UCSF UC San Francisco Previously Published Works

Title

Informed consent for innovative surgery: A survey of patients and surgeons

Permalink

https://escholarship.org/uc/item/72v119cr

Journal

Surgery, 153(4)

ISSN

0039-6060

Authors

Char, Susan J Lee Hills, Nancy K Lo, Bernard <u>et al.</u>

Publication Date

2013-04-01

DOI

10.1016/j.surg.2012.08.068

Peer reviewed



NIH Public Access Author Manuscript

Surgery. Author manuscript; available in PMC 2014 April 01.

Published in final edited form as:

Surgery. 2013 April; 153(4): 473–480. doi:10.1016/j.surg.2012.08.068.

Informed consent for innovative surgery: A survey of patients and surgeons

Susan J. Lee Char, J.D., M.D.¹, Nancy K. Hills, M.B.A, M.A., Ph.D.², Bernard Lo, M.D.³, and Kimberly S. Kirkwood, M.D.¹

¹Department of Surgery, University of California, San Francisco

²Department of Neurology, University of California, San Francisco

³Department of Medicine, Program in Medical Ethics, University of California, San Francisco

Abstract

Background—Unlike new drugs and medical devices, most surgical procedures are developed outside clinical trials, without regulatory oversight. Surgical professional organizations have discussed how new procedures should be introduced into practice, without agreement on what topics informed consent discussions must include. To provide surgeons with more specific guidance, we wanted to determine what information patients and surgeons consider essential to disclose before an innovative surgical procedure.

Methods—85 attending surgeons and 383 adult postoperative patients completed surveys. Using a 6-point Likert scale, participants rated the importance of discussing 16 types of information preoperatively for 3 techniques (standard open, laparoscopic, robotic) offered for a hypothetical partial hepatectomy.

Results—Compared with surgeons, patients placed more importance on nearly all types of information, particularly volumes and outcomes. For all 3 techniques, around 80% of patients indicated that they could not decide on surgery without being told whether it would be the surgeon's first time doing the procedure. When considering an innovative robotic surgery, a clear majority of both patients and surgeons agreed that it was essential to disclose the procedure's novel nature, potentially unknown risks and benefits, and whether it would be the surgeon's first time performing the procedure.

Conclusions—To promote informed decision making and autonomy among patients considering innovative surgery, surgeons should disclose the procedure's novel nature, potentially unknown risks and benefits, and whether the surgeon would be performing the procedure for the first time. When accurate volumes and outcomes data are available, surgeons should also discuss these with patients.

Conflicts of interest:

^{© 2012} Mosby, Inc. All rights reserved.

Corresponding author, including reprint requests: Dr. Kimberly S. Kirkwood, Professor of Surgery, University of California, San Francisco, 521 Parnassus Ave., C341, Box 0790, San Francisco, CA 94143-0790, Office: 415-476-0762, Fax: 415-476-8694, Kim.Kirkwood@ucsfmedctr.org.

The authors have no conflicts of interest to declare.

Publisher's Disclaimer: This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final citable form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.

INTRODUCTION

Surgical innovation has led to new and effective approaches for treating disease, as in the case of solid organ transplant and minimally invasive surgery. However, during the development of new procedures, patients may be subject to significant risks, some of which may be unforeseen. Laparoscopic cholecystectomy was widely adopted, then found to have increased risk of bile duct injury.(1) Extracranial-intracranial arterial bypass for ischemic stroke was ultimately found to be associated with increased risk of stroke.(2–3) Knee arthroscopy for osteoarthritis was later shown to be ineffective,(4) after exposing numerous patients to operative risks for no benefit.

While the introduction of new drugs and medical devices is strictly regulated,(5) the vast majority of patients undergoing innovative surgery do so outside the protections of clinical trials,(6–7) which require institutional review board approval and detailed, comprehensive informed consent. Outside the context of clinical trials, patients still must consent to the surgery, but there is no legal requirement to inform them of its innovative nature.(8) Surgical professional organizations and ethicists have published general guidelines on introducing new technology into practice, but have not specified what aspects of the innovative procedure should be discussed with patients during informed consent.(9–13)

We surveyed separate samples of patients and surgeons to determine what they considered essential to discuss during informed consent for an innovative surgical procedure, then compared patients' and surgeons' responses. Based on our data, we offer some concrete recommendations for discussing innovative procedures with patients.

METHODS

Patients

Eligible patients were English-literate adults with the ability to consent who were attending their first postoperative visit at 1 of 3 surgery clinics affiliated with University of California, San Francisco (UCSF): General Surgery Faculty Surgery Practice, Colorectal Surgery Clinic, and Breast Cancer Clinic. Consecutive eligible patients were invited to complete the survey and return it at the end of their visit. From October 2009 through February 2010, 383 of 541 eligible patients completed surveys (71% response rate).

Surgeons

Two groups of surgeons were eligible: (1) Department of Surgery clinical faculty at UCSF and (2) attending surgeons at UCSF-affiliated hospitals in San Francisco (California Pacific Medical Center, Kaiser Permanente, Veterans Affairs Medical Center), who had the assistance of a UCSF general surgery resident for at least 1 case over the last year. Surveys were distributed at division meetings and grand rounds. Attendings who were absent received an email invitation to complete the survey online. Attendings received a \$5 Starbucks gift card for completing the survey. Between January and March 2010, 85 of 113 surveys were completed (75% response rate). Twelve of the 85 surgeons had cared for patients who participated in this study. Although the survey's hypothetical scenario involved a partial hepatectomy, we did not limit participation to liver surgeons, so that an adequate number of surgeons could be surveyed.

Survey

All surveys were anonymous. The survey asked surgeons to imagine their patient required a partial hepatectomy. Patients were asked to imagine that they "needed to have part of their liver removed." The procedure was selected as our pilot data indicated that it was easy to

understand the rationale and objective for the surgery. Three methods were proposed for the partial hepatectomy: standard open surgery, laparoscopic surgery, and robotic surgery. The survey explained that although laparoscopic surgery is "commonly used to remove the gallbladder and appendix, this approach is fairly new for a partial hepatectomy." Robotic surgery was described as a technique that "has been used in a small number of patients over the last few years and is *even newer* than the laparoscopic technique." Patients and surgeons used a 6-point Likert scale to rate the importance of discussing 16 different types of information for each of the 3 techniques preoperatively. On the Likert scale, 1 represented "Completely unimportant" and 6 represented "Extremely important, a patient could not decide without this information." Surgeons and patients also provided demographic data. Please see Online Appendix for the complete surveys.

The surveys were developed through a pilot study of 5 attending surgeons and 40 postoperative outpatients at UCSF, who took the survey and were then interviewed about issues such as clarity, time efficiency, discrimination, and construct validity. Earlier versions of the patients' survey tested Likert scales with broader numeric ranges, including varying levels of unimportance. Patients rejected those Likert scales because they did not feel there were meaningful gradations of unimportance.

Data analysis

To analyze Likert scores, we used the Skillings-Mack test to assess: (1) the relative importance of the 6 broader categories of information shown in Table 3, regardless of the level of innovation; and (2) whether the importance of information varied among the 3 surgical techniques. Because a particular participant's responses would likely be more similar than other participants' responses, we used statistical techniques for dependent observations. The non-parametric Friedman test, which permits comparison of 3 or more levels of a variable, precluded analysis of any questions where responses were not given for all 3 surgical techniques. Therefore, we used the Skillings-Mack test, which allows for data missing at random.

We also calculated the proportion of participants who rated each type of information "extremely important" as a percentage of the total number of participants (n = 383 for patients, n = 85 for surgeons), rather than as a percentage of the number of actual respondents to a particular question. This had the effect of providing a more conservative estimate. We compared these percentages for standard versus robotic procedures using repeated measures logistic regression models, which allow for analysis of dependent nominal data.

To compare the percentage of patients and surgeons who rated each type of information "extremely important," we used Pearson's χ^2 test.

STATA version 10 was used for all statistical analyses. A statistically significant difference was defined as p < 0.05. Although we made a number of comparisons, no adjustment was made for multiple comparisons. We wanted to assess each type of information in its own right, rather than test the null hypothesis that there was no difference among all 16 types of information when comparing the 3 surgical techniques and when comparing patients' and surgeons' opinions.(14) In addition, results that are significant and make sense as a group are less likely to be significant solely by chance.(15)

Ethical issues

The UCSF Committee on Human Research granted the study of surgeons exempt status and approved the patients' study. Written consent was waived for both studies.

RESULTS

Patient and surgeon characteristics

The majority of patients were Caucasian and college educated. Women outnumbered men. A majority of patients preferred a shared model of medical decision making, involving both the patient and surgeon. Many patients had multiple prior operations, but few had had an innovative procedure, defined as "involv[ing] a new technique or device, making the surgery different from how it is normally done." (Table 1.)

Surgeons were predominantly middle-aged, Caucasian men. The median time in practice after completing residency was 12 years. The largest groups of subspecialists were general surgeons and vascular surgeons. Approximately half practiced primarily at an academic or tertiary referral center. (Table 2.)

What do patients want to know before choosing any surgery?

Regardless of innovation, the single most important type of information for patients was whether the surgeon was performing the procedure for the first time (mean score for all 3 surgical techniques = 5.81 on the 6-point Likert Scale) (Table 3). Approximately 80% of patients indicated they could not decide on surgery without this extremely important information (Table 4).

Not surprisingly, patients placed great importance on discussing risks and benefits. They rated risks and benefits as the most important category of information, regardless of the degree of innovation (mean score 5.75) (Table 3). Over 70% of participants considered the following 3 topics essential for deciding whether to undergo surgery, regardless of innovation: known risks, known benefits, and potentially unknown risks (Table 4).

The least important category of information was the surgeon's potential conflicts of interest (mean score 4.50) (Table 3). Only 24% of patients thought it was essential to know whether the surgeon planned to publish an article about the patient's operation (Table 4).

What types of information are important to patients considering innovative surgery?

Over 70% of patients reported they could not decide whether to have robotic surgery without the following information: a general description of the procedure, known risks and benefits, acknowledgement of potentially unknown risks and benefits, whether the surgeon was doing the procedure for the first time, and the surgeon's special training for the procedure (Table 4).

Patients placed more importance on discussing nearly every topic prior to innovative laparoscopic or robotic surgery compared to standard surgery, although for most topics absolute differences were small (Tables 3, 4).

How do patients' and surgeons' opinions compare?

Compared with surgeons, a larger percentage of patients reported that they could not decide on surgery without discussing nearly all types of information (Table 4). Although these differences were generally small in magnitude, there was a greater than 20 percentage-point difference between the percentage of patients versus surgeons who rated the following types of information essential when considering robotic surgery: technical details of the procedure, other surgeons' volumes and outcomes, the surgeon's own volumes and outcomes, and the surgeon's special training. Around two-thirds or more of both patients and surgeons agreed that patients could not decide whether to undergo innovative robotic surgery without the following information: a clear statement that the procedure is new rather than standard, known risks, potentially unknown risks and benefits, and whether it would be the surgeon's first time performing the procedure (Table 4).

DISCUSSION

Preoperative conversations between a surgeon and patient have several objectives, including information exchange, logistical preparation, and establishing trust. Both parties benefit from a shared understanding of the extent of uncertainty in the risks and outcomes of the proposed procedure. In the present study, the case scenario involved two areas of uncertainty: the surgeon's lack of experience with the procedure and the overall novelty of the approach.

Regardless of innovation, the most important topic for patients was whether their surgeon would be performing the procedure for the first time. Around 80% of patients stated they could not decide on surgery without this information, whereas about 60% of surgeons believed this information was essential. When an innovative laparoscopic or robotic procedure was proposed, patients placed greater importance on nearly all types of preoperative information, especially surgeons' volumes and outcomes.

Compared with surgeons, more patients considered many types of information essential to decision making, particularly regarding surgeons' volumes and outcomes. However, around two-thirds or more of both patients and surgeons agreed that the following 5 topics were essential for deciding whether to have an innovative robotic surgery: a clear statement that the procedure is new rather than standard, known risks, potentially unknown risks and benefits, and whether it would be the surgeon's first time performing the procedure.

Implications for surgical practice

Our study is the first to identify what specific information patients believe is essential to discuss with their surgeon before agreeing to an innovative procedure. Our findings suggest a number of recommendations for surgeons obtaining informed consent for innovative surgery.

Description of procedure—The Society of University Surgeons has published guidelines on how surgical innovations should be developed and introduced into practice. Although the guidelines do not address all the specific elements of informed consent, the guidelines state that informed consent "should include discussion of the innovative aspect of the procedure" and that "its novelty should be described to the patient as an integral part of the informed consent process."(12) Ethicists have recommended "additional informed consent…specific to the experimental nature of the procedure," without providing more detailed guidance.(13) In our study, nearly two-thirds of patients considered it essential to have a clear statement that the proposed robotic procedure was new rather than standard, suggesting that surgeons should specifically state this when obtaining consent. Only 20% of surgeons considered the procedure's technical details essential to discuss with patients prior to robotic surgery, while almost 60% of patients reported they could not decide without that information. Surgeons should consider offering to discuss the technical details with patients preoperatively, particularly if the proposed innovation is technical in nature, like a new application of robotic techniques.

Potentially unknown risks—One court, interpreting a North Carolina statute, found that health care providers had a duty to disclose the novel nature of "relatively new" procedures

Lee Char et al.

and "any uncertainty regarding the risks" associated with such procedures.(16) The patient suffered a gunshot wound to the knee, leading to a pseudoaneurysm. Surgeons and radiologists consented him for a "percutaneous steel coil embolization" of the injured artery, which was a "relatively new" procedure at the time. They informed the patient that the procedure "might not work," but did not inform him of their "lack of knowledge of the risks." After embolization, the patient developed critical limb ischemia. Bypass was unsuccessful and the patient underwent amputation. However, a subsequent case interpreting the same statute declined to follow that interpretation.(8) We found that 75% of patients said it was essential to know that some risks may be unknown when considering an innovative robotic procedure, suggesting that surgeons should openly address this uncertainty.

Surgeon's volumes and outcomes—The surgical community has long debated whether outcomes data for individual surgeons should be public, citing concerns about data accuracy, and whether patients would want or understand such data.(17–20) Courts are also split regarding whether surgeons must disclose their experience with a procedure when obtaining informed consent.(21–24) More than two-thirds of our patients reported that they could not decide on robotic surgery without this information. Compared with patients, surgeons in our study considered information about their surgeon's volumes and outcomes less important to patient decision making. Surgeons may be reluctant to discuss inevitably imperfect outcomes for many reasons, including fear of losing patient trust, professional regard, or even possibly revenue. During consultation for elective innovative surgery, if accurate data are available, surgeons should discuss them with patients. To facilitate this disclosure, medical centers need to develop mechanisms for surgeons to readily analyze their own outcomes data. Surgeons may also consider tracking innovative procedures and outcomes using the American College of Surgeons' online surgical innovations database at http://web.facs.org/innovations/innovationsdefault.htm.

Surgeon's first time—For robotic procedures, nearly two-thirds of surgeons and nearly 80% of patients believed it was essential to discuss that it would be the surgeon's first time performing the procedure. All surgical procedures are associated with a "learning curve," during which complication rates are higher due to surgeon inexperience. Surgeons may be able to minimize this added risk by augmenting their skills before performing the new procedure, or by seeking an expert's assistance when performing the procedure. Some procedures, such as laparoscopic hepatectomy, may be amenable to a graduated approach by starting with a simpler related procedure, such as laparoscopic hepatic wedge resection. Ultimately, however, one patient must be the first. Patients responding to our survey said that the first patient should be told that he or she is the first. When disclosing this, it may be useful to focus on the clinical indications that prompted trying a new technique, as innovations most often arise when a standard procedure is inadequate for a particular patient. Additionally, surgeons may want to describe their volumes and outcomes for similar procedures, any special training relevant to the novel procedure, as well as the planned participation of an expert assistant.

Given the importance patients placed on whether it was their surgeon's first time performing a procedure and their surgeon's volumes and outcomes, it seems likely that even if it is not the surgeon's first time performing a new procedure, but the learning curve for that procedure is long, many patients may still want to know where their surgeon is on that learning curve. Further research may be needed to establish this, but if the learning curve for a new procedure has been defined, surgeons should consider disclosing this information.

Implications for legal standards and ethics guidelines

Empirical data such as ours may be helpful to courts deciding what types of information must be disclosed to patients during an informed consent discussion. In approximately half of U.S. states, courts define the scope of disclosure based on what a "reasonable patient" considers relevant for deciding whether to have surgery, while in the other half, the scope of disclosure is based on what the court believes a "reasonable physician" would consider relevant.(25–26)

The "reasonable patient" standard has been interpreted with wide variability. In one case, the defendant surgeon had taken a 2-day class on laparoscopic cholecystectomy, where he had performed the procedure in 3 pigs. When he obtained the patient's consent, he did not disclose that he had done the procedure only on pigs. After sustaining a bile duct injury, the patient sued for breach of informed consent. The court found that under the "reasonable patient" standard, "a surgeon's lack of experience in performing a particular surgical procedure is not a material fact for the purposes of finding liability predicated on failure to secure informed consent."(22) In other words, the court sided with the surgeon, finding no breach of informed consent because a "reasonable patient" would not have considered a surgeon's lack of experience relevant when deciding whether to undergo surgery. In contrast, around 80% of our patients said they could not decide whether to have surgery without knowing it would be the surgeon's first time performing it. In interpreting the reasonable patient standard, courts may find it useful to consider empirical data on what information actual patients consider essential when deciding to have surgery.

To our knowledge, there are no judicial opinions applying the "reasonable physician" standard in a breach of informed consent case involving an innovative surgical procedure. To establish what information is material and therefore required for informed consent under a "reasonable physician" standard, courts typically rely on competing testimony from a small number of surgeons retained as expert witnesses by the plaintiff and defendant.(27) In addition to expert testimony, courts who are interpreting the reasonable physician standard may also wish to consider empirical data on what surgeons consider essential to disclose before surgery.

Regardless of legal requirements, the ethical principle of respect for patient autonomy supports discussion of the following 5 topics before innovative surgery, given the large majority of patients who considered those topics essential for deciding whether to have robotic surgery: a clear statement that the procedure is new rather than standard, known risks, potentially unknown risks and benefits, and whether it would be the surgeon's first time performing the procedure. By highlighting these 5 topics, we do not intend to imply that the remaining topics do not need to be discussed. They may also need to be addressed, depending on individual patients' informational needs or the nature of the operation.

Limitations

First, the survey involved a hypothetical case, not actual informed consent discussions. Few patients actually had innovative surgery. Our study design did not permit us to directly compare the responses of patients and their individual surgeons. Directly comparing patients' and surgeons' perspectives on the actual information discussed prior to an innovative surgery should be the subject of further investigation.

Second, the hypothetical case was limited to informed consent for a partial hepatectomy. Responses may have differed if the proposed procedure had been a coronary artery bypass graft or inguinal hernia repair, involving more or less risk than a partial hepatectomy. Third, patients rated most types of information "very important" or "extremely important." Although the differences in Likert scores were statistically significant, they were relatively small and may not represent clinically significant differences. It is possible a "ceiling effect" prevented further differentiation between the importance of different types of information. However, participants had no difficulty using this Likert scale to clearly identify some types of information, such as potential conflicts of interest, as less important to decision making.

Fourth, our study may have underestimated the importance patients place on potential conflicts of interest because our survey asked about only research publications and consultancy fees. Additional research should explore the importance of discussing a broader range of potential conflicts of interest, such as surgeons receiving financial incentives for implanting specific devices.

Fifth, our study does not directly examine whether providing patients all the desired "extremely important" information actually affects their decision to undergo an innovative procedure. This should be investigated in future studies.

Finally, our results may not be generalizable to other patient populations, practice settings, or geographic areas. Our participants had surgery recently, which may have rendered them more attentive to issues related to preoperative disclosure. They were also predominately female and well educated. In some studies, these characteristics were associated with higher informational requirements before medical interventions.(28–35) Additional studies are needed to confirm our results in other contexts.

CONCLUSION

A large majority of both surgeons and patients agreed that the following types of information were essential for patients deciding whether to have an innovative robotic procedure: a clear statement that the procedure is new rather than standard, known risks, potentially unknown risks and benefits, and whether it would be the surgeon's first time performing the procedure. Patients also expressed a strong preference for information about their own surgeon's volume and outcomes, which surgeons regarded as less important. We suggest that these topics should be discussed with patients preoperatively under both the reasonable physician and the reasonable patient standards for informed consent. Furthermore, even if such disclosure were not legally mandated, ethical principles support disclosure in order to promote informed, autonomous decision making by patients considering an innovative surgical procedure.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

Sources of financial support:

Dr. Lee Char - Greenwall Foundation

Dr. Lo – National Institutes of Health (NIH) Grant Number 1 UL1 RR024131-01 from the National Center for Research Resources (NCRR) and NIH Roadmap for Medical Research, and the Greenwall Foundation

References

 Strasberg SM, Ludbrook PA. Who oversees innovative practice? Is there a structure that meets the monitoring needs of new techniques? J Am Coll Surg. 2003; 196:938–48. [PubMed: 12788432]

- 2. The EC/IC Bypass Study Group. Failure of extracranial-intracranial arterial bypass to reduce the risk of ischemic stroke: Results of an international randomized trial. N Engl J Med. 1985; 313:1191-200. [PubMed: 2865674]
- 3. Burger I, Sugarman J, Goodman SN. Ethical issues in evidence-based surgery. Surg Clin North Am. 2006; 86:151-68. x. [PubMed: 16442426]
- 4. Moseley JB, O'Malley K, Petersen NJ, Menke TJ, Brody BA, Kuykendall DH, et al. A controlled trial of arthroscopic surgery for osteoarthritis of the knee. N Engl J Med. 2002; 347:81–8. [PubMed: 12110735]
- 5. U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Belmont Report. Federal Register. 1979; 44:23191–917. [PubMed: 10241035]
- 6. Mastroianni, AC.; Jansson, RL. The legal treatment of surgical innovation. In: Reitsma, AM.; Moreno, JD., editors. Ethical guidelines for innovative surgery. Hagerstown, Maryland: University Publishing Group; 2006. p. 93-116.
- 7. Mastroianni AC. Liability, regulation and policy in surgical innovation: the cutting edge of research and therapy. Health Matrix Clevel. 2006; 16:351-442. [PubMed: 16948248]
- 8. Osburn v. Danek Medical, Inc., 520 S.E.2d 88 (N.C. Ct. App.1999).
- 9. American College of Surgeons Committee on Emerging Surgical Technology and Education. ST-18 Statement on emerging surgical technologies and the evaluation of credentials. 1994. (http:// www.facs.org/fellows_info/statements/st-18.html)
- 10. American College of Surgeons Committee on Emerging Surgical Technology and Education. ST-23 Statement on issues to be considered before new surgical technology is applied to the care of patients. 1995. (http://www.facs.org/fellows_info/statements/st-23.html)
- 11. American College of Surgeons Committee on Emerging Surgical Technology and Education. ST-30 Verification by the American College of Surgeons for the use of emerging technologies. 1998. (http://www.facs.org/fellows_info/statements/st-23.html)
- 12. Biffl WL, Spain DA, Reitsma AM, Minter RM, Upperman J, Wilson M, et al. Responsible development and application of surgical innovations: a position statement of the Society of University Surgeons. J Am Coll Surg. 2008; 206:1204-9. [PubMed: 18501819]
- 13. Reitsma, AM.; Moreno, JD. Ethics guidelines for innovative surgery: Recommendations for national policy. In: Reitsma, AM.; Moreno, JD., editors. Ethical guidelines for innovative surgery. Hagerstown, Maryland: University Publishing Group; 2006. p. 199-212.
- 14. Perneger TV. What's wrong with Bonferroni adjustments. BMJ. 1998; 316:1236-8. [PubMed: 9553006]
- 15. Bacchetti P. Peer review of statistics in medical research: the other problem. BMJ. 2002; 324:1271-3. [PubMed: 12028986]
- 16. Estrada v. Jaques, 321 S.E.2d 240 (N.C. Ct. App. 1984).
- 17. Burger I, Schill K, Goodman S. Disclosure of individual surgeon's performance rates during informed consent: ethical and epistemological considerations. Ann Surg. 2007; 245:507-13. [PubMed: 17414595]
- 18. Marshall MN, Shekelle PG, Leatherman S, Brook RH. The public release of performance data: what do we expect to gain? A review of the evidence. JAMA. 2000; 283:1866–74. [PubMed: 10770149]
- 19. Schneider EC, Epstein AM. Use of public performance reports: a survey of patients undergoing cardiac surgery. JAMA. 1998; 279:1638-42. [PubMed: 9613914]
- 20. Schwarze ML. The process of informed consent: neither the time nor the place for disclosure of surgeon-specific outcomes. Ann Surg. 2007; 245:514-5. [PubMed: 17414596]
- 21. Johnson v. Kokemoor, 545 N.W.2d 495 (Wis. 1996).
- 22. Whiteside v. Lukson, 947 P.2d 1263 (Wash. Ct. App. 1997).
- 23. Barriocanal vs. Gibbs, 697 A.2d 1169 (Del. 1997).
- 24. Rado SG. A patient's right to know: a case for mandating disclosure of physician success rate as an element of informed consent. Health Matrix Clevel. 2008; 18:501-30. [PubMed: 19739575]
- 25. Noah L. Informed consent and the elusive dichotomy between standard and experimental therapy. Am J Law Med. 2002; 28:361-408. [PubMed: 12516174]

Lee Char et al.

- Lo, B. Resolving ethical dilemmas: a guide for clinicians. 4. Philadelphia: Wolters Kluwer Health/ Lippincott Williams & Wilkins; 2009.
- 27. 61 Am Jur 2d Physicians, Surgeons, and Other Healers §178 (2010).
- Courtney MJ. Information about surgery: what does the public want to know? ANZ J Surg. 2001; 71:24–6. [PubMed: 11167593]
- 29. Elder MJ, Suter A. What patients want to know before they have cataract surgery. Br J Ophthalmol. 2004; 88:331–2. [PubMed: 14977762]
- 30. Braaten EB, Handelsman MM. Client preferences for informed consent information. Ethics Behav. 1997; 7:311–28. [PubMed: 11655337]
- Waitzkin H. Doctor-patient communication. Clinical implications of social scientific research. JAMA. 1984; 252:2441–6. [PubMed: 6481931]
- El-Wakeel H, Taylor GJ, Tate JJ. What do patients really want to know in an informed consent procedure? A questionnaire-based survey of patients in the Bath area, UK. J Med Ethics. 2006; 32:612–6. [PubMed: 17012508]
- Janssen NB, Oort FJ, Fockens P, Willems DL, de Haes HC, Smets EM. Under what conditions do patients want to be informed about their risk of a complication? A vignette study. J Med Ethics. 2009; 35:276–82. [PubMed: 19407030]
- Dawes PJ, Davison P. Informed consent: what do patients want to know? J R Soc Med. 1994; 87:149–52. [PubMed: 8158593]
- Losanoff JE, Litwinczuk KM, Ranella MJ, Basson MD. Elective inguinal hernia repair: a unified informed consent, or who wants to know what? Am Surg. 2009; 75:296–300. [PubMed: 19385288]

Table 1

Characteristics of patients

	Participants (n=383)
Mean age ± SD, years	49 ± 15
Gender	
Male	143 (37%)
Female	229 (60%)
No response	11 (3%)
Race	
Caucasian/White	261 (68%)
Asian/Pacific Islander	30 (7%)
African/Black American	21 (5%)
Other	35 (9%)
Don't know/No response	36 (9%)
Hispanic	44 (11%)
Education	
Less than college degree	141 (37%)
College degree or more	227 (59%)
No response	15 (4%)
Family income	
<\$100,000/year	187 (49%)
\$100,000year	154 (40%)
No response	42 (11%)
Preference for decision making	
Surgeon mainly makes decision	63 (16%)
Shared decision making	209 (55%)
Patient mainly makes decision	67 (17%)
No response	44 (11%)
Median number of operations	3 (Interquartile range 2 to 5)
Most recent operation was laparoscopic	190 (50%)
Most recent type of operation	
General surgery	217 (57%)
Colorectal surgery	136 (36%)
Breast surgery	30 (8%)
Prior innovative surgery	
Yes	52 (14%)
No	188 (49%)
Don't know	110 (29%)
No response	33 (9%)

Table 2

Characteristics of surgeons

	Surgeons (n=85)
Average age ± SD, years	50 ± 10
Gender	
Male	61 (72%)
Female	21 (25%)
No response	3 (4%)
Hispanic/Latin American	2 (2%)
Race	
Caucasian/White	49 (58%)
Asian	30 (35%)
African/Black American	2 (2%)
No response	4 (5%)
Median years in practice after residency	12 (IQ range 7 to 25)
Surgical subspecialty	
General surgery	15 (18%)
Vascular	13 (15%)
Transplant	8 (9%)
Cardiothoracic	7 (8%)
Colorectal	6 (7%)
Pediatric	6 (7%)
Plastics	5 (6%)
Trauma	5 (6%)
Hepatobiliary	4 (5%)
Surgical oncology	4 (5%)
Bariatric	3 (4%)
Endocrine	3 (4%)
Breast	2 (2%)
Other/No response	4 (5%)
Practice site	
Tertiary referral/Academic	41 (48%)
Community	24 (28%)
County	9 (11%)
Veterans affairs	4 (5%)
Other/No response	7 (8%)
Experience with innovative surgery	
Median number of innovative surgeries last year	5 (IQ range 1 to 15)
Median % of innovative surgeries over career	5 (IQ range 1 to 10)

Lee Char et al.

Table 3

Importance of information to patients, based on 6-point Likert Scale

	Mean Likert score for all 3 techniques st	Standard	Laparoscopic	Robotic	p- value †
Overall description of procedure	5.49				
General description of procedure	5.60	5.52	5.61	5.69	< 0.0001
Technical details of procedure	5.30	5.17	5.32	5.44	< 0.0001
Clear statement procedure is new or standard	5.50	5.37	5.55	5.59	< 0.0001
Overall risks and benefits	5.75				
Risks	5.80	5.79	5.81	5.78	0.19
Benefits	5.71	5.68	5.73	5.71	0.065
Risks unknown	5.77	5.74	5.80	5.77	0.027
Benefits unknown	5.71	5.65	5.74	5.68	0.006
Other surgeons' experience	5.16				
Number of times procedure done by anyone	5.14	4.90	5.16	5.40	< 0.0001
Other surgeons' outcomes	5.17	5.03	5.19	5.33	< 0.0001
Your surgeon's experience	5.60				
Number of times procedure done by your surgeon	5.62	5.52	5.62	5.70	< 0.0001
Your surgeon's outcomes	5.59	5.53	5.60	5.65	< 0.0001
Your surgeon's first time	5.81	5.81	5.82	5.82	0.084
Surgeon's special training	5.64	5.55	5.65	5.73	< 0.0001
Overall surgeon's personal interest	4.50				
Plans to publish article	3.94	3.90	3.97	4.00	< 0.0001
Doing research	4.45	4.39	4.47	4.50	< 0.0001
Paid consultant	5.13	5.08	5.14	5.18	< 0.0001
* Skillings-Mack p < 0.0001 comparing mean Likert st	cores for the 5 categories of information in bold	_			

Surgery. Author manuscript; available in PMC 2014 April 01.

 $\stackrel{\scriptstyle \prime}{/}$ Skillings-Mack comparison of Likert scores across all 3 surgical techniques

Table 4

Percentage of patients and surgeons who considered each type of information essential for patients to make decisions about surgery

Lee Char et al.

	Patients	Surgeons	Patients	Surgeons	Patients	Surgeons	P-value*
rall description of procedure							
eneral description of procedure	65%	58% †	68%	58%‡	72%	80%	<0.001
echnical details of procedure	48%	$13\% \delta$	52%	16% §	57%	20% <i>§</i>	<0.001
lear statement procedure is either new or standard	57%	$51\%^{\circ}$	62%	53% t	63%	65%//	<0.001
rall risks and benefits							
isks	%LL	72%	%6L	72%	%LL	75% †	0.066
enefits	71%	65% <i>‡</i>	74%	67%‡	72%	62% §	0.140
sks unknown	75%	66% §	78%	2%69%	75%	18%//	0.022
snefits unknown	%69	62% †	74%	64%	%02	//%69	0.0009
er surgeons' experience							
umber of times procedure done by others	41%	15% \$	47%	19% §	56%	39% §	<0.001
her surgeons' outcomes	44%	20%	49%	21% §	54%	28% <i>§</i>	<0.001
con's own experience							
umber of times procedure done	63%	25% §	66%	31% §	68%	$41\% \delta$	<0.001
rgeon's own outcomes	63%	34% §	66%	$34\% \delta$	67%	44% §	<0.001
rgeon's first time	%6L	55% §	81%	59% §	78%	64% §	0.064
rgeon's special training	64%	31% §	68%	$34\% \delta$	71%	44% §	<0.001
all surgeon's personal interest							
ans to publish article	24%	$6\% \delta$	24%	\$%L	24%	8% §	0.008
oing research	27%	20%//	28%	21%//	28%	26%//	<0.001
id consultant	51%	40%	52%	41%	52%	42%	$<\!0.001$

Surgery. Author manuscript; available in PMC 2014 April 01.

[†]Pearson's χ^2 comparing percentage of patients and surgeons p < 0.05 [‡]Pearson's χ^2 comparing percentage of patients and surgeons p 0.01 NIH-PA Author Manuscript

 $^{S}_{F}$ Pearson's χ^{2} comparing percentage of patients and surgeons p $\,$ 0.001

//Pearson's χ^2 comparing percentage of patients and surgeons p 0.05, not a significant difference