio recording reviews of surgical consent), then multiplied by 100.

Descriptive statistics were used to describe patient characteristics and surgical data. Comparison of women's percent recall immediately following surgical consent versus recall at 6 weeks postoperatively and changes in UDI-6 scores were performed with Student's *t* tests. Women's recall of specific risks, benefits, alternatives, and procedural items were correlated using Spearman's rank correlations with DRS-PFD scores, catheter dependence at discharge, occurrence of intraoperative or postoperative complications, and health literacy scores. Since the incidence of intra- and postoperative complications was low, for analyses, all complications were combined and dichotomized to present or not. Regression analyses were used to determine variables that predicted lower consent recall and higher regret scores. Significance was set at $p<.05$.

Results

Eighty-two women gave surgical consent for MUS and completed the 21-item checklist, the UDI-6, and the health literacy scale. No woman underwent concomitant surgeries; 71/82 (87 %) underwent MUS and 11/82 (13 %) subjects cancelled surgery for various reasons. Women who participated were predominantly non-Hispanic White, highly educated, had high health literacy scores, and were middle-aged (Table 2). Mean time spent in surgical consent counseling was 15 ± 7 min. Women who chose to proceed with their surgery did not differ from women who cancelled their surgery. All women except two were counseled about mesh during their surgical consent.

Subjects underwent MUS with either a retropubic (n=61) or transobturator (n=10) approach. The incidence of intraoperative and postoperative complications was low; the most frequent intraoperative complication was bladder perforation. Postoperative complications were led by the “other” category, which was predominated by overactive bladder symptoms (Table 3).

Eighty-nine percent of women who underwent MUS surgery completed the 6-week postoperative questionnaires (n=63). Patient characteristics or surgical variables did not differ between women who completed their 6-week questionnaires and those that did not. Mean UDI-6 scores improved from 50.5 ± 20.4 to 20.3 ±20.0, p< .001, indicating that the MUS surgery, as expected, was effective in treatment of stress urinary incontinence. Age, education, race/ethnicity, health literacy scores, presence of complications, and UDI-6 scores were not correlated with decreased recall of risks at 6 weeks postoperatively, while catheter dependence at discharge was associated with decreased recall of risks at 6 weeks postoperatively (p<.001). Multivariate analysis controlling for baseline characteristics did not change these conclusions.

Regression analysis revealed that length of time spent in surgical consent counseling was associated with improved recall of surgical risks immediately following surgical consent (p=.03). However, this association was no longer present by 6 weeks postoperatively. Recall of dummy items did not change from baseline to 6 weeks postoperatively, indicating that women were not answering questions by rote. The 6-week recall of surgical risks deteriorated when compared to immediate recall documented on audio files, while recall of benefits, alternatives, and procedural items did not change (Table 4). In contrast, women had 92 % correct recall of surgical risks at the time of surgical consent compared to 72 % at 6 weeks postoperatively (p<.001). Specific recall regarding risks of mesh placement declined at 6 weeks postoperatively. Immediately following surgical consent, nearly all women (98 %) correctly recalled that mesh would be placed during surgery versus 84 % at 6 weeks postoperatively (p=.01). Recall of the risks for mesh erosion went from 91 % immediately post consent down to 64 % at 6 weeks postoperatively (p<.001).

Overall, DRS-PFD scores were low, indicating low regret with MUS surgery (mean score 1.1 ± 0.3; scale from 1–5; higher scores indicating more decision regret). However, poorer recall of surgical risks at 6 weeks follow-up was correlated with greater decision regret (Spearman’s coefficient 0.31, p=.02). Unadjusted regression models to predict decision regret were evaluated with age, risk recall, complications, and catheter dependency at

discharge as regressors. Number of complications and diminished risk recall 6 weeks postoperatively were both independent predictors of increased decision regret (p<.001).

Discussion

We found that women's recall of risks of MUS surgery significantly declined when compared to their recall of benefits, alternatives, and specific procedural items. In addition, 16 % of women did not recall that they had a permanent mesh placed and 36 % did not recall that the mesh might erode even at the immediate postoperative follow-up of 6 weeks. Finally, we found that the combination of complications and poor risk recall of MUS surgery was associated with increased decision regret for the procedure.

The comprehension rates in our study are comparable to those reported in a large randomized trial of teach-back versus standard consent [11]. Fink et al. included 575 subjects and compared comprehension scores immediately post consent. This trial measured consent understanding using a 23- to 26- item checklist specific to each surgical procedure. Checklist scores ranged from 71.4 % in the repeat back group to 68.2 % in the usual consent group. Our participants also completed a checklist of 21 items which we validated with a review of the literature, focus groups, as well as a survey of gynecologic surgeons who perform MUS procedures. Like Fink et al.'s trial, we found that length of surgical consent counseling correlated with immediate recall, but not prolonged recall at 6 weeks postoperatively. We hypothesize that the length of surgical consent counseling may have little effect in the longer term following a surgical procedure.

Both our trial and previous trials investigating patient understanding of consent [12] are limited by the choice of how to measure patient understanding. Like previous trials we utilized a checklist "score" of specific questions regarding risks, benefits, alternatives, and procedural items as our measure of understanding. Whether or not these scores are an accurate representation of what a reasonable patient would want to know is undetermined, although we did find that lack of risk recall was associated with worsened decision regret 6 weeks following surgery. A meta-analysis of studies investigating methods of improving informed consent reviewed 44 articles and found that a variety of interventions all improved patient comprehension immediately post consent including repeat back methods, written and multimedia interventions, and extended informed consent discussions [12]. In the meta-analysis, most trials examined immediate patient comprehension; fewer studies examined patient recall following their procedure as we did. It is unclear whether better recall would decrease decision regret, although others have found that women who feel unprepared for their surgery report high rates of dissatisfaction postoperatively [13].

Particularly alarming in the present study is the number of patients who did not recall having permanent mesh placed or that there were specific complications associated with mesh use, including mesh erosion. In a general surgery study evaluating patient's understanding and recall of permanent mesh placement for hernia repair, only 66 % (57/87 subjects) recalled that a mesh was placed 3 days postoperatively, and of those who recalled that the mesh was placed, only slightly more than half (56 %, 32/57) could report why the mesh was used [14]. The implications for poor retention of information regarding permanent implants may have a

significant impact on the patient's future health. For example, women are often asked to continue the use of vaginal estrogen following the placement of vaginal mesh to prevent future complications; lack of understanding of why the estrogen is recommended may lead to poor compliance. Finally, complications from the placement of vaginal mesh may occur remotely from the time of surgery. In a systematic review of complications attributable to the use of mesh for prolapse surgery, mesh erosions presented 6 weeks to 12 months after the surgery [15]. While the incidence of mesh erosion following MUS surgery is lower than that accompanying prolapse surgery using mesh, mesh erosions following sling surgery can still occur remote from surgery [16].

Strengths of our study include the audio recording of the consent process and review of audio files by two researchers blinded to the research hypothesis, making a comparison of recall at the 6-week postoperative visit to what was actually discussed possible. Thus recall scores reflected what the surgeon actually discussed and patients were not penalized on their recall scores for topics not introduced during surgical consent. We had considered standardizing consent sessions but felt that having patients undergo consent as usual was more reflective of a medical practice setting. We included patients from four academic hospital settings from throughout the USA. Finally, our study population all underwent standardized surgeries with relative consensus regarding the risks, benefits, alternatives, and procedural items.

Weaknesses include that our study population was fairly homogeneous. All the women in this study were highly educated and had high health literacy scores on the Chew questionnaire. This population may not be representative of women with poor health literacy. Poor health literacy has been shown by others to be associated with poorer comprehension at the time of surgical consent [17]. Increased age and lower socioeconomic status are associated with lower health literacy [18], and again, our population is fairly homogeneous in these aspects. In addition, understanding and recall are overlapping but distinct constructs. Certainly it is important that patients understand the information presented about their surgery and remember it until the risks have abated.

Our prior work has shown that surgeons are more likely to disclose surgical risks than benefits or alternatives [7]. Despite more emphasis on risks than benefits, alternatives, or procedural items, we found that deterioration of recall was greatest for surgical risks. This may be because if patients do not experience any of the risks described, the risks are no longer relevant to them and they no longer recall them. Risks immediately associated with surgery such as intra- or immediate postoperative bleeding or organ damage during surgery may be unnecessary to recall once the period of increased risk has passed. On the other hand, the delayed risks of MUS surgery including the risk of mesh problems, chronic urinary tract infections, and the development of urgency might be important for patients to recall in the longer term.

In conclusion, we found that women's recall of risks following surgical consent deteriorated at 6 weeks postoperatively and that women forgot that they had a permanent mesh implanted and that the mesh might erode. Interventions to improve patient understanding and recall are needed to improve the surgical consent process. Further studies are needed to determine

what is necessary for patients and surgeons to achieve and measure adequate informed consent that improves patients' understanding and recall of surgical risks, including the long-term risks of mesh placement.

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Table 1

21-item surgical consent checklist

Please check the box next to any of the items below that you remember discussing with your surgeon			
	Yes	**No**	
a	☐	☐	Bleeding during the surgery
b	☐	☐	Infection after the surgery
c	☐	☐	Damage to you bowel, bladder, nerves, blood vessels, or ureters during the surgery
d	☐	☐	Not being able to urinate well or at all after surgery
e	☐	☐	Continued leakage of urine after the surgery
f	☐	☐	Troubled seeing well after the surgery
g	☐	☐	Worsened urge incontinence symptoms (“ got to go” feelings) after your surgery
h	☐	☐	You may need to have the sling taken out after the surgery if you are unable to urinate
i	☐	☐	Less leakage of urine following the surgery
j	☐	☐	Being more likely to be able to do more things you enjoy following the surgery
k	☐	☐	You could take antidepressants instead of having the surgery
l	☐	☐	Thigh or groin pain following the surgery
m	☐	☐	The mesh that is put in during the surgery may erode into your vagina, bladder, or urethra
n	☐	☐	Decreased chance of getting a cold following the surgery
o	☐	☐	You could use a pessary instead of having surgery
p	☐	☐	You could get chronic urinary tract infections following surgery
q	☐	☐	Your surgeon is going to make an incision in the vagina as well adjust above your pubic bone or just inside each of your thighs
r	☐	☐	You could perform “Kegel” or pelvic floor exercises instead of having surgery
s	☐	☐	Your surgeon is going to place mesh underneath your urethra
t	☐	☐	Your surgeon is going to look inside you bladder with a camera
u	☐	☐	You could have another kind of surgery instead of the one you are having now

Dummy items are “‘f” and “n”

Table 2

Subject characteristics

Characteristic	***n*=71**
Age, mean (SD)	52.3 (10.3)
Race/Ethnicity (%)	
American Indian	8.8
Asian	1.8
Black	7.0
White	82.5
Hispanic	12.3
Primary language (% English)	90.0
Education (%)	
High school degree or less	33.8
Some college or greater	66.2
Parity, Mean (SD)	2.1 (1.2)
Previous gynecologic surgeries (%)	40.9
Previous urinary incontinence surgery	7.1

SD standard deviation

Table 3

Surgical details

Detail or complication	***n* = 71 (%)**
Retropubic sling	61 (85.9)
Transobturator	10 (14.1)
Estimated blood loss (ml), mean (SD)	88 (128)
Intraoperative complications	8 (11.4)
Bladder perforation	4 (5.6)
Vaginal perforation	0
Hemorrhage	2 (2.8)
Other	3 (4.2)
Postoperative complications	18 (26.9)
UTI (culture proven)	5 (7.0)
Symptomatic hematoma	3 (4.2)
Mesh extrusion/erosion	1 (1.4)
Wound infection	0
Thigh or groin pain	1 (1.4)
Other	11 (15.5)
Any complications (intra- or postoperative)	21 (29.6)
Days admitted, mean (SD)	0.6 (3.5)
Catheter dependent at discharge	14 (20.9)
Days of catheter use, median (range)[a]	4.5 (1–20)

SD standard deviation, *UTI* urinary tract infection

[a]For Those catheter dependent at discharge

Table 4

Difference in recall at consent and 6 weeks postoperatively

Checklist items	Immediate post-consent % recall (SD)	6 weeks postoperatively % recall (SD)	*p*[a]
Risks (10 items)	92 (12.3)	72 (21.6)	<.001
Benefits (2 items)	96 (21.3)	100 (0)	.33
Alternatives (4 items)	76 (34.5)	67 (39.1)	.15
Descriptions of surgery (3 items)	90 (20.0)	83 (27.7)	.09

SD standard deviation

[a]paired *t* test of differences