GENERAL GYNECOLOGY

The debate over robotics in benign gynecology

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The debate over the role of the da Vinci surgical robotic platform in benign gynecology is raging with increasing fervor and, as product liability issues arise, greater financial stakes. Although the best currently available science suggests that, in the hands of experts, robotics offers little in surgical advantage over laparoscopy, at increased expense, the observed decrease in laparotomy for hysterectomy is almost certainly, at least in part, attributable to the availability of the robot. In this author's opinion, the issue is not whether the robot has any role but rather to define the role in an institutional environment that also supports the safe use of vaginal and laparoscopic approaches in an integrated minimally invasive surgery program. Programs engaging robotic surgery should have a clear and self-determined regulatory process and should resist pressures in place that may preferentially support robotics over other forms of minimally invasive surgery.

Key words: minimally invasive surgery, robotic surgery

The da Vinci Robotic Surgical platform received Food and Drug Administration (FDA) approval for gynecological use in 2008; not long thereafter, gynecological procedures overtook urological procedures in rates of robotic surgical volume. The arguments for the adoption of robotic surgery have always been complex, and frequently nonmedical; issues of institutional marketing (patients, payers) and recruitment (training applicants, faculty candidates) largely dominated the conversation. There were tremendous debates about the role of the robot in gynecology: should it be reserved for surgeons already accomplished in minimally invasive surgery (MIS) procedures, or should its benefits as a facilitative technology allow open surgeons to begin a minimally invasive approach?

Although nuanced and often lacking rigorous data, the argument for robotics proved compelling for a growing number of institutions, and the popularity of robotic surgery flourished; national robotic surgical procedure volumes increased from 228,000 in 2010 to 367,000 in 2012, with gynecology accounting for the majority of that increase.

Perhaps associated with this increase in volume, the number of events reported to the FDA increased, and investigations by the FDA (some of which were comprised of routine postmarketing surveillance) triggered rumors and wild fluctuations of the manufacturer's stock value. The first product liability case was concluded in favor of the defendant, the manufacturer; their legal arguments were that the surgeon's judgment, not the company's training policies, was the reason that a patient (the surgeon's first after training on the device) suffered complications and, 4 years subsequently, died.[1]

The Massachusetts Medical Society sent an advisory to hospitals, raising concerns about robotic surgery, and suggested that marketing efforts (both in terms of corporate marketing to hospital executives, preying on insecurities about falling behind in a competitive technology arms race, and doctors marketing their practices and recruiting patients) might be leading to the use of robotics in cases in which the complexity exceeded the capability of the machine or the experience of the surgeon to use it safely.

A variety of attention-grabbing advertisements and web sites (such as BadRobotSurgery.com) recruiting plaintiff/patients began making appearances. Several peer-reviewed, randomized controlled trials have failed to demonstrate clinical or cost-effective superiority of the robot over traditional laparoscopy for hysterectomy or for some forms of pelvic reconstructive surgery.[2-4]

Soon after the Massachusetts Medical advisory was released, the manufacturer countered with a statement, in which it pointed out that other forms of minimally invasive surgery (ie, vaginal and laparoscopic hysterectomy) had reached a plateau and that abdominal hysterectomy rates remained greater than 60% nationally until robotic technology was applied to this procedure. Many surgeons trained robotically were steadfast in their belief in the enhancements provided by the technology, and critics of the randomized controlled trials that fail to show robotic superiority point out that the institutions producing them had already highly experienced and accomplished laparoscopists, limiting the generalizability.

So the debate has increased in intensity, with strenuously delivered dogmatic points of view. As is often the case, the all-or-none vitriol misses the truths that lie on both sides of the argument.

Observations

- Opportunities for training are very different between the forms of

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Received Nov. 21, 2013; revised Jan. 6, 2014; accepted Jan. 9, 2014.

The author reports no conflict of interest.

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0002-9378/$36.00

http://dx.doi.org/10.1016/j.ajog.2014.01.016

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minimally invasive surgery in gynecology. Robotic surgery has been characterized by readily available training with a reasonably sensible curriculum, run and sometimes supported by the corporation, and hospital credentialing systems that are also usually relatively rigorous. Support for training in advanced laparoscopic surgery is less consistently available; although some with industry-sponsored support is sometimes available, resident experience is variable (the median resident experience for laparoscopic hysterectomy in 2012 was 35 cases; range, 2–138),[5] and credentialing expectations and guidelines are not consistent between institutions.

- Vaginal surgery may be the least well-supported approach, with resident vaginal hysterectomy experience decreasing from a median of 33 cases in 2003 to 18 in 2012,[5] and recent Accreditation Council for Graduate Medical Education minimum expectations have been set at 15 cases.[6] This is particularly concerning because estimates of experience required for a resident to demonstrate competence in vaginal hysterectomy are, depending on the testing modality, between 21 and 27 cases.[7] Additionally, post-residency training opportunities are much less commonly available, with little industry support.
- Although national trends are coming into clearer view, trends within institutions sometimes demonstrate important principles. For instance, in a database study with information on 441 hospitals and nearly 265,000 women, the overall laparoscopic hysterectomy rates in the United States increased in recent years; however, this was attributable to an increase in total laparoscopic hysterectomy among institutions without robots.[8] This is likely a response to perceived market pressures. Notably, however, in institutions with robots, both vaginal and laparoscopic hysterectomy declined. It would appear that institutions that have invested in robots feel pressure to use them. In addition, requirements put in place in many robotic programs regarding annual minimum case volumes for surgeons may accentuate the pressure to use robotics as the primary (or dominant) MIS approach.
- I personally visited an institution for a robotic surgery executive course. At that session, data from hysterectomy outcomes were presented. Although outcomes for robotic surgery were good, the overall rate of vaginal hysterectomy was dramatically low. Historically, vaginal hysterectomy has been associated with the lowest complication rates; however, in this instance, vaginal hysterectomy was associated with the highest complication rate. In my opinion, this institution had given up on vaginal hysterectomy, and this was reflected in their outcomes. This may represent a cautionary tale regarding the all-in model of robotics in an MIS program.

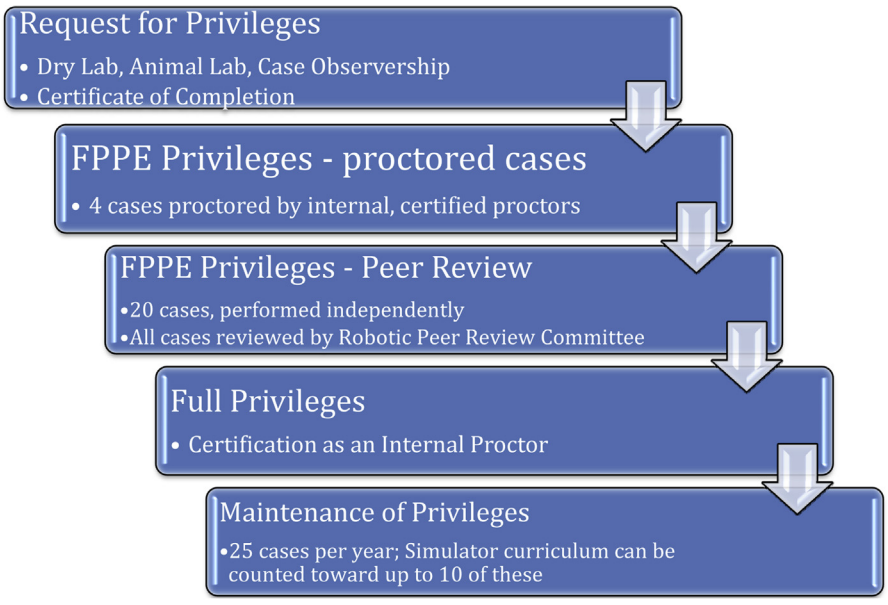
Embracing robotic surgery but as one of the forms of minimally invasive surgery: what we have done at Women and Infants Hospital

Robotic surgery

Credentialing process. We have developed a robust process of credentialing for use of the robotic platform; robotic privileges reflect the use of the equipment alone, and any surgeon seeking to perform a procedure robotically must already have privileges for the procedure to be performed. Following completion of the standard didactic, dry laboratory, and animate laboratory training sessions, a surgeon can be granted robotic privileges under 2 levels of focused professional practice evaluation. In the first of these levels, 4 cases are performed under proctorship and with focused professional practice evaluation evaluations filled out. Following successful completion of this stage, the surgeon can then book and perform cases independently, but at the conclusion of 20 cases performed, all 20 cases are reviewed in full by the Robotic Surgery Peer Review Committee. If no deficiencies or opportunities for improvement are found, the individual is recommended for full privilege status and also is granted the status of proctor for surgeons in training within the institution. This process is illustrated in Figure 1.

Maintenance of privileges and annual case requirements. Like many institutions, we

FIGURE 1
Process of robotic privileges



FPPE, focused professional practice evaluation.

Rardin. The debate over robotics in benign gynecology. Am J Obstet Gynecol 2014.