Virtual Mentor
American Medical Association Journal of Ethics
January 2011, Volume 13, Number 1: 6-9.

CLINICAL CASE
When the Evidence Isn't There—Seeking Informed Consent for New Procedures
Commentary by Peter Angelos, MD, PhD

Mr. Roberts had been having difficulty urinating and, because he was 68, figured it was just a normal part of the aging process. Eventually, however, Mr. Roberts noticed that he was starting to have pain with urination as well, and went to his physician to get checked out. A few weeks and a biopsy later, Mr. Roberts was told by his physician that he had prostate cancer. Mr. Roberts was frightened and filled with uncertainty. His physician told him not to worry and recommended an excellent surgeon with whom Mr. Roberts could discuss his treatment options.

That's how Mr. Roberts ended up at Dr. Klein's urology clinic. Dr. Klein was a renowned expert in laparoscopic prostatectomy and had built a reputation based on his unusually low rate of complications. Shortly before Mr. Roberts' visit, Dr. Klein and his colleagues had begun offering robotic-assisted laparoscopic prostatectomy to patients like Mr. Roberts. After looking carefully at Mr. Roberts' lab and biopsy reports, Dr. Klein believed that surgery was the best option for this patient.

Dr. Klein admitted that the robotic procedure was much newer to him than the laparoscopic approach he had been using with success for so many years, but he said that he believed it would soon become the standard protocol for uncomplicated prostatectomy. Nevertheless, Dr. Klein offered Mr. Roberts the choice between robot-assisted prostatectomy or the standard laparoscopic prostatectomy. The robotic surgery, for one thing, was costlier.

Mr. Roberts found himself presented with a decision he did not feel qualified to make. He asked Dr. Klein about the risks and benefits of the two techniques. Dr. Klein was able to give Mr. Roberts an accurate description of the risks of the laparoscopic procedure, both from his personal experience and from hard evidence collected by urologists over many years. When Mr. Roberts asked Dr. Klein to do the same for the robotic procedure, Dr. Klein had to rely upon his limited experience. He was able to tell Mr. Roberts that in the past few months, all of his patients had had a good experience with the robotic procedure, and he thought he was already beginning to see quicker recovery times with those patients. Dr. Klein admitted, however, that more objective data for the robotic procedure was still somewhat sparse, although rapidly accumulating.

Somewhat confused and more than a little frightened by the whole prospect, Mr. Roberts told Dr. Klein that he wanted to have the procedure that Dr. Klein thought was best for him and that he would abide by whatever decision Dr. Klein made.

Commentary

Although some might argue about the details of the case and what the data really show with respect to the benefits of robotic-assisted prostatectomy, the case raises the ethical issues that every surgeon must address when considering using a new or innovative surgical procedure on a patient. As such, it is most helpful to look beyond the differences in risks and benefits between robotic prostate surgery and laparoscopic prostatectomy and consider the more general question of how surgeons should discuss innovative surgical procedures with their patients. The ethical issues in such situations revolve around three central topics: (1) the assumption that something new must be better, (2) informed consent when risks may not be fully known, and (3) how to safely acquire new surgical skills.

To begin with, there is an overwhelming assumption by the public that whatever is new must be better. This idea is captured in the ubiquitous use in advertising of the term "new and improved." In contemporary America, where technology seems to make our computers and smartphones obsolete within years (if not months), the assumption that new must be better is deep-seated. Add to this assumption the fact that the new surgical procedure is robotic, and the public will often find its lure to be almost irresistible. This observation is not lost on marketing professionals, who have come to see that the use of a robot in surgery is taken by the public as virtual proof that the operation must be better.

Unfortunately, the allure of the new and high-tech affects not only patients but also surgeons. The desire to be doing "cutting-edge" procedures with the latest technology is very strong for many surgeons, a fact that often makes the objective assessment of the value of innovative technologies difficult for both surgeons and patients [1]. To address this issue in an ethical fashion, the surgeon must carefully separate the potential benefits to the patient from the potential benefits to the surgeon him- or herself.

Second, since a recently developed procedure has, by definition, been performed on a much smaller number of patients than the conventional method, less is known about it. This lack of information can make the informed consent process particularly difficult for surgeons and patients. In an effort to obtain full informed consent, the surgeon will undoubtedly talk about the risks and benefits of the innovative procedure, but will probably have significantly less data to share. As a result, a surgeon who is not careful might wind up conveying the assumed benefits of the new procedure without any mention of unexpected risks. A surgeon in this circumstance will often present options to the patient and allow him or her to make a decision, much as Dr. Klein has done. Although respecting the autonomous choices of patients is always a good thing, this choice can trouble a patient who has no basis for making it.

Third, the surgeon must thoughtfully consider whether he or she has taken all appropriate steps to acquire the necessary surgical skills prior to offering them to patients. Unlike new drugs, new surgical procedures do not generally require an approval process. As a result, there is no oversight about what a surgeon can offer his or her patients [2]. We must assume that in the present case scenario, Dr. Klein has gained the appropriate skills before offering the robot-assisted procedure to his patients. At the very least, Dr. Klein would be expected to have experience performing the procedure either in simulation, on a cadaver, or on an animal prior to offering it to a human.

As part of the consent process, the surgeon must fully disclose to the patient the degree of experience he or she has with the procedure they are considering together. The very fact that the technique is new and that the surgeon's experience with it is limited must be explained in the consent process.

In this case, we see that Dr. Klein has tried to be honest with Mr. Roberts about the lack of good data about the new procedure and about his lack of experience with it. As a result, Mr. Roberts is put in the position of having to make a decision with little good data upon which to base it. As so often occurs in cases like this, Mr. Roberts is "confused" and "frightened" and wants Dr. Klein to make the decision for him. Although giving patients information and options is valuable and fits into the contemporary ethos of respecting patient autonomy, patients sometimes feel that they need more than just options and choices. I might be comfortable with a waiter at a restaurant telling me what is on the menu, but I want more from my surgeon. I want an actual recommendation. How then, can Dr. Klein make a recommendation for Mr. Roberts about a procedure for which relatively little outcome data is available?

In this circumstance, Dr. Klein must objectively consider what the potential benefits of the new procedure might be and then determine what value Mr. Roberts might place on these specific benefits. For example, if the benefit is the potential for more rapid return to work, but the new procedure will be more costly, Dr. Klein must discuss these issues with Mr. Roberts, so that Mr. Roberts can weigh these particular costs and benefits. Dr. Klein is being asked, in this case, to act according to the highest levels of professionalism. He must ignore the benefits to himself of performing the new procedure and focus only on those for the patient. Although some might argue that we are asking too much of Dr. Klein, I believe that we are, in fact, asking Dr. Klein to live up to the ideals of surgery and make a decision that is in the patient's best interest.

References

1. Angelos P. The ethical challenges of surgical innovation for patient care. *Lancet*. 2010;376(9746):1046-1047.
2. Biffl WL, Spain DA, Reitsma AM, et al. Responsible development and application of surgical innovations: a position statement of the Society of University Surgeons. *J Am Coll Surg*. 2008;206(3) 1204-1209.

Peter Angelos, MD, PhD, is professor and chief of endocrine surgery and associate director of the MacLean Center for Clinical Medical Ethics at the University of Chicago, where he runs the first surgical ethics program in the United States. Dr. Angelos's clinical research focuses on improving patient outcomes following endocrine surgery and methods of teaching ethics to medical students and surgical residents.

Related in VM

Technical Skill and Informed Consent, February 2010

Rating Medical Evidence, January 2011

The people and events in this case are fictional. Resemblance to real events or to names of people, living or dead, is entirely coincidental.

The viewpoints expressed on this site are those of the authors and do not necessarily reflect the views and policies of the AMA.