

# MD ADVISOR

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## ELECTION UPDATE: PUTTING YOUR FINGER ON THE PULSE OF POLICIES, POLITICS AND ISSUES.



## Minimally Invasive Robotic Surgery:

# THE GOOD & THE BAD\*

**A Discussion with  
Domenico Savatta, MD**

→ *Interviewed by Theresa Foy DiGeronimo*

In Part I of this article series, Anthony Quartell, MD, Director of Minimally Invasive Gynecologic Surgery at Saint Barnabas Medical Center, mapped out the benefits and risks of laparoscopy for a hysterectomy over traditional open surgery.<sup>1</sup> In Part II, Steven McCarus, MD, Chief of the Division of Gynecologic Surgery at Florida Hospital Celebration Health, discussed patient safety and informed consent as they relate specifically to minimally invasive surgery.<sup>2</sup> This third and final installment in the series now discusses the pros and cons of minimally invasive robotic surgery.

Minimally invasive surgery (MIS) is in high demand in various surgical specialties such as urology, gynecology, thoracic surgery, general surgery and head and neck surgery.<sup>3</sup> The use specifically of robotic MIS is growing rapidly; the number of these surgeries jumped from 292,000 to 367,000 between 2011 and 2012—a 26 percent increase. However, many patients are not aware that all MIS procedures are not the same—and therefore not equal in the benefit/risk ratio. During the period of rapid increase in robotic surgeries, the number of adverse event reports (AERs) associated with this type of surgery rose from 211 to 282—a 34 percent increase.<sup>4</sup> This increase has moved the U.S.

\*This is the third of a three-part series on minimally invasive surgery.

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comes in potency and urinary control for prostate cancer surgery.”

Food and Drug Administration (FDA) to survey surgeons using this form of MIS to better understand the risks and benefits.<sup>3</sup>

While this survey is under way, patients and their physicians are left to wonder if the increase in AERs with robotic surgery indicates a need for caution. To answer this question, it is important to understand exactly how robotic surgery is different from other minimally invasive surgeries and how those differences affect safety, outcome and cost.

## ROBOTIC SURGERY VS. OTHER MINIMALLY INVASIVE SURGERIES

In general, patients understand that robotic surgery is similar to laparoscopic surgery in that surgical instruments are inserted into small incisions and controlled by the surgeon. However, many do not realize that robotic surgery is quite different in that there is a computerized system between the surgeon and the patient. Domenico Savatta, MD, Chief of Minimally Invasive and Robotic Adult Urologic Surgery at Newark Beth Israel Medical Center, clarifies the difference for his patients, noting: “The surgeon drives the robotic system in the same way that a driver steers a car. The surgeon looks into a 3D headset that is at the console and uses two joysticks and foot pedals to control surgical instruments that the robotic system holds to allow surgical instruments to move in a natural way similar to open surgery. The surgeon controls the camera and three additional instruments, and all of these instruments are held in place by the robotic system.”

**The Advantages of Robotic Surgery:** Physicians favoring robotic surgery over other types of MIS point to multiple advantages. These include improved dexterity, tremor reduction, movement precision, direct correlation between hand movement and robot movement (rather than mirror-image movements of laparoscopy), improved visualization with magnification and 3D, scaling down of hand movement to enable microscopic procedures, short learning curve and less fatigue.<sup>3</sup>

Savatta concurs. He notes that although some of the benefits for the patient are similar to those of other types of minimally invasive surgery (including smaller incision, less blood loss, shorter hospital stay and quicker return to physical activity), he acknowledges that “for surgeries that require a high level of precision, such as a prostatectomy for prostate cancer, the high-definition MIS vision and smaller scissors and other instruments of robotics can allow for a more precise surgery, which can lead to improved out-

**Disadvantages and Risks of Robotic Surgery:** As with most surgical procedures, the benefits of robotic surgery coexist with disadvantages and risks. Various reasons have been proposed for the 34 percent increase in AERs in robotic surgery.<sup>4</sup> It has been noted that “there is no standardized process for credentialing, teaching, proctoring or obtaining hospital privileges for robotic-assisted surgery.”<sup>6</sup> In fact, the Institute of Medicine and the FDA have called for a revision of the process by which new devices enter into practice.<sup>7,8</sup>

Additionally, there are factors in robotic surgery itself that some surgeons find troublesome. As outlined in the *Medscape* article, “Robotic Surgery: Too Much, Too Soon?,” these include loss of tactile and force feedback (which increases the risk of rupturing sutures during knotting), limited placement of trocars required to avoid hitting robotic arms, less aesthetic result due to larger trocars and forced arch placement compared to laparoscopy, limited access to the patient due to the cart with the robotic arms and the need for very specialized physicians and nurses.<sup>3</sup>

Additionally, Savatta notes the danger of tissue damage from an instrument’s heat or electrical current. He cautions, “Prior to placing instruments into the surgical field for any minimally invasive surgery, we need to place ports and insufflate the space with carbon dioxide. Organs and blood vessels are at risk during this part of the procedure. The robotic benefit of increased magnification can become a negative here because it reduces the size of the surgical field. Therefore, surgical teams need to use exceptional care not to injure organs that are not in the surgical field.”

However, Savatta does not feel that the limited surgical field is necessarily a disadvantage. “Almost all of the reports of AERs that I have read about,” he notes, “are due to complications that are inherent to surgery in general or to the procedure being performed. Since the machine is an integral part of any procedure, it is the interaction between the surgeon and the machine and the skill of the surgeon that are responsible for the outcome. The risks have to be weighed against advantages that robotic surgery provides and the experience of the surgeon.”

Other reports agree that the AERs associated with robotic surgery are not necessarily rooted in the procedure itself. It is possible that the jump in AERs is evidence of improved data scrutiny. As hospitals develop better over-

sight systems to enhance collection and reporting of AERs, the numbers will naturally increase.<sup>9</sup>

Savatta also notes that the length of a physician's learning curve has to be considered when evaluating the safety of a robotic procedure. "The first reported urological robotic surgery was in 2001. The effect of training and the learning curve on safety," he notes, "is dependent on a surgeon's skill and experience with surgery, as well as how comfortable he or she is at using controls to operate instruments." This comfort level is certainly tied to experience; when reviewing AER statistics, one must keep in mind that other forms of robotic surgery have been in use for only eight years. The rate of AERs is likely to be high when no practitioner has more than eight years' experience.<sup>10</sup> This can be particularly true given that the learning process for robotic surgery is relatively informal; continuing education courses and proctoring sessions are sponsored by Intuitive Surgical, Inc. (manufacturer of the da Vinci Surgical System), but there is no national standard by which an organization credentials surgeons to perform robotic surgery.<sup>11</sup>

## EVALUATING SAFETY

Whatever the cause of the AERs in robotic surgery, the question remains: Is it safe? "Any operation has risks and complications associated with it," says Savatta. "Many factors can decrease or increase the risk of surgery. I have performed thousands of cancer surgeries open and laparoscopic prior to performing robotic surgeries. I converted each of the operations I performed with non-robotic surgery to robotic surgery as I gained more experience because I felt there were advantages with robotic surgery including fewer risks and complications. I do feel that robotic surgery is safe in experienced hands."

The safety comparisons of laparoscopic versus robotic surgery are of particular interest to physicians. Unfortunately, no randomized trials have compared the different types of surgery.<sup>11</sup> To date, the studies that compare laparoscopy and robotic procedures "are of poor quality and suffer from significant heterogeneity and control bias."<sup>12</sup>

Still, Savatta believes that most of the risks associated with robotic surgery are similar to those of laparoscopic surgery. "Laparoscopic surgery provides highly magnified images," he says, "but only in 2D, which limits depth perception. Most instruments move in a counterintuitive way, and it is much more difficult to perform precise surgery. For

complicated surgery, in experienced hands laparoscopic surgery is as safe as robotic theoretically, but more difficult to perform, which can lead to poorer outcomes. I explain to my patients that there is a less than one percent chance of having a surgical complication with robotic surgery, which includes the reported adverse events. I then allow time for patients to ask specific questions and think about it."

## MISLEADING MARKETING?

Although robotic surgeons are careful to explain the risks of robotic surgery to their patients, there is concern in the medical community that hospitals market their robotic capabilities in ways that mislead patients and drive up medical costs. In a 2011 study, investigators reported that of the 41 percent of hospitals that use websites to describe their capabilities, 86 percent of these sites claimed clinical superiority of robotics, and none mentioned risks.<sup>13</sup> In addition, the information disseminated by hospitals regarding robotic surgery is not evidence-based and is influenced by the manufacturer.<sup>14</sup>

**"the advantages of robotic surgery are highlighted while the disadvantages of robotic surgery are often ignored."**

Savatta worries about this trend of overhyping robotic surgery. "I have seen advertisements by both hospitals and physicians in which I feel that the advantages of robotic surgery are highlighted while the disadvantages of robotic surgery are often ignored. Given the learning curve involved in robotic surgery, the generic claims that hospitals make may not apply to inexperienced surgical teams. With experience in surgery, the possible risks and complications are better appreciated, and surgeons can take steps to minimize these risks in how they perform the surgery. But the general claim of superiority of this surgery is often more opinion than fact. To be fair, I have also read articles and opinions of leading physicians that do not perform robotic surgery that highlight the negative factors associated with robotic surgery and not the advantages."

## COST FACTOR


Whether superior, inferior or equal to other types of surgery, robotic surgery is expensive. The machines themselves cost between \$1.5 and \$2.2 million, and service contracts run from \$160,000 to \$170,000 per year. According to Savatta, disposable instruments for urological robotic surgery range from \$200 to \$500, and each procedure can use three to five

instruments. For other types of surgeries, disposable instruments may cost as much as \$1,000, with up to eight instruments used per procedure. An analysis published in March 2013 reported that da Vinci surgeries add incremental costs of 20 percent per procedure, which are absorbed by the hospitals.<sup>12</sup>

Savatta further explains: “The majority of the cost is in the purchase of the robotic system for the hospital. (The robots I have used are usually replaced after about five years.) There is also a yearly maintenance fee and a per-case instrument cost. A large variable cost is the procedure time. Operating room costs are expensive; whether a surgeon takes two hours or four hours to perform the same surgery with the same outcome creates a considerable cost difference. On the other hand, savings in robotic surgeries are seen by shortened hospital stays and less complications. In the end, in order for a hospital to break even or make money, a high-volume program of efficient surgical teams is needed. I believe that most hospitals will lose money with robotic surgery.”

The high cost of robotic surgery may also be the result of the market monopoly of the da Vinci system—it is the only FDA-approved robotic system on the market. Savatta believes that pricing for robotic systems would be reduced if there were more than one company to work with. “I believe, with any technology or industry, having more than one choice is a benefit for the consumer—or in this case, the hospital, physician and patient. Also, I believe that competing companies would offer more support to customers to try to gain more business and future business.”

As the medical community continues to monitor and evaluate the pros and cons of robotic surgery, at this time, it is still unclear whether this surgery has a superior advantage in most general surgeries. However, as with other minimally invasive procedures, it is clear that as physicians gain continued training and experience, the AERs will diminish and the benefits will outweigh the remaining disadvantages.

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<sup>2</sup> McCarus, S. (2013, Summer). Minimally invasive surgery: Patient safety & informed consent. *MDAdvisor*, 6(3), 24-27.

<sup>3</sup> Peckham, C., & Schwaitzberg, S. (2013, August 8). Robotic

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<sup>4</sup> Lowes R. (2013, April 30). FDA investigates robotic surgery system after adverse event spike. *Medscape Medical News*. [www.medscape.com/viewarticle/803339](http://www.medscape.com/viewarticle/803339).

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<sup>6</sup> Parsons, J. K., & Berman, S. (2013, July 15). Making the most of robotic-assisted surgery: An interview with Dr. J. Kellogg Parsons. *Medscape*. [www.medscape.com/viewarticle/807521\\_1](http://www.medscape.com/viewarticle/807521_1).

<sup>7</sup> U.S. Food and Drug Administration. (2012, December 3). FDA announces public-private partnership to develop regulatory science that will speed patient access to new medical device technologies. [www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm330416.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm330416.htm).

<sup>8</sup> Institute of Medicine. (2011). *Medical devices and the public's health: The FDA 510(k) clearance process at 35 Years*. Washington, DC: The National Academies Press.

<sup>9</sup> Colella, J., & Peckham, C. (2013, June 20). Is robotic surgery worth its price? An interview with Dr. Joseph Colella. *Medscape*. [www.medscape.com/viewarticle/806484\\_1](http://www.medscape.com/viewarticle/806484_1).

<sup>10</sup> Renaud, M., Reibel, N., Zarnegar, R., Germain, A., Quilliot, D., Ayav, A., Bresler, L., & Brunaud, L. (2013, July 7). Multifactorial analysis of the learning curve for totally robotic Roux-en-Y gastric bypass for morbid obesity. *Obesity Surgery*. [www.ncbi.nlm.nih.gov/pubmed/?term=Multifactorial+analysis+of+the+learning+curve+for+totally+robotic+Roux-en-Y+gastric+bypass+for+morbid+obesity](http://www.ncbi.nlm.nih.gov/pubmed/?term=Multifactorial+analysis+of+the+learning+curve+for+totally+robotic+Roux-en-Y+gastric+bypass+for+morbid+obesity).

<sup>11</sup> Parsons, J. K., & Berman, S. (2013, July 15). Making the most of robotic-assisted surgery: An interview with Dr. J. Kellogg Parsons. *Medscape*. [www.medscape.com/viewarticle/807521\\_1](http://www.medscape.com/viewarticle/807521_1).

<sup>12</sup> Northland Capital Markets. (2013, March 4). Initiating coverage: Intuitive Surgical, Inc. (ISRG) expectations have a lunar trajectory. [Internal publication].

<sup>13</sup> Jin, L. X., Ibrahim, A. M., Newman, N. A., Makarov, D. V., Pronovost, P. J., & Makary, M. A. (2011). Robotic surgery claims on United States hospital websites. *Journal for Healthcare Quality*, 2011(33), 48-52.

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