Comparative Effectiveness Research on Robotic Surgery

Joel S. Weissman, PhD
Michael Zinner, MD

DURING THE LAST 10 YEARS, THE USE OF ROBOTIC-assisted surgery has substantially increased, beginning with urologic procedures and expanding to include gynecologic procedures and many others.[1,2] Robotic-assisted surgery is a type of minimally invasive procedure that in fact facilitates laparoscopic surgery. Both approaches provide benefits compared with open surgery, including smaller incisions, shorter hospital stays, less postoperative pain, and possibly quicker return to function.[2] As of 2009, more than 200 000 robotically assisted operations had been performed worldwide.[2] The reason for its rapid dissemination in the United States may be linked to a number of converging factors, including better ergonomics for the surgeon, marketing campaigns, and the national fascination with technology and innovation. Under other circumstances, this might be an unparalleled success story of US medical ingenuity. However, critics of robotic surgery claim that it is more expensive without providing a concomitant benefit.[3,4]

In this issue of *JAMA*, Wright et al[5] compared the use of robotically assisted hysterectomy for benign gynecologic disease with other approaches. Whereas past research relied on smaller samples in single institutions with limited generalizability, this study used a large national database involving 264 758 women who underwent hysterectomy at 441 hospitals and included detailed clinical variables, comorbidities, and outcomes of perioperative mortality and morbidity. The findings were stark. From 2007 to 2010, overall use of robotically assisted hysterectomy increased from 0.5% to 9.5%, and at hospitals that performed robotic procedures, robotically assisted hysterectomy accounted for 22.4% of all hysterectomies within 3 years. In addition, compared with laparoscopic surgery, robotic surgery was much more expensive—$2000 more per case or nearly a third higher than the median total cost for laparoscopic hysterectomy—without a significant advantage in clinical outcomes.

See also p 689.

The study by Wright et al[5] leaves some important unanswered questions. Robotic surgery may have a shorter learning curve than laparoscopic surgery,[6,7] making it an enabling technology that allows surgeons otherwise unable to perform minimally invasive surgery to offer this benefit to their patients. Because either approach tends to have better outcomes than open laparotomy, in a cost-blind world there may be benefit from the rapid dissemination of a technique that enables access to a minimally invasive procedure for more patients. However, this presumes that laparoscopic surgery is unavailable in areas that offer robotic surgery. The study by Wright et al[5] tracked the apparent replacement of laparoscopic surgery by robotic surgery in hospitals that have machines but did not indicate whether and how often minimally invasive alternatives were available. In addition, training surgeons is expensive. Would it be a better use of resources to train more surgeons in laparoscopic techniques than to spend the money on more robot machines?

A second issue is whether robotic surgery could be valuable for subgroups of patients with select comorbidities or anatomy. It may be necessary to continue to collect detailed registry data to understand if this is the case. Similarly, the results of this study should not be generalized to other clinical conditions for which benefits may accrue from the use of robotic surgery. As always is the case with observational studies, possible selection bias can affect results, although the authors were careful in their analyses by using propensity score methods.

A third issue involves the commercialization of this technology, which has raised eyebrows in the media and elsewhere.[1,8] Considerable debate surrounded the emergence of direct-to-consumer advertising of prescription drugs in the 1990s. Robotic surgery takes this marketing to a higher level with advanced campaigns not only by industry, but also by surgeons and the hospitals that own the machines.[8] Such consumer-directed advertising is not without merit if it uses consumer awareness to advance underused medical discoveries that benefit the population. However, when the innovation being advertised is

Author Affiliations: Center for Surgery and Public Health (Dr Weissman), Patient-Centered Comparative Effectiveness Research Center (Dr Weissman), Brigham and Women's Hospital (Drs Weissman and Zinner), Boston, Massachusetts.
Corresponding Author: Joel S. Weissman, PhD, Center for Surgery and Public Health, Brigham and Women's Hospital, One Brigham Circle, 1620 Tremont St, 4-020, Boston, MA 02120 (jweissman@partners.org).

of questionable advantage, direct-to-consumer promotion may only fuel unnecessary utilization.[9] Consumer advertising of expensive devices should be subjected to the same scrutiny as that of new and expensive medications.

In the absence of additional research or decreases in price, the path taken by the medical and payer community should be one of caution. At a minimum, manufacturers might begin by voluntarily restricting their promotional activities. Public health entities could consider exercising greater oversight over claims that appear on websites. Meanwhile, physicians and hospitals have a duty to inform their patients of the benefits, risks, and costs of the options. There may also be a role for medical societies, which could join other specialties in the Choosing Wisely initiative of the American Board of Internal Medicine, aimed at identifying services whose "use should be reevaluated by patients and clinicians."[10]

As reimbursement policies stand today, payments for laparoscopic surgery are the same whether or not the procedures are robotically assisted.[2] Therefore, neither patients, physicians, nor hospitals have the motivation to pursue the less expensive option. The results of this study could inform the development of medical payment policy, that is, the set of decisions made by public and private payers about whether to cover a procedure or service or, if covered, how to manage its utilization. The application of research findings to payment policy can be thought of as a matrix of scenarios depicting value to the health system, with comparative effectiveness (better, equal, worse) on one axis and comparative cost (higher, equal, lower) on the other. Different scenarios suggest different opportunities. For example, in the current US political environment, restricting coverage is difficult when a new technology is more effective, even if it is much more expensive than the technology currently available. Decisions should be more straightforward, however, when a new technology is equally or less effective and more expensive than a current technology. Robotic surgery for conditions such as benign gynecologic disease would seem to fall into the latter category.

Several potential strategies exist. If patient preferences drive the increase in use, it may be appropriate to institute higher copayments or even a reference payment whereby the insurer only covers the cost of the less expensive but equally effective technology. If physicians and hospitals are driving the increase in utilization, they could be asked to justify using the more expensive technology for certain cases. Alternatively, episode-based payments and global contracts promoted under the Affordable Care Act seek to change the payment system so that the incentive to provide high-value care rests with health care organizations, thereby avoiding intrusion by payers into medical decision making. For example, if accountable care organizations or other risk-bearing entities consider robotic surgery a low-value option, they may discourage their surgical groups from making the capital purchase or limit the number of purchases. What is not available cannot be overused.

Inefficiency in health care delivery can trace some of its roots to the use of new and expensive interventions for conditions where other effective treatment options already exist. Evidence-based medicine and comparative effectiveness research (CER) can help ensure the optimal treatment for a given class of patients by reducing the influence of nonclinical factors. By generating evidence comparing the benefits and harms of 2 or more medical interventions, CER can lead to improved patient outcomes, lower cost, or both.

The nation's pursuit of CER will be worthwhile only if the results are used to inform treatment decisions by payers, physicians, hospitals, and patients. The United States is embarking on an unprecedented era in support of evidence-based medicine. The Patient-Centered Outcomes Research Institute was created under health care reform to move the field forward and will have significant resources. The hope is that better and more widely available research will reduce the uncertainty around choosing the optimal intervention, thereby reducing the effect of nonmedical factors such as clinician bias for newer technologies or the profit potential of manufacturers. The medical and surgical community can move more quickly to improved patient outcomes and higher value by not spending scarce resources on less-effective options.

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