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Editorial

# Robotic-assisted surgery in gynecologic oncology: A Society of Gynecologic Oncology consensus statement

## Developed by the Society of Gynecologic Oncology's Clinical Practice Robotics Task Force

### Introduction

The Society of Gynecologic Oncology's ("SGO") Clinical Practice Committee has developed a series of Clinical Documents designed to improve the overall quality of women's cancer care; reduce the use of unnecessary, ineffective or harmful interventions; as well as facilitate the optimal treatment of patients with a goal to maximize the therapeutic benefit, and minimize the risk of harm, at acceptable cost.

In developing clinical documents, SGO follows a rigorous process to assure that any conflicts of interest are disclosed and appropriately addressed and that relationships with manufacturers and other third parties do not influence the development process.

More specifically, SGO adheres to the principles adopted by the Council of Medical Specialty Societies ("CMSS") in developing, adopting and promulgating clinical guidelines and consensus statements. Consistent with CMSS principles, SGO received no funding from any manufacturer to support the development of this Consensus Statement nor any other clinical consensus statement or practice guideline developed and published by SGO.

In accordance with CMSS principles, SGO requires that its clinical documents be subject to multiple levels of review beginning with a review by SGO's full Clinical Practice Committee. After review and approval by the Clinical Practice Committee, Consensus Statements are submitted to the SGO Council which is SGO's governing body which reviewed and approved the Consensus Statement for submission to SGO's Journal. None of the members of the SGO Council has a financial or other relationship with Intuitive.

In accordance with those principles, each member of the Robotics Clinical Task Force which developed the Consensus Statement executed a detailed disclosure statement prior to participating in the Task Force.

There is currently only one manufacturer of robotic gynecology technology, Intuitive Surgical Inc., of Sunnyvale, California ("Intuitive"). One member of the thirteen members of the Robotics Clinical Task Force has a consulting relationship with Intuitive and receives honoraria from Intuitive for teaching advanced courses at his institution.

SGO has received unrestricted educational grants from Intuitive to provide educational support for its annual and winter meetings at approximately $25,000 a year over 5 years. All content for these educational programs was developed in accordance with ACCME standards.

Clinical Documents are intended to be educational devices that provide information that may assist healthcare providers in caring for patients. This Clinical Document is not a rule and should not be construed as establishing a legal standard of care or as encouraging, advocating, requiring or discouraging any particular treatment. Clinical Documents are not intended to supplant the judgment of the health care provider with respect to particular patients or special clinical situations. Clinical decisions in any particular case involve a complex analysis of a patient's condition and available courses of action with the ultimate determination to be made by the health care provider in light of each individual patient's circumstances. Therefore, clinical considerations may lead a healthcare provider to appropriately take a course of action that varies from this Document.

This Clinical Document has met SGO's criteria of an Expert Clinical Opinion Document.

The Clinical Practice Committee of the Society of Gynecologic Oncologists recently proposed that a Consensus Statement be developed by leaders in the field of minimally invasive surgery to provide the members of the society a document outlining the current status of robotic surgery and its application in the management of patients with gynecologic malignancies. The Consensus Statement has been developed by a Task Force composed of a balanced group of individuals with experience and interest in the assessment of minimally invasive surgery. The goal of this document is to present an unbiased view, informed by the available literature, of the critical aspects of robotic surgery that impact the management of patients with gynecologic malignancies.

Robotic-assisted surgery has had a significant impact on the minimally invasive surgical approach to patients with gynecologic malignancies in the United States. The daVinci Surgical System® (Intuitive Surgical Inc, Sunnyvale, CA) was cleared for use by the U.S. Food and Drug Administration in 2005 for gynecologic surgery. Robotic technology incorporates three-dimensional stereoscopic vision and wristed instrumentation that allows for better dexterity and precision than can be achieved with traditional laparoscopy. Although robotic technology has been widely embraced by gynecologists and gynecologic oncologists in the United States, there have been frequent discussions and debates about various aspects of robotic gynecologic surgery. In this consensus statement, the Society of Gynecologic Oncology provides an overview of the current state of robotic surgery as interpreted by a group of leaders in the field of minimally invasive surgery in gynecologic oncology.

### Clinical impact

In the United States, robotic surgery is increasingly being used in the management of early-stage cervical cancer and early-stage

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endometrial cancer. There is currently less experience of its use in the management of ovarian cancer.

*Cervical cancer*

Several investigators have recently reported outcomes with robotic radical hysterectomy for the treatment of cervical carcinoma. Compared to traditional open radical hysterectomy, the robotic approach is associated with less blood loss, fewer operative complications, higher lymph node yields, and a shorter length of hospital stay [1,2].

Compared to traditional laparoscopic (hereafter referred to as just "laparoscopic") radical hysterectomy, the robotic approach is associated with shorter operative times, less blood loss, and shorter lengths of hospital stay. Rates of conversion to laparotomy and rates of operative complications appear similar between the robotic and laparoscopic approaches [1]. However, data should be interpreted with caution as all studies are retrospective and comparisons between laparoscopy and robotics often reflect sequential time comparisons or single surgeon experience. Comparative data on long-term survival outcomes for patients treated with robotic radical hysterectomy versus laparoscopic or open radical hysterectomy are limited. However, preliminary information suggests that oncologic outcomes are similar for the three approaches [2].

For fertility-preserving surgery, early reports indicate that robotic surgery is safe and feasible. Data on robotic radical trachelectomy are limited, but results to date have shown that the procedure is associated with minimal blood loss, short length of hospital stay, low rates of intraoperative and postoperative complications, and adequate surgical specimens [3,4].

*Endometrial cancer*

A number of retrospective studies have been performed comparing robotic or laparoscopic hysterectomy with traditional open hysterectomy in the treatment of patients with endometrial cancer. The largest series to date was a systematic review that included eight comparative studies with a combined total of 1591 patients (robotic surgery = 589, laparoscopic surgery = 396, and laparotomy = 606). The authors found that estimated blood loss was lower for robotic hysterectomy than for laparoscopy ($P = 0.001$) or laparotomy ($P < 0.005$). Length of hospital stay was shorter for both robotic and laparoscopic hysterectomy than for laparotomy ($P < 0.01$). Operative time for robotic hysterectomy was similar to that for laparoscopic hysterectomy but longer than that for laparotomy ($P < 0.005$). The rate of conversion to laparotomy was 4.9% for robotic hysterectomy and 9.9% for laparoscopic hysterectomy ($P = 0.06$). Rates of vascular, bowel, and bladder injuries, cuff dehiscence, and thromboembolic complications were similar for the three surgical methods [5].

Recent studies have shown that in obese patients with endometrial cancer, robotic surgery offers advantages over laparoscopy in terms of blood loss, transfusion requirements, rate of conversion to laparotomy, operative time, and length of hospital stay [6]. It should be noted that these studies are not prospective randomized trials, and therefore there is a potential for selection bias.

On the basis of these data, the consensus in the literature is that robotic surgery may be equivalent to laparoscopy and in certain situations may offer an advantage over laparoscopy in patients with endometrial cancer. One potential drawback of robotic surgery is the limited access to the supramesenteric para-aortic lymph nodes with the standard robotic set up.

*Ovarian cancer*

To date, only a few isolated cases have been reported of the use of robotic surgery in the management of ovarian cancer [7]. Currently, early-stage or small volume disease may be more amenable than more advanced disease to robotic surgery. Robotic surgery is poorly suited for use in patients with advanced ovarian cancer as upper abdominal access is limited with the standard trocar set-up for pelvic surgery.

## Patterns of clinical practice

Over the past 10 years, there has been a rapid rise in the number of robotic systems available in hospitals across the United States. As of this writing, over 1400 robotic systems have been installed in 950 hospitals. In 2010 alone, over 1200 gynecologic surgeons were trained to use the da Vinci robotic system. Over 200 articles dedicated to robotics in gynecologic surgery have been published since the beginning of 2008. The introduction of robotic surgery has markedly changed the patterns of practice within the gynecologic oncology community. Endometrial cancer staging has emerged as the most common indication for the use of robotic surgery, followed by cervical cancer. Emerging indications for the use of robotic surgery include highly complex procedures such as pelvic exenteration and extraperitoneal para-aortic lymphadenectomy.

## Training impact

*Learning curve — robotic surgery versus traditional laparoscopy*

For robotic surgery, surgeons must first become proficient in port placement, set-up, and docking. Then surgeons must gain proficiency in performing individual procedures.

Surgical proficiency in minimally invasive techniques has been assessed using metrics such as total operative time, estimated blood loss, rate of intraoperative complications, and rate of conversion to laparotomy. However, these metrics may not accurately reflect when competence has been achieved because as a surgeon becomes more comfortable with the techniques, he or she may operate on more challenging patients (obese patients and those with prior surgeries or more advanced cancers) or may incorporate trainees in key portions of the procedures.

A study comparing the first 10 and last 10 cases in a cohort of 100 patients undergoing robotic staging for endometrial cancer revealed a shorter operative time, a higher number of lymph nodes retrieved, and a lower rate of operative complications in the later cases [8]. Others have demonstrated that proficiency in robotic hysterectomy with pelvic–aortic lymphadenectomy is achieved upon completion of approximately 20 cases and that efficiency continues to improve over time [9]. For radical hysterectomy, advantages of the robotic approach over laparotomy were seen even among the initial cases performed; these advantages included decreased operative time, decreased blood loss, and a shorter length of hospital stay [10]. The number of cases required for surgical proficiency has yet to be fully established.

In addition to the acquisition of surgical skills, an important factor in the successful implementation of a robotic surgical program is the establishment of a robotic surgical team, including surgical scrub and circulating nurses as well as bedside surgical assistants who are familiar with the robotic equipment. In the adoption of a hospital robotics program, training of bedside assistants is essential, and the effect of such training on reducing total operative time and surgical errors has been documented [11].

In reviewing the data on learning curves for robotic and traditional laparoscopic surgery, several important points must be considered. First, much of the literature on skill acquisition in traditional laparoscopy is more than 5 years old, but there have been many recent improvements in standard laparoscopic instruments, cameras, and monitors as well as vessel sealing devices. Second, many gynecologic oncology trainees now enter fellowship with substantial experience with and skill in minimally invasive surgery, which may shorten the

learning curve for robotic surgery. Third, many of the surgeons publishing their experience with robotic surgery have had considerable experience with laparoscopy before adopting robotic technology. Overall, the published data suggest that the learning curve for robotic surgery is shorter than that for traditional laparoscopy.

*Training methods*

Surgeons can gain substantial knowledge of robotic tools and techniques through didactics, on-line tools, dry laboratory training, and animal laboratory training. In the operating room, trainees frequently begin as patient-side assistants and subsequently progress to working at the robotic console. Results from a recent survey of U.S. gynecologic oncology fellowship programs indicated that 95% of programs had a robot at their institution [12]. With the launch of robotic surgery programs, a dramatic shift in case load and fellow training experience occurs, which allows for increasing fellow experience in minimally invasive surgery, especially for endometrial and cervical cancer [13]. Fellows should be trained to perform minimally invasive surgery and should graduate from their fellowship with skills in both robotic and traditional laparoscopic surgery.

Tools have been developed to enrich training. The touch-screen robotic illustrator allows experienced surgeons to add visual cues to the image seen by trainees inside the console and thereby enhances trainer–trainee communication and interaction. The dual-console robot allows an experienced surgeon and a trainee to sit at side-by-side consoles, swap instruments, and retract for each other, all using robotic instrumentation. A robotic simulator is currently available that allows for practice in multiple tasks and for an objective measurement of performance. As technology advances, newer methods of proctoring are in development. One such method is telerobotic proctoring, which could increase the availability of robotic proctoring of surgeons in training at remote locations.

## Cost analysis

One of the biggest concerns expressed about the adoption of robotic technology is its high cost. Robotic surgical systems have a fixed cost of between $1.5 million and $1.75 million. Further, the adoption of new surgical technologies can lead to longer operating room times during the robotic surgical team's learning period, which may theoretically have the effect of reducing efficient operating room utilization. Finally, critics have appropriately questioned whether robotic technology might burden the healthcare system by encouraging more surgical procedures than were previously being performed, as in the case of prostate cancer [14].

Ideally, comparisons of cost between robotic and other approaches to surgery should include both direct and indirect costs. The fixed cost of a robotic system is significant; the robotic system is usually amortized over its expected life span and the expected volume of procedures. The fixed costs of laparoscopic and open procedures, insofar as they differ from the fixed costs of the robotic approach, should also be included in such comparisons. Other costs to be included in comparisons between robotic, laparoscopic, and open surgery are the costs of all operating room supplies and equipment; operating and recovery room time; physicians' fees; laboratory, radiology, and pharmacy costs; and hospital room and board. Further, it is important to account for costs due to complications, care-giving, and lost productivity associated with recovery. It is also important to keep in mind that the economics of medicine differ around the world as healthcare systems, reimbursement, and even access to technology differ substantially. Costs need to be evaluated at all levels: patient, physician, hospital, community, and nation as well as from a global perspective.

To date, three groups in the United States have compared the costs of robotic and other approaches to the management of endometrial cancer. One group compared 110 women who underwent robotic, laparoscopic, or open procedures for endometrial cancer. Laparotomy was found to be significantly more expensive than either laparoscopy or robotic surgery, mostly because of differences in length of hospital stay and lost productivity during recovery to normal level of activity [15]. Another group found that robotic-assisted procedures resulted in higher total hospital costs and mean operative costs than laparoscopic procedures. Operative cost differences were driven by the cost of disposable instruments and to a lesser degree by longer operating room time [16]. A third group used published clinical data to build decision models to compare the costs of robotic, laparoscopic, and open surgery for endometrial cancer and identify the most important factors that contributed to cost differences [17]. Itemized costs collected locally included medical professionals' time, operating room equipment, operating room and anesthesia time, pharmacy charges, recovery room time, hospital room and board, and the robotic surgical system. For a “societal perspective” model, caregiver/lost productivity costs associated with recovery time were also incorporated. Professional reimbursements were obtained using Medicare data, while costs of operating room equipment were calculated as the amount paid by the hospital. Fees or charges to the patient were converted to cost using standard ratios. In the societal perspective model, laparoscopy was the least expensive approach, followed by the robotic and open approaches. The most important factors driving the relative costs of the three methods were the time to return to full activity (most favorable for robotic surgery) and the cost of disposable equipment (least favorable for robotic surgery).

Minimally invasive procedures are less costly than open procedures when the costs associated with hospital stay and recovery time are incorporated. Robotic procedures are generally more costly than laparoscopic procedures, in large part because of the costs of disposable materials and reusable instruments. Operating room time is a key determinant of the cost of robotic procedures, and therefore efficiency in the operating room is the key to maximizing utilization and minimizing hospital costs associated with robotic surgery. Intangible advantages of robotic surgery that may not directly impact cost, such as improved ergonomics and potentially a higher success rate in completing staging procedures, should also be considered in comparisons of robotic surgery with other surgical techniques.

Historically, costs of new technologies are high and drop as physicians gain experience with new procedures, the market grows, and industry competition drives down costs of equipment. In addition, the learning curve associated with a new surgical approach needs to be considered in these early studies comparing costs of the two minimally invasive techniques. It is expected that procedures will initially take longer when a new approach is being learned. Because robotic systems have seemingly encouraged many surgeons to perform minimally invasive surgery when they otherwise would not, robotic surgery may yet increase the safe use of minimally invasive surgery, which could have a favorable impact on overall cost.

Robotically assisted minimally invasive procedures are not associated with additional reimbursement from Medicare or private insurers above that for a traditional laparoscopic procedure. The “modifier 22” for “Increased Procedural Services”, a code often used when the work required to provide a service is substantially greater than typical surgical effort, does not apply to robotic procedures. Occasionally payers will accept Healthcare Common Procedure Coding System level II codes such as “S2900”, a notation for “surgical procedures requiring the use of robotic surgical system”. However, S codes are not reimbursable by Medicare and likewise are typically not honored by most private insurers.

## Patient and physician quality of life

Only one trial has been published that was adequately powered to address the issue of patient quality of life after minimally invasive

surgery for gynecologic malignancies. In this phase III randomized trial conducted by the Gynecologic Oncology Group, patients were randomly assigned to laparoscopy or laparotomy for endometrial cancer staging. The results demonstrated that in the first 802 patients who had an evaluation of quality of life, over the 6-week postoperative period, patients who underwent laparoscopy reported significantly better physical functioning, better body image, less pain and its interference with quality of life, and earlier resumption of normal daily activities, including earlier return to work. By 6 months, however, differences in quality of life between the two surgical groups had disappeared except in the realm of body image, which was still better in the laparoscopy group [18].

A number of studies suggest that compared to laparotomy or traditional laparoscopy, robotic surgery results in fewer complications that might adversely impact quality of life. However, data implying a better quality of life among women who undergo robotic surgery consist largely of physicians' observations; *patient-reported* quality of life has not been formally assessed. In one study, patients undergoing robotic surgery for endometrial cancer were stratified into younger and older (age > 70 years) cohorts. The authors assessed postoperative quality of life and found that both younger and older patients were highly satisfied with the procedure [19]. In a survey of the Society of Gynecologic Oncology membership, participants reported that the greatest benefit of robotic surgery was its ease of use and perceived improvement in patient quality of life [20]. In future clinical studies of robotic surgery, patient-reported quality of life should be included among the assessments. One ongoing prospective trial from MD Anderson Cancer Center is comparing laparoscopic or robotic radical hysterectomy with abdominal radical hysterectomy for the treatment of early-stage cervical cancer. The primary endpoint is disease-free survival, but secondary endpoints include patterns of recurrence, overall survival, treatment-related complications, cost and cost-effectiveness, and quality of life [21].

One issue that has not been addressed is the impact of robotic surgery on physician quality of life. The ability to control the binocular visual field, the elimination of tremor through use of rotational wristed instrumentation with gear ratios, and the ergonomic console control system facilitate difficult pelvic dissections with less surgeon effort and fatigue. Looking to a future of predicted physician shortages, regional disparities in the availability of specialized medical care, and an aging surgeon workforce, the applicability of robotic surgery to telemedicine should not be underestimated.

## Credentialing and liability

While the use of robotic surgery in the treatment of gynecologic cancers continues to expand, it is important to examine both credentialing and the medical-legal aspects of using the robotic platform. Currently, there is no standard for credentialing among robotic surgeons. The American College of Surgeons has proposed general guidelines for introducing new technology into surgical practice, including assessing a surgeon's eligibility to use the new technology on the basis of previous training and experience; requiring education to ensure adequate understanding of the new technology; and ensuring an environment appropriate for use of the new technology.

To date, several processes are available to ensure that a new robotic surgeon has a minimal level of competence prior to incorporating robotic surgery into his or her practice. Basic training typically incorporates both online training and animate laboratory training. Proctoring is strongly encouraged during the initial phases of learning. The Society of Gynecologic Oncology and the American Association of Gynecologic Laparoscopists continue to provide postgraduate courses for both new and more experienced robotic surgeons that incorporate both robotic simulators and hands-on training. Ultimately, however, an individual hospital determines what requirements need to be met for a surgeon to be credentialed in robotic surgery.

Examination of patient safety factors associated with medical malpractice shows that most adverse events are associated with system failures, most commonly inexperience or lack of technical competence. However, this is in reference to all medical errors rather than specific to the robotic technology. The primary surgeon, even during a proctored case, carries the overall responsibility for the well-being of the patient as well as full legal responsibility [22]. The law does not hold the proctor responsible as he or she has no physician–patient relationship. As the number of robotic surgeons continues to grow, development of practice guidelines, establishment of requirements for achieving and maintaining certification, and standardization of training methods such as proctoring and simulation will be essential to limit medical liability and increase patient safety.

## Obstacles to future trials

Evidence-based medicine relies on the premise that changes in standard clinical practice are based on a foundation of well-conducted prospective randomized trials. One major prospective randomized trial has been conducted comparing laparoscopy to laparotomy in patients with endometrial cancer (GOG-LAP2). Another prospective randomized trial initiated by MD Anderson Cancer Center is currently under way that is comparing laparotomy to minimally invasive surgery in patients undergoing radical hysterectomy.

However, a number of barriers exist that limit the implementation or completion of prospective randomized trials comparing minimally invasive surgery to laparotomy or robotic surgery to laparoscopy. Among the most important barriers are the following: patients generally do not wish to be randomized to the laparotomy arm; surgeons may already be biased toward a specific approach; differences in perioperative parameters among the surgical modalities are so small that large numbers of patients would be required to detect a statistically significant difference in outcome; broad access to the instrumentation and technology required may not be readily available; and the pool of patients who would be potential candidates may be limited. The need for randomized controlled trials to compare outcomes of robotic technology to other forms of minimally invasive surgery is a topic of debate. Robotics simply represents a new tool to accomplish a minimally invasive procedure. As with other tools for minimally invasive surgery, their broad-based use has been largely incorporated into standard surgical practice based on retrospective analysis and surgeon preference.

## Conclusion

Robotic-assisted surgery offers distinct advantages over open surgery in the management of patients with gynecologic cancer. Current evidence supports equivalence of robotic surgery and laparoscopy in many perioperative outcomes measures. The cost of robotic technology remains a potential barrier to widespread acceptance of robotic surgery; however, overall cost advantages of robotic surgery over open surgery have been documented, and the cost of robotic surgery may further decrease with increasing utilization. Fellowship programs should include standardized training in both robotic surgery and traditional laparoscopic surgery. We must strive to implement clear guidelines for training and to assure proper credentialing in all institutions.

**Conflict of interest statement**
No conflict of interest.

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