GYNECOLOGY

A randomized controlled trial to determine whether a video presentation improves informed consent for hysterectomy

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BACKGROUND: Informed consent is an integral part of the preoperative counseling process. It is important that we know the best way to relay this information to patients undergoing surgery, specifically, hysterectomy.

OBJECTIVE: We sought to determine whether supplementing normal physician counseling with a video presentation improves patient comprehension during the informed consent process for hysterectomy.

STUDY DESIGN: In a randomized, mixed factorial controlled trial, standard physician counseling (control arm) was compared to physician counseling plus video presentation (video arm) during the prehysterectomy informed consent process. Primary outcome was improvement in patient comprehension measured by assessments at baseline, postcounseling, day of surgery, and postsurgery. Patient satisfaction was measured by a validated questionnaire. Audiotaped patient-physician interactions were analyzed to determine time spent counseling, number of patient questions, and whether standard counseling included 11 predetermined critical components included in the video. A sample size of 60 per group (N = 120) was planned to compare both groups.

RESULTS: From May 2014 through June 2015, 120 patients were enrolled and 116 randomized: 59 to the video arm and 57 to the control arm. All characteristics were similar between groups. Video arm subjects demonstrated greater improvement in comprehension scores in both postcounseling (9.9% improvement; 95% confidence interval, 4.2–15.7%; $P = .0009$) and day-of-surgery questionnaires (7.2% improvement; 95% confidence interval, 0.96–13.4%; $P = .02$). Scores 4–6 weeks after surgery returned to baseline for both groups. Control subjects were less likely to be counseled about risk of thrombosis ($P < .0001$), colostomy ($P < .0001$), further medical/surgical therapy ($P = .002$), hormone replacement therapy ($P < .0001$), or postoperative expectations ($P < .0001$). Physicians spent more time counseling patients who did not watch the video (8 vs 12 minutes, $P = .003$) but number of questions asked by patients in each group was similar.

CONCLUSION: Enhancing prehysterectomy counseling with a video improves patient comprehension through day of surgery, increases thoroughness of counseling, and reduces physician time.

Key words: hysterectomy, informed consent, video

Introduction

Informed consent is a central aspect of the medical decision-making process, and represents an essential tenet of patient autonomy and respect for persons; this is especially critical before a patient undergoes a medical procedure.[1] While informed consent has a medicolegal component, the primary aim is for the patient to understand the purpose, risks, benefits, and alternatives of the procedure when deciding on a treatment course.[2] Unfortunately, due to the complexity of medicine and medical terminology and the overall health illiteracy of the general population, studies repeatedly show that patients poorly understand their medical treatments.[3] Although patient autonomy requires diligent efforts to ensure patients comprehend their surgical procedures, this is made difficult by time constraints in the office, and the increasing pressure on physicians to provide better, more cost-effective health care while meeting high patient satisfaction standards.[4] Novel techniques to deliver health care information that improve patient comprehension, satisfaction, and physician efficiency are paramount in this era of medicine governed by health care delivery reform.

In an effort to harness growing technology resources and improve counseling effectiveness, thoroughness, and efficiency, our study aims to determine whether including a video-based multimedia presentation improves patient comprehension during informed consent for hysterectomy. Secondary outcomes include patient satisfaction, thoroughness of counseling content, and physician time efficiency.

Hysterectomy provides a promising test arena for enhanced patient counseling and surgical consent for several reasons. Firstly, as one of the most common surgeries performed in the United States, with >400,000 cases per year,[5] improvements in both comprehension and efficiency with this procedure alone have the potential for broad impact. Moreover, there are clear indications for hysterectomy, well-defined risks and benefits, and often, common alternatives to the procedure to discuss or consider. Discussion of the procedure should include expectations of preoperative, intraoperative (including a description of the procedure itself), and short- and long-term postoperative periods. These known factors lend themselves to inclusion in a standardized video presentation.

Materials and Methods

A prospective, randomized mixed factorial design was used to compare standard physician interaction (control

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AJOG at a Glance

Why was this study conducted?

To determine the effectiveness of audiovisual materials on providing informed consent for a large proportion of the gynecological patient population, namely those undergoing hysterectomy.

Key findings

Patients who were presented with audiovisual aids for their preoperative counseling for their upcoming hysterectomy had better knowledge of their procedure and retention of that knowledge. Also, using these materials reduced the time the physician spent with the patient during their preoperative visit.

What does this add to what is known?

This is the first study performed evaluating audiovisual tools to provide informed consent for this type of procedure in the gynecological field. Therefore, it is directly applicable to our patient population as gynecologists.

arm) to standard physician interaction plus audiovisual presentation (experimental arm) during the preoperative visit for patients undergoing hysterectomy. The primary outcome was improvement in patient comprehension as measured by knowledge assessments at baseline, immediately postcounseling, day of surgery, and postsurgery. A sample size of 50 patients in each group was planned to detect at least a 10% improvement on postcounseling knowledge assessments for a within-subjects comparison of comprehension between cohorts. The Brooke Army Medical Center Institutional Review Board approved this study (Clinicaltrials.gov, NCT01933139).

All adult female patients during the study period (May 2014 through June 2015) undergoing vaginal, abdominal, or laparoscopic hysterectomy with or without salpingo-oophorectomy for benign indications at San Antonio Military Medical Center (SAMMC) were offered participation in the study (Figure 1). Patients were excluded if they had a malignant indication for the surgery, had vision and/or hearing impairments, were unwilling or unable to provide research consent, were age <18 years, or were not primarily English speaking. Eligible patients were identified from the master surgery schedules within the SAMMC Gynecology Clinic. A study investigator then contacted the patient by telephone for recruitment and prescreening. On the day of the scheduled preoperative appointment, interested patients were individually consented for research participation. Subjects were then randomized via a computer-generated allocation sequence into the experimental or control groups. The randomly assigned study group was revealed to the investigator and patient. All subjects completed the Rapid Estimate of Adult Literacy in Medicine questionnaire, a validated assessment of medical literacy, to ensure that medical literacy was equivalent between the 2 cohorts (http://healthliteracy.bu.edu/all). Demographic data were obtained and tabulated in the Table.

The primary investigators scripted the multimedia video used in this study, which was produced by a professional company with feedback from a study investigator with subject matter expertise in psycholinguistics. The video was designed to be 10 minutes in length to balance informational content with brevity. In general, the video aims to explain the indications and routes for hysterectomy, risks, benefits, expectations, and long-term complications: topics that should be discussed in every standard preoperative visit. Along with the audio script, the video includes diagrams, illustrations, and animations to support the key content areas.

The study investigators deemed 11 key aspects of the surgical consent discussion essential and addressed them in the video. The investigators used these components to create a checklist by which to evaluate the comprehensiveness of informed consent given by physicians in the control group.

All subjects underwent knowledge assessment via specialized questionnaires at 4 separate time points: (1) prior to the preoperative appointment (ie, baseline), (2) immediately after the preoperative appointment, (3) day of surgery, and (4) 6-week follow-up visit. Of note, the preoperative appointment was within 30 days of surgery, and time points 1 and 2 were on the same day for all patients.

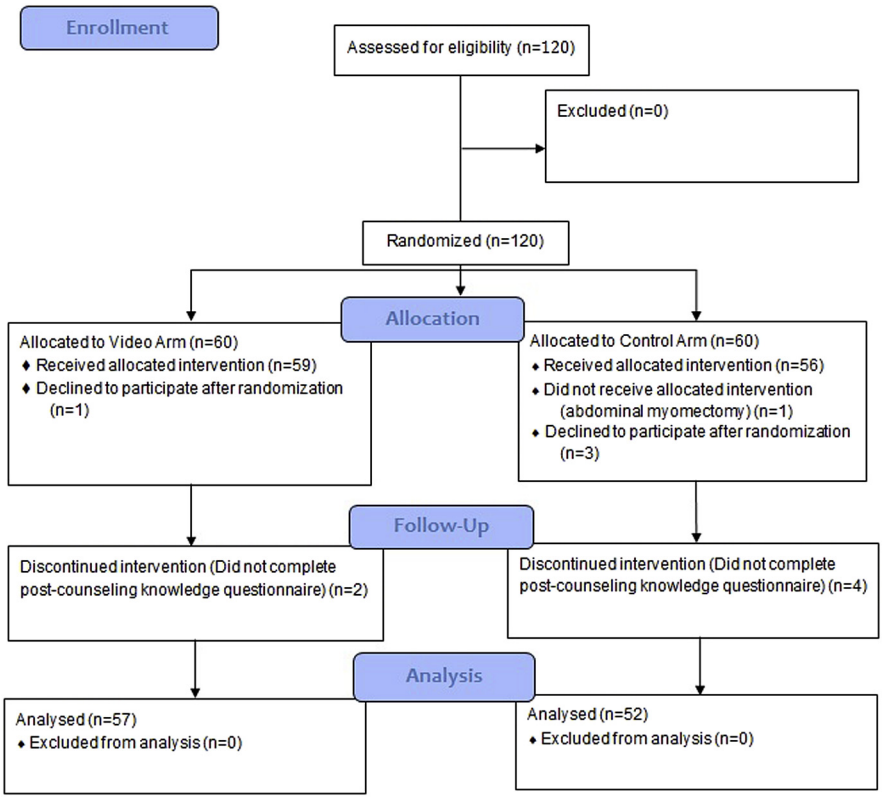
The questionnaires include true/false and multiple choice assessments based on the video script and were developed to evaluate both knowledge and comprehension of prehysterectomy counseling elements. To minimize practice effects while allowing for a within-subjects comparison of learning, investigators developed 4 versions of the questionnaire, 1 per time point. Each version of the questionnaire targeted 4 key areas: background information (eg, general information about hysterectomy and the female reproductive system), procedure-specific information (eg, similarities and differences between abdominal and laparoscopic hysterectomy), risks (eg, nearby organs that can be damaged during hysterectomy), and expectations (eg, what to expect before, during, and after surgery). Questions within each topic area were further grouped by related question stem, which allows each research participant to serve as their own control to minimize variance due to language comprehension and background medical knowledge. For example, each version of the questionnaire has 1 "background" question about the definition of "total hysterectomy," but the question stem and possible answer choices are distinct. Every subject saw each version of the questionnaire at 1 of the 4 time points, but the order in which versions were presented, as well as the order of questions themselves, was varied. Each version was pilot-tested for readability and clarity by approximately 20 clinic staff, to include nurses, medical technicians, and front desk personnel.

Following medical literacy and baseline knowledge assessments, the control group received standard presurgical counseling and informed consent, which at SAMMC includes face-to-face interaction with a senior resident surgeon, discussion and questions, and signing a surgical informed consent document. The intervention group watched the video on a hand-held interactive tablet. After watching the video, this group received the standard face-to-face interaction with the surgeon. The surgeon was aware of their patients' participation in the study and to which arm they belonged; however, they were not privy to the initial knowledge questionnaire performance and were not restricted in their surgical counseling. All subjects signed the same institutional presurgical informed consent form. At the conclusion of the preoperative visit, subjects completed a validated satisfaction questionnaire (Client Satisfaction Questionnaire-8) to compare patient satisfaction scores between the 2 cohorts (http://www.csqscales.com/).

All patient-physician interactions (control and experimental) during the preoperative appointment were audiotaped to assess the number of patient questions asked, total time spent with each patient, and the number of the 11 key elements of prehysterectomy counseling discussed with the control group. Both patients and physicians gave consent to be recorded during the encounters. The study investigators took no part in guiding the physician interaction format or content at any time during this study and were not present during the preoperative visit. Data abstraction from the audiotapes was performed by a study investigator who was blinded to the identity of the physicians providing surgical consent.

Patient knowledge assessment score at time point 2 was the primary outcome evaluated, represented as a continuous variable (0−100%). A within-subjects analysis was performed using 2-tailed *t* tests for the 2 groups to determine whether subjects' change in comprehension is greater after watching the video plus patient-physician interaction or after patient-physician interaction alone.

FIGURE 1
CONSORT diagram



Allocation of patients.

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Secondary endpoints evaluated included knowledge retention at time points 3 and 4, patient satisfaction scores, quality of physician-directed consent relative to the 11 key elements of prehysterectomy counseling, number of patient questions asked, and time spent with the patient during their preoperative visit. Two-tailed *t* tests were used for continuous variables and Fisher exact test was used for categorical variables.

Results

In all, 120 patients were enrolled in the study, 109 of whom completed precounseling and postcounseling knowledge questionnaires (Figure 1). Precounseling average percent-correct scores were equivalent between the 2 cohorts (65.5% vs 62.1%, $P = .17$). Subjects in the video arm scored nearly 10% (9.9%; 95% confidence interval, 4.2−15.7%) higher on postcounseling questionnaires than the control arm (15.1% ± 2.04% improvement in the video arm vs 5.2% ± 2.1% in the control arm; $P = .0009$). Percent improvement continued to be higher in the video arm the day of surgery (8.3% ± 2.3% vs 1.2% ± 2.01%; $P = .02$), by which time control subjects had on average returned to baseline knowledge levels. Scores were equivalent at the 6-week postoperative visit, and back to baseline for both groups (Figure 2). Patient satisfaction scores between the 2 cohorts were the same (raw score 30.9, both cohorts).

Complete audio data were available for 99 of the 113 subjects, 55 in the video arm and 44 in the control arm. All video arm subjects received the 11 predetermined key components of counseling through video content prior to in-person physician counseling. Of these 11 components (Figure 3), patients in the control arm were less likely to be counseled about risk of thrombosis ($P < .0001$), risk of colostomy ($P < .0001$),

TABLE
Demographics

Demographic information

Characteristic	Control n = 60	Video n = 60	*P* value[a]
Age, y	44.2	41.4	
Race			
Caucasian	24 (40)	25 (41.7)	
African American	21 (35)	21 (35)	
Hispanic	11 (18.3)	12 (20)	
Asian	2 (3.3)	0	
Other	2 (3.3)	1 (1.7)	
Gravidity	3	3	
Parity	2	2	
Military status			
Active duty	15 (25)	22 (36.7)	
Dependent	26 (43.3)	29 (48.3)	
Retired	16 (26.7)	7 (11.7)	
Civilian	3 (5)	2 (3.3)	
Hysterectomy			
Abdominal	18 (32.1)	15 (25.4)	
Laparoscopic	18 (32.1)	30 (50.8)	
LAVH	5 (8.9)	2 (3.4)	
Vaginal	13 (26.8)	12 (20.3)	
Education level			
<High school	0	1 (1.7)	
High school	16 (26.7)	14 (23.2)	
Higher education	44 (73.3)	47 (75)	
Previous health care worker	27 (45)	26 (43.3)	
Currently employed	40 (66.7)	39 (65)	
REALM score	64.4	65.2	.77

Values expressed in n (%) unless otherwise notes.

Age, gravidity, parity, and REALM scores are averages.

LAVH, laparoscopic-assisted vaginal hysterectomy; *REALM*, Rapid Estimate of Adult Literacy in Medicine.

[a] All *P* values are >.05 unless otherwise stated.

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further medical and/or surgical therapy ($P = .002$), possible need for hormone replacement therapy ($P < .0001$), or postoperative expectations or limitations in the hospital and/or home ($P < .0001$). Face-to-face counseling was shorter for those patients who viewed the video (8 vs 12 minutes, $P = .003$), but the number of questions asked was similar in each group (2.5 vs 2.8, $P = .59$).

Comment

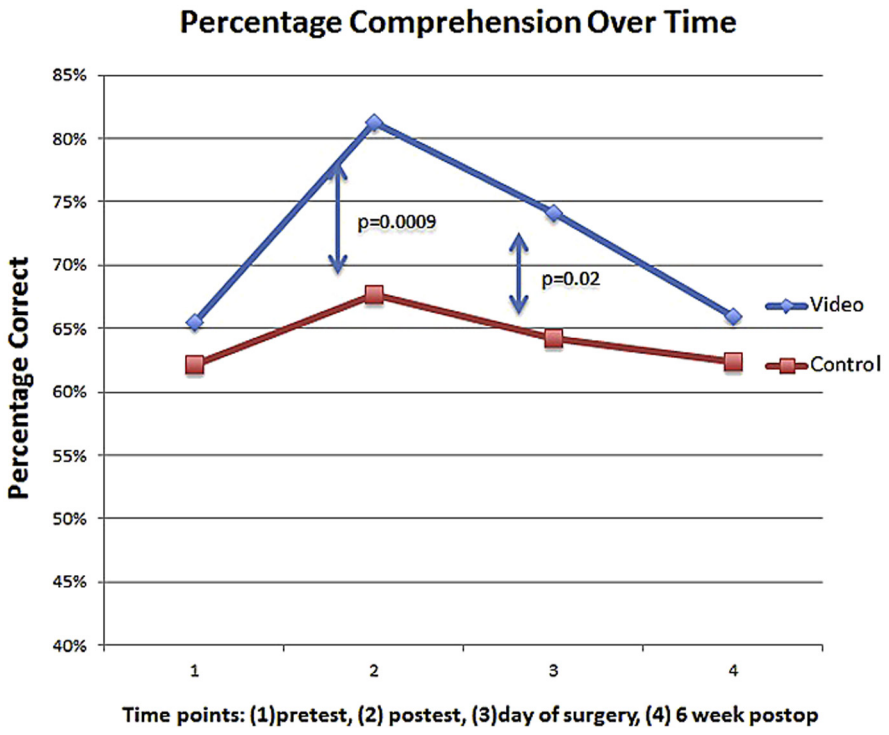
Patient autonomy requires thorough counseling to allow proper informed consent before medical procedures. Our study demonstrates that by including a video presentation as adjunct to standard physician counseling, patients undergoing hysterectomy have improved comprehension about their procedure on the day of their preoperative counseling and the day of surgery compared to those who did not view the video. Additionally, providers frequently leave out key information that should be included in the discussion.

Our study is consistent with literature: patient comprehension improves significantly, and in critical areas, when a video presentation supplements standard preoperative consent processes. A systematic review by Nehme et al[3] highlighted the importance of multimedia programs as an adjunct to the patient-physician discussion: 16 of 22 studies demonstrated statistically significant improvement in patient comprehension with the use of audiovisual aids. Positive results were depicted in favor of multimedia tools whether groups received different methods of consent or the intervention was performed in sequence with standard consent. Only 1 study in this review was gynecological in nature, specifically for bilateral tubal ligation. Patients demonstrated significant improvement in comprehension when an instructional video was used to supplement provider discussion: 90% vs 57.5% correct on a knowledge questionnaire.[5]

Measuring baseline knowledge prior to education in the preoperative appointment is what separates our study from those in the literature currently. Interestingly, the control group showed only a 5% improvement in comprehension between time points 1 and 2. Given that many aspects influence a patient's ultimate understanding of their procedure throughout the informed consent process, assessing baseline knowledge adds value to the interpretation of knowledge improvement over time. The meager increase leaves much room for enhancing the "usual" consent process that many physicians currently use.

In our study, while comprehension scores were initially higher in the video arm, scores returned to baseline by the 6-week postoperative appointment in both arms, suggesting that knowledge gained through counseling degrades over time. Notably, subjects who underwent standard counseling failed to show improved knowledge relative to baseline as early as the day of surgery. Similarly, in

FIGURE 2
Percentage correct over time



Patient questionnaire average percentage correct over time comparison between arms.

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orthopedics, one of the most studied fields, patients scored 70.7% correct after a standardized consent, but retention was significantly decreased to 59.5% by the time of the first postoperative visit 1−2 weeks later.[6] Another orthopedic consent study similarly showed a decrease in retention postoperatively; however, unlike our present study, there was still a statistically higher recall rate in the multimedia presentation group compared to verbal counseling.[7]

The American College of Surgeons recommends that informed consent includes operative indications, risks and alternatives, the likely result if the operation is not performed, how the operation may improve quality of life, hospitalization time, recovery expectations, and long-term effects.[8] While many of these components may be contained within the informed consent document, surgeons cannot ensure the patient reads or understands the entire document before signing. It is imperative that physicians perform proper counseling. Furthermore, there is significant heterogeneity in physician communication quality, style, and content. Previous studies have shown that formal training improves surgical residents' ability to discuss and document informed consent.[9] By training residents to standardize the process, specific components necessary for informed consent were more likely to be discussed. In line with this, the video arm in our study provided similar standardization, ensuring thorough counseling and improved comprehension while reducing provider time and maintaining patient satisfaction.

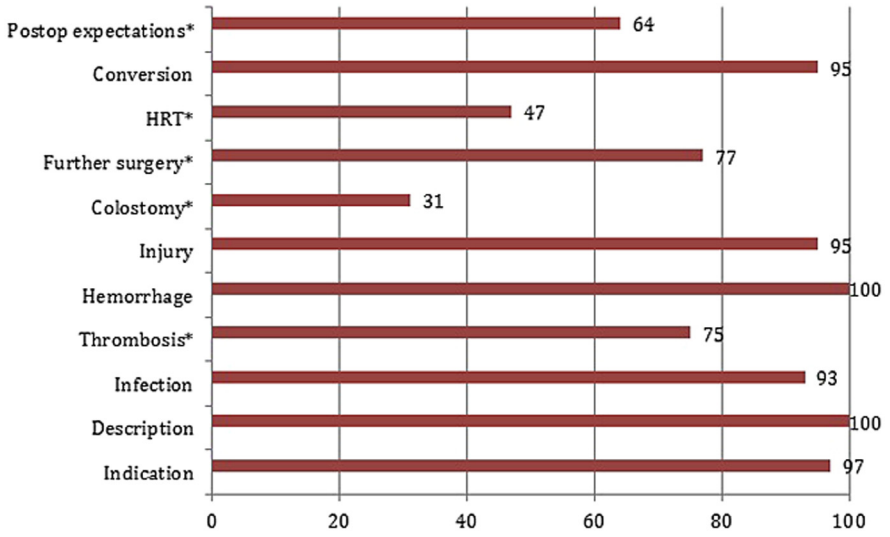
At least 5 of the 11 predetermined essential components of preoperative counseling were less likely to be included during standard consent, and were thus never presented to patients in the control arm. While we recognize that some of these components may be deemed essential by some but not by others and vice versa, this lack of thoroughness may explain why control subjects showed less improvement in comprehension following counseling. Intuitively, patients are unlikely to improve their comprehension if key components are omitted from the discussion; the standardized content, rather than the use of a video, may underlie the difference between groups.

Despite improved thoroughness and comprehension when a video is included, physicians spent less actual time with the video group. With the increasing emphasis both on the value of health care and the efficiency of health care delivery, the time spent by physicians with patients has become an increasingly important resource.[10] However, despite less face-to-face patient time, the video group had higher comprehension and equivalent satisfaction scores compared to the control group.

Preoperative counseling has an important medicolegal dimension in the current health care environment. In many countries, it has become law that the patient maintains full understanding of relevant information before giving consent.[6] Poor communication and inadequate informed consent have been implicated in many malpractice claims, including, for example, in 90% of ophthalmology cases.[2,11] Despite some physician unease with addressing risks of each procedure, patients actually prefer to be aware of common and rare complications for the benefit of full disclosure.[1] Video supplementation may help offset communication barriers and reduce the potential for implicit or explicit bias to impact delivery of key information. Our study demonstrates the utility of video supplementation in increasing comprehension and standardizing content, which may reassure physicians reluctant to use technological tools due to fear of medicolegal consequences.

The strengths of this study include prospective randomized design, assessment of baseline knowledge and medical literacy, assessment of comprehension at multiple time points, and audiotaped physician encounters. As baseline knowledge and medical literacy were equivalent between the 2 groups, we could ensure that group differences at the outset could not account for our

FIGURE 3
Counseling content comparisons



Percentage of each of 11 predetermined components in control arm included during counseling compared to video. *Statistically significant ($P < .01$).

HRT, hormone replacement therapy.

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results. Our study further reduces variance due to these factors by allowing patients to be their own controls, thereby allowing us to assess more accurately the gain from the video aid. Assessing patient comprehension at multiple time points allows us to link these results to a timeline appropriate for patient care by evaluating whether patients have an understanding of critical information before, during, and after surgery. Lastly, audiotaping the patient-physician interaction allowed for evaluation of the number and type of questions asked, identification of potentially confusing topics in the consent process, and assessment of whether physicians are comprehensively counseling the patient before surgery.

However, there were limitations. Performance on our knowledge and comprehension assessments may not represent an accurate portrayal of patient understanding. While medical literacy, content areas, and readability were considered carefully, patients were not solicited for feedback during development of the video or questionnaires. While this study limited enrollment to English-speaking patients, the video's animations and illustrations, and its inclusion of the 11 key counseling elements, make it amenable to translation. To provide external validity and allow for meaningful analysis of the content of preoperative counseling, the physicians' surgical consent was not standardized, but allowed providers to counsel patients "as usual." While the results suggest providers frequently skip key content areas, we are unable to evaluate whether this is due to providers' assessment of patient-specific needs, conversational cues, implicit or explicit bias,[12] or other unidentified factors. Although patient knowledge was assessed at 2 postoperative time points, this study focused largely on a single preoperative patient-physician encounter and did not record additional patient encounters, although characterization of other discussions may reveal insights about the relative importance of key counseling elements at particular times in the treatment trajectory. Another limitation was, for reasons of ethics, all counseling physicians were aware of, and had consented to, the audiotaping. Any resulting selection bias or Hawthorne effect would intuitively improve the thoroughness of physician counseling, so our results may represent a best case control group scenario, minimizing the discrepancies between routine counseling and a video-aided process. The relatively small number of patients who were predominately associated with the military is also a study limitation.

Our study demonstrates that hysterectomy patients have improved and longer-lasting informed consent comprehension after enhancing normal physician counseling with a video presentation. As the delivery of medical care evolves, metrics like quality and value of care, efficiency, and cost-effectiveness have become increasingly important. Application of creative technology may be one solution to this growing need. Solutions could also integrate the in-person counseling more directly with supplementation, for example, by using physician-guided technologies. Regardless of the platform, harnessing technology may augment thoroughness, consistency, and fairness in patient counseling while improving physician efficiency. ■

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