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Do Patients Want to Know about Surgeon Experience?

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Abstract

Introduction: We assess patient interest in obtaining information on surgeon training as part of informed consent before undergoing a "new" procedure.

Methods: After receiving institutional review board approval a survey was administered by neutral third parties to patients at 2 outpatient settings. Exclusion criteria were reading level below sixth grade, nonEnglish speakers and pregnancy. Demographic data included age and race as gender was controlled for only females. Occupational health care background was investigated at clinic 2 only. The survey included the 3 components of the REALM-SF (rapid adult literacy estimate based on 7 medical words), STAI-X2 (trait anxiety questionnaire) and a specifically designed observer questionnaire with yes/no answers. This questionnaire included question 1 (Q1)—Should the consent form include the number of times a surgeon has performed this type of new surgery? and question 2 (Q2)—Should a consent form include when the surgeon started to perform this new surgery? Descriptive statistics were used.

Results: There were 22 patients at location 1 and 97 at location 2 who met the study inclusion criteria. Overall 77.3% of patients from both locations wanted to obtain this information (ie answered yes to Q1 and Q2). Age ($p=0.0153$) and race ($p=0.0250$) were statistically significant factors for Q1 but not for Q2. REALM-SF and STAI-X2 scores did not significantly affect responses at either location, nor did occupational health care background at clinic 2.

Conclusions: Three-quarters of the women queried would like to know more about their surgeon's expertise with a new type of procedure before consenting to it.

Key Words: informed consent, clinical competence, surgical mesh, female, reconstructive surgical procedures

Abbreviations and Acronyms

FDA = U.S. Food and Drug Administration

REALM-SF = Rapid Estimate of Adult Literacy in Medicine-Short Form

STAI-X2 = State-Trait Anxiety Inventory

The rapid development of new technologies contributes to the pressure on urologists to learn surgeries by new techniques at ever increasing rates.[1] Regarding the use of mesh in the repair of pelvic organ prolapse, the FDA issued public health notifications in 2008 and 2011 to surgeons and patients for the purpose of disclosing and understanding the

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risks of mesh implantation as part of the informed consent process.[2,3] A third notification was issued by the FDA on March 27, 2013 as part of the informed consent process for the use of mesh sling in the repair of stress urinary incontinence.[4] In this document it is suggested that before deciding to undergo stress urinary incontinence surgery, patients ask their surgeon to disclose what "type of specialized training he/she received with a particular product and/or procedure." Another recommendation is for the patient to question the surgeon on "how often he/she has performed this surgery with this particular product."

The 5 basic tenets of informed consent include disclosure, capacity, voluntariness, comprehension and consent.[5] Nowhere is surgeon experience involved in the informed consent process, yet it is now part of an official recommendation issued by the FDA regarding synthetic sling surgery. Based on these recommendations we developed a questionnaire to study patient desire to have the surgeon disclose information during the informed consent process about how long the surgeon has been performing a given new surgery, presumably after adequate training to do so, and the number of times the surgeon has performed that specific procedure.

Materials and Methods

For the purpose of this study we designed a survey with 2 questions that assessed patient desire for disclosure by the surgeon of how many times (Q1) and for how long (Q2) he/she has performed a given new surgical procedure. The primary outcome of interest was patient desire to know surgeon experience. The secondary outcome of interest was disparity among age, race, literacy level, anxiety level and health care background (clinic 2 only). This questionnaire consisted of 2 questions that were given consecutively to patients at 2 clinical locations (see Appendix). We hypothesized that patients would like to know surgeon experience and that there would not be significant disparities, especially given the recent attention to mesh lawsuits by various media, including television and newspaper advertisements. The survey was in the English language and prepared for a sixth grade reading level.

After obtaining institutional review board approval at 2 institutions the questionnaire was administered during a 3-month period at the 2 locations. Patients were all comers, including postoperative, preoperative, new and followup clinic visits. Location 1 is a county hospital that sees all general and subspecialty urology cases, while location 2 is a private practice clinic that sees female pelvic medicine and reconstructive surgery cases. Both locations are affiliated with the same medical school and residency program, and are based in a university setting. A third party administered the survey to consecutive patients at each location. Exclusion criteria were nonEnglish speaking, a reading level less than sixth grade and pregnancy. Demographic data included age, race and experience in the medical field (acquired for location 2 only).

Two additional forms were administered to assess patient literacy levels and anxiety levels. Literacy was assessed using the REALM-SF, which consists of 7 medical terms which the patient pronounces verbally.[6,7] The maximum time to pronounce each word is designated as 5 seconds for a total of 35 seconds for completion. Scores range from 0 to 7. If a word is mispronounced or not stated within 5 seconds it is considered missed.

Anxiety was assessed using the trait portion (form X-2) of the State-Trait Anxiety Inventory.[8] This form consists of 20 questions intended to rate how anxious a patient generally feels. Answers include almost never, sometimes, often and always, and scores range from 20 to 80. The total time to complete the questionnaire and additional forms averaged 5 minutes by design to encourage participation.

Descriptive statistics involved means, ranges, frequencies and percentages. Whether a value was predictive of a patient being willing to consent was analyzed using logistic regression, with location included as a controlling factor in the model. All statistical analyses were performed using SAS® 9.3 for Windows®.

Results

Overall 77.3% of patients from both locations wanted a consent form to include the number of times a surgeon performed the surgery and 77.3% wanted the inclusion of the date the surgeon first performed the surgery. There was no difference in responses between the clinic locations. Demographics and scores for the REALM-SF and STAI-X2 are listed in table 1.

REALM-SF and STAI-X2 scores were not predictive of patients wanting their surgeon to disclose the number of times the surgeon had performed the surgery or the date the surgeon began to perform the surgery, when controlled for both clinics. Health care background (tested at clinic 2 only) was also not predictive of patient desire to know the number of times a new surgery was performed or the date the new surgery was first performed. However, there was a statistically significant difference when age and race were assessed. Older patients and nonHispanic patients were more likely than their younger and Hispanic counterparts to favor disclosure of the number of times the surgeon performed the surgery (Q1) ($p=0.0153$ and $p=0.0250$, respectively), but this was not statistically significant with regard to wanting