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Ethical Issues in Surgical Innovation

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Abstract

Innovation is responsible for most advances in the field of surgery. Innovative approaches to solving clinical problems have significantly decreased morbidity and mortality for many surgical procedures, and have led to improved patient outcomes. While innovation is motivated by the surgeon's expectation that the new approach will be beneficial to patients, not all innovations are successful or result in improved patient care. The ethical dilemma of surgical innovation lies in the uncertainty of whether a particular innovation will prove to be a "good thing." This uncertainty creates challenges for surgeons, patients, and the healthcare system. By its very nature, innovation introduces a potential risk to patient safety, a risk that may not be fully known, and it simultaneously fosters an optimism bias. These factors increase the complexity of informed consent and shared decision making for

the surgeon and the patient. Innovative procedures and their associated technology raise issues of cost and resource distribution in the contemporary, financially conscious, healthcare environment. Surgeons and institutions must identify and address conflicts of interest created by the development and application of an innovation, always preserving the best interest of the patient above the academic or financial rewards of success. Potential strategies to address the challenges inherent in surgical innovation include collecting and reporting objective outcomes data, enhancing the informed consent process, and adhering to the principles of disclosure and professionalism. As surgeons, we must encourage creativity and innovation while maintaining our ethical awareness and responsibility to patients.

Introduction

Albert Einstein, one of the great innovators of all time, has been quoted as saying, “If you always do what you always did, you will always get what you always got.” This seems an encouragement to change our methods creatively, which in turn will produce different outcomes. The underlying assumptions driving innovation are that change is usually good and that there is almost always room for improvement. This is certainly one of the core ideas behind surgical innovation. Another is the concept of progress, as in development or growth, or movement toward a goal—again ideas with positive connotations. Extending this concept further, innovation in medicine is sanctioned and encouraged in a progressive society, such as ours [1]. Certainly, innovation is responsible for most advances in the field of surgery, innovations that have decreased morbidity and mortality and improved patient outcomes. For example, the innovation of organ transplantation created a surgical solution for patients with end-organ failure and has saved thousands of lives. The technique of laparoscopy, first widely applied to cholecystectomy, revolutionized the field of general surgery for both patients and surgeons. It improved postoperative pain and shortened hospital stays for patients, and it allowed surgeons to operate from a visually superior vantage point.

More recent innovations that focus on decreasing the physical burden of surgery or increasing patient satisfaction also can be viewed as progress. These include less invasive approaches that decrease the number of incisions, such as single-incision laparoscopic surgery or endovascular repairs of abdominal aortic aneurysms, or even avoid a skin incision completely, as in natural orifice transluminal endoscopic surgery. Other techniques effectively hide incisions in less obvious places for improved aesthetic results, for example mastectomy via periareolar incisions.

It seems that surgical innovation is meant to be beneficial, in particular for patients.

Innovation in surgery may describe practices ranging from minor technical modifications in standard procedures to novel approaches bordering on human subjects research [2]. As such, innovation may arise from a variation, an irregularity, or even an error. It also may arise from a desire to perform an operation superiorly, i.e., to be faster or more efficient. Regardless of the source, innovation is invariably based on the surgeon's expectation that the new approach will lead to better patient outcomes.

Variations in the reasons for surgical innovation and the nature of innovation itself create ethical challenges for patients, surgeons, and the larger healthcare system. While surgical innovation may result in progress, that is, improved patient care and outcomes, not all innovations are successful or beneficial to patients. Yet it is almost impossible to predict with certainty which innovations will prove to be a "good thing" without a period of trial and error. The ethical dilemma of surgical innovation lies in this uncertainty. By examining the risks to patient safety, issues of informed consent and shared decision making, cost considerations, conflicts of interest, and threats to professionalism, in the following pages, we will more fully explore and address these ethical challenges.

Risks to patient safety

At the forefront of ethical dilemmas in surgical innovation are the risks and benefits to patients, particularly with respect to safety and potential harm. Due to the inherent nature of innovation, the real risks of a new technique may not be known at the time of implementation. If a particular risk is very small and infrequent, one might have to study thousands of patients to assess whether the new technique is as safe as the traditional approach. This is illustrated in the innovation of laparoscopic cholecystectomy. Developed as an alternative to the open approach, it was widely adopted in the United States in the late 1980s [3]. However, it was not until the Department of Health of New York State published a registry of operative complications that it became obvious that the low incidence of common bile duct injury in open cholecystectomy was actually increased by 15-fold in laparoscopic cholecystectomy [4].

Similarly, if a complication develops months or years after the procedure, one would not discover its true incidence until many years of outcomes data have been gathered. In the case of jejunioileal bypass, a procedure used in the 1970s to treat morbid obesity, postoperative diarrhea and electrolyte imbalances were apparent within weeks. Yet the more serious complications of nephrolithiasis, cholelithiasis, and cirrhosis developed and persisted at 5 years postoperatively, eventually leading

to the abandonment of the procedure [5].

Although it is important to establish that an innovative procedure does not pose a disproportionate risk of operative complications, it is equally important to demonstrate that it results in long-term outcomes comparable to those of the traditional procedure. This is particularly applicable to procedures performed for cancer with curative intent. Again, this information is generally not known at the time of innovation. More than a decade passed between adoption of laparoscopic colectomy for colon cancer and the publication of the COST study, a randomized, controlled trial that demonstrated similar rates of recurrence, postoperative mortality, and intraoperative complications in the open and laparoscopic colectomy groups [6]. While gathering this critically important data, hundreds of patients underwent the laparoscopic procedure with the potential risk that it could have provided inferior cancer control treatment.

In addition, risks to patient safety may be related to new equipment or technology that accompanies the new technique. For example, fiberoptic cables used as light sources for laparoscopic cameras can burn holes in drapes and potentially ignite fires in the operating room [7, 8]. The complication of a burn or inhalational injury is in addition to the operative risks one would expect with a laparoscopic procedure and, again, would be difficult to predict at the time of innovation. Such rare and extreme complications may only present themselves in an accidental fashion, similar to other unintentional errors associated with new technology, such as the misfiring of a stapler when creating an anastomosis.

A less obvious risk to patient safety develops as an innovative procedure gains popularity and more surgeons begin to perform it. While the procedure may have a low complication rate in the hands of the innovator, it is reasonable to expect that others will face a “learning curve” as they gain experience with the new technique. This “learning curve” refers to the increased risks to patients during the period when an individual surgeon or surgical team gain confidence with the new procedure [9]. During this period, surgeons may have a greater number and wider variation of complications than those that would be expected from the experienced innovator. As more surgeons adopt the procedure, there will be more patients on whom the new procedure is performed for the first time, and an even greater number of patients along each surgeon’s learning curve. Thus, the dissemination of a surgical innovation increases the number of patients potentially exposed to increased risk as each surgeon masters the new technique.

Informed consent and shared decision

making

The second ethical dilemma to address in surgical innovation, informed consent, is in many ways closely related to the considerations regarding risks to patient safety. As outlined above, the problem lies in the near impossibility of knowing the true incidence and spectrum of short- and long-term complications of the innovative procedure. This poses a challenge to the disclosure portion of informed consent, as one cannot disclose risks that are not yet known. For innovative procedures, the critical elements of disclosure require explaining the risks, to the extent that they are known, and emphasizing that there are risks that may not yet be known. Additionally, it should be made clear when the risk assessment for the new procedure is based on similar operations for which data exist. For example, the University of Chicago liver transplant team estimated that the living-donor mortality risk for a parent donating a portion of their liver to a child was 0.05 to 1 %, an estimate based on the operative risk of adult hepatic resections for reasons other than living-liver donations [10].

In addition to informing patients about potential risks, disclosure includes providing information regarding the benefits and alternatives of a procedure. Generally the alternative to an innovative procedure will be the traditional procedure, or the choice of no procedure, depending upon whether it is an elective or emergency procedure. But just as innovation poses a challenge to knowing the true risks of a new procedure, it makes ascertaining the true benefits equally difficult. Additionally, the relative value of a benefit may vary from patient to patient [11]. For example, the benefit a particular patient derives from a nipple-sparing mastectomy will depend on her individual physical and psychological characteristics. This subjective benefit cannot reasonably be compared to either the benefit she would derive from a traditional mastectomy or the benefit another patient would experience as a result of a nipple-sparing mastectomy.

After the known and potential risks, benefits, and alternatives of an innovative procedure have been as fully disclosed as possible, informed consent further requires comprehension—the patient must understand the information presented. Again, the inherent nature of innovation poses a challenge for the patient to understand and objectively weigh the risks and benefits of a new procedure. Both the surgeon and patient are likely to arrive at the shared decision-making table with an optimism bias [12]. The surgeon, as the innovator, has invested time and energy in the new procedure and almost certainly believes that it offers a benefit. The patient may be seeking the new procedure with an expectation of the same benefit. The bias in favor of the new procedure on the part of both surgeon and patient often results in focusing on the potential benefits of the new procedure, whereas the risks (both known and unknown) tend to fade into the background. This lack of

objectivity may lead to misunderstanding and false hope on the part of the patient, and the shared decision to proceed may be buoyed by optimism. Even more alarming is the situation in which the patient has already decided, often prematurely, that the expected benefit outweighs any potential risk and may be unwilling or unable to objectively engage in shared decision-making with the surgeon.

Cost considerations

At a time when healthcare costs are closely scrutinized, the financial aspects of surgical innovation must be considered. New techniques frequently involve new technology, which can be expensive to purchase and maintain. For example, robotic surgical systems have prices ranging from \$1 to \$2.5 million, require costly maintenance, and necessitate additional consumables, such as single-use robotic appliances [13]. A hospital or surgical practice must decide whether or not to invest in the technology that accompanies a new procedure, frequently before data are available on patient safety or long-term outcomes. Training for the surgeon planning to perform the new procedure also may be costly, especially if it involves a long-distance apprenticeship to learn from the original innovator. Once the surgeon is familiar with the procedure and new technology, the operative team must then be trained, requiring an additional investment of time and resources. Supporting the concept of the “learning curve,” a new procedure almost always takes longer to perform than the traditional alternative [14]. Given that operating room time is expensive and limited, it may be difficult to rationalize spending it on the completion of one new procedure when two or three of the conventional operations could be performed in the same amount of time.

The cost of an innovative procedure may be a factor in determining which patients and how many patients ultimately receive it. If it is prohibitively expensive, or offered at a few select centers, only patients with adequate personal resources will be able to afford it. Overall resource allocation is also important to consider in the current atmosphere of budgetary constraints. If limited financial resources are spent on one innovation, another more successful discovery may be inadvertently overlooked or unsupported.

Conflicts of interest and threats to professionalism

Surgical innovation has the potential to create conflicts of interest for individual surgeons and for institutions. For the surgeon-innovator, the optimism bias is a threat to equipoise in that he or she has personally invested intellectually, and often financially, in the innovation and believes that it is beneficial. In order to demonstrate that benefit with clinical evidence, he or she needs to perform the new procedure on patients. Therefore, the first conflict of interest may be in recruitment, the “selling” of the new procedure over the conventional one, even to patients who present with no prior knowledge of the new procedure or expectation of its benefit. The second conflict of interest arises in the natural desire to obtain positive outcomes when implementing an innovation that one believes is beneficial. Although subconscious, this tendency may lead to bias in patient management decisions and data collection and reporting, and may unfairly skew results in favor of the innovation.

In addition, frequently there are specific benefits to the surgeon if his or her innovation proves to be successful. A novel procedure or technique will bring academic prestige and often a namesake legacy, i.e., Hartmann’s procedure or the Nissen fundoplication. As the first surgeon performing the procedure, patient referrals will expand operative volume, increasing both the reputation and productivity of the surgeon and the institution. If there is new technology involved, a relationship may be forged with a medical device company that may benefit the surgeon financially or in other ways. These potential benefits to the surgeon create conflicts of interest and may compromise his or her ability to objectively care for patients.

If they remain unexamined, each of these conflicts of interest also represents a threat to the professionalism of the surgeon. The surgeon-innovator must preserve the best interests of the patient, rather than his or her own self-interest, and uphold ethical standards when making decisions about the application and dissemination of a new procedure or technique.

With respect to institutions, the major conflict of interest lies in recouping the opportunity cost of the innovation. The investment in human and financial resources at the outset is expected to be offset by the revenue generated by increased operative productivity. However, this may lead to premature advertising of potential outcomes or benefits in order to attract patients. This, in turn, may increase patients’ optimism bias and the likelihood that they will arrive in the surgeon’s office having already made up their minds that the new operation is “better.” This situation poses even greater challenges to informed consent. If results turn out to be less successful than expected, patients may feel slighted or taken advantage of. This may give rise to unintended consequences, such as fueling the public’s increasing mistrust of the medical profession, and discouraging patients from considering future surgical innovations as treatment options.

Addressing the ethical dilemmas of surgical innovation

Innovation is responsible for most advances in the field of surgery, advances that have brought significant benefits to patients. In order to ensure that innovation continues, we must encourage responsible and thoughtful actions with respect to the ethical issues it raises. To address the risks to patient safety, meticulous records of patient outcomes should be kept, and patients should be followed to assess long-term results, such as symptom or disease recurrence. These data are critical to evaluate whether the new procedure or technique is safe and effective, and whether it is ready for adoption by others. One method of collecting and documenting such data would be to enter patients into national registries with standardized classifications of complications and outcomes [15]. In addition to clinical results, patient-reported outcomes, such as the impact on health-related quality of life, are important to assess [16]. Interpreting and sharing this data among surgeons early in the process of applying the innovation will help to quantify both the risks to patient safety and the benefits to patient well-being.

Increased knowledge regarding the risks and benefits of an innovation will also address the central ethical issue of informed consent. However, even with accurate information, an optimism bias may persist on the part of both the surgeon and the patient. One option to temper the patient's bias would be to require a "cooling off" period between the first discussion and a second visit at which informed consent would be formally obtained. Modeled after the two-stage process initially used to ensure the informed consent of living related liver donors for pediatric liver transplantation at the University of Chicago in 1989 [10], the "waiting period" allows the patient time to more thoughtfully consider the innovative procedure after receiving the information elements but prior to authorizing informed consent. Another strategy to dilute the optimism bias would be to involve a third party in the decision, such as a "consent advocate" [10]. This person could be a healthcare professional other than the surgeon with adequate understanding of the surgical options and alternatives, and would serve as a resource for the patient.

The ethical challenges posed by the "learning curve" for a new procedure can be addressed in two ways. Because of the novelty of the procedure, the surgeon should disclose his or her level of experience with it during the informed consent process. Given the increased risks to patient safety during this period, the patient should have this information available, especially when choosing whether or not he or she would like to be the first patient undergoing this new procedure in the hands of a surgeon performing it for the first time. However, in advance of the first procedure

on a patient, the surgeon's skills could be developed with prior training, for example by completing an apprenticeship with the original innovator or by practicing the technique on a cadaver or simulated model. Such experiences might lead to greater confidence with the new procedure, allow opportunities for troubleshooting, and accelerate the learning curve. Prior training may also decrease the expected lengthy operative times early in the surgeon's operative experience with the new procedure, which could defray costs. The addition of an experienced proctor to the operating team when the surgeon first performs the new procedure may assist in navigating technical nuances and addressing practical questions as they arise in real time. A surgeon with greater experience with the new procedure is in the unique position to offer advice specific to the operation itself, as well as provide guidance with potential perioperative patient care issues.

The conflicts of interest that arise with surgical innovation should be dealt with in an honest and transparent manner. Any potential bias in data collection and reporting can be avoided by designating an objective, and even blinded, third party to manage data, analogous to the practice in clinical research. Surgeons must be self-aware of the financial and academic benefits of their innovation and remain committed to the best interest of their patients over themselves. Innovators must carefully maintain professional relationships with device and technology companies and disclose all relevant ties. Perhaps they also should disclose to patients and the institution their conflict of interest even when it relates to a procedure and not a device. Institutions should rely on verified data when promoting new procedures and avoid overstating potential benefits to attract patients.

Innovation poses a threat to professionalism only if these vital ethical issues remain unaddressed. The tenet of beneficence requires that physicians act in the best interests of their patients, while nonmaleficence protects patients from harm. It may be difficult to protect patients from all harm during the process of innovation for the very reason that success is derived from trial and error, and this success may ultimately be in the best interest of the individual patient and future patients. Surgeons must respect patient autonomy and avoid bias while participating in shared decision making, and both surgeons and institutions must be aware of the concept of justice when making decisions about the availability and cost of innovative treatments.

Conclusions

Successful surgical innovation is not easy and it is relatively rare. Yet it is responsible for much of the progress in the field of surgery and has certainly been

beneficial to patients. Examples of such innovations include coronary artery bypass grafting for coronary heart disease, endoscopic sinus surgery, and cochlear implantation for sensorineural hearing loss. Albert Einstein's inspirational quote calls us to innovate if we desire something new, and we most often equate "new" with "improved" [11]. We must remember that surgical innovation is a process, and we have the responsibility to respect and protect our patients from harm, especially during the period when the true risks and benefits are not yet known. We must also strive to decrease the costs of innovation in part to reduce disparities in the application of the innovation. As surgeons, we must remain altruistic in our motivations and promote thoughtful decision making with our patients. As a profession, we should continue to encourage creativity and innovation while maintaining our ethical awareness and responsibility to patients.

Conflicts of interest

None.

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