Robot-Assisted Surgery for Noncancerous Gynecologic Conditions

ABSTRACT: For noncancerous conditions, such as hysterectomy, a minimally invasive approach to gynecologic surgery has well-documented advantages—including faster return to normal activities, decreased length of stay, and better quality of life—compared with an abdominal approach. Although the quality of data for robot-assisted surgery is still low to moderate, the use of robot-assisted surgery has rapidly increased since its approval, which highlights the need to develop effective and thoughtful strategies for its implementation. Reporting of adverse events currently is voluntary and nonstandardized; therefore, the true rate of complications is not known. Adoption of new surgical techniques should be driven by what is best for the patient and by evidence-based medicine, rather than external pressures. Although training in robot-assisted surgery increasingly is incorporated into obstetric and gynecologic residency programs, exposure to and training with robotic devices varies nationally. Obstetrician–gynecologists not previously trained in robot-assisted surgery can acquire the necessary skills through independent robot-assisted training programs and through courses offered and accredited by organizations such as the American College of Obstetricians and Gynecologists, the Society of Gynecologic Surgeons, the American Association of Gynecologic Laparoscopists, the Society of Gynecologic Oncology, and the American Urogynecologic Society. Ongoing quality assurance is essential to ensure appropriate use of the technology and, most importantly, patient safety. Well-designed studies are needed to determine which patients are most likely to benefit from robot-assisted surgery over other minimally invasive approaches.

Recommendations and Conclusions

The American College of Obstetricians and Gynecologists (ACOG) and Society of Gynecologic Surgeons (SGS) make the following recommendations and conclusions:

• Studies suggest that robot-assisted gynecologic surgery can be performed safely in centers with experienced surgeons and has perioperative outcomes equivalent to laparoscopy and improved outcomes compared with laparotomy.
• Robot-assisted cases should be selected based on the likelihood of improved outcomes compared with other surgical approaches due to the complexity of the case or patient factors, with appropriate consideration to costs.
• Robot-assisted surgery provides an alternative surgical tool for minimally invasive gynecologic surgery. Further comparative studies are needed to assess long-term outcomes and patient safety, and to identify specific subgroups of patients who would benefit from a robot-assisted approach.
• As with any procedure, informed consent should be obtained from patients before surgery with discussion of the surgeon’s experience with robot-assisted surgery, indications for surgery, and potential risks and benefits associated with the robot-assisted technique.
compared with alternative surgical approaches and other therapeutic options.

- Both ACOG and SGS recommend the development of a registry of robot-assisted gynecologic procedures and the use of the U.S. Food and Drug Administration’s (FDA) Manufacturer and User Facility Device Experience Database (MAUDE) to report adverse events.

This Committee Opinion is updated to reflect an expansion of the literature regarding the role of robot-assisted surgery in patients with endometriosis. The document has been revised to exclude gynecologic malignancies.

**Background**

For noncancerous conditions, such as hysterectomy, a minimally invasive approach to gynecologic surgery has well-documented advantages—including faster return to normal activities, decreased length of stay, and better quality of life—compared with an abdominal approach. The field of robot-assisted surgery has developed rapidly and is considered an alternative to laparoscopy. Although vaginal surgery is the approach of choice whenever feasible for hysterectomy, the addition of robot-assisted surgery offers an alternative surgical tool for minimally invasive gynecologic surgery (3). Reported advantages of using a robotic device are improved visualization, dexterity, elimination of tremor, and improved ergonomics. Small pilot studies have suggested that surgeons may experience less neck, shoulder, and back discomfort with robot-assisted surgery compared with laparoscopy (4).

Perceived limitations related to robot-assisted procedures include lack of haptic feedback, nonstandardized training requirements, and difficulties measuring value due to variability in cost reporting based on usage-based purchasing contracts, surgeon preferences, and site-specific factors. Although the quality of data for robot-assisted surgery is still low to moderate, the use of robot-assisted surgery has rapidly increased since its approval, which highlights the need to develop effective and thoughtful strategies for its implementation (5). Hospitals and physicians actively advertise and promote robot-assisted surgery programs, often with claims of improved outcomes and patient safety that are not based on evidence (6–8). Adoption of new surgical techniques should be driven by what is best for the patient and by evidence-based medicine, rather than external pressures (9). Reporting of adverse events currently is voluntary and nonstandardized; therefore, the true rate of complications is not known. Both ACOG and SGS recommend the development of a registry of robot-assisted gynecologic procedures and the use of the FDA’s Manufacturer and User Facility Device Experience Database (MAUDE) to report adverse events; [https://www.fda.gov/industry/fda-esubmitter/electronic-medical-device-reporting-emdr](https://www.fda.gov/industry/fda-esubmitter/electronic-medical-device-reporting-emdr).

The purpose of this Committee Opinion is to provide background information on robot-assisted surgery for noncancerous gynecologic conditions, review the literature on this topic, and offer practice recommendations. This Committee Opinion will include a summary of the results and conclusions of studies on robotic techniques on specific surgical interventions (hysterectomy, myomectomy, surgery for endometriosis, and sacrocolpopexy). Robot-assisted surgery for gynecologic oncology will not be addressed. For information on robot-assisted surgery for cancerous conditions, see the Society of Gynecologic Oncology’s consensus statement on robot-assisted surgery in gynecologic oncology (10).

**The Robot-Assisted Approach for Gynecologic Surgery**

Although low-quality or low-certainty evidence suggests little difference in complication rates between robot-assisted surgery and conventional laparoscopic surgery for benign conditions, high-quality data are not available on patient outcomes, safety, or cost (11). Nevertheless, rapid adoption of robot-assisted technology for gynecologic surgery in noncancerous conditions continues. A wide array of literature exists, but most studies are retrospective, observational, and noncomparative. There are very few data that compare robotic laparoscopic surgery to vaginal surgery, and that topic is beyond the scope of this document. Multiple randomized controlled trials (RCTs) compared robot-assisted surgery for noncancerous gynecologic disease with laparoscopy and none demonstrated superiority of the robot-assisted approach (12–19). These studies suggest that robot-assisted gynecologic surgery can be performed safely in centers with experienced surgeons and has perioperative outcomes equivalent to laparoscopy and improved outcomes compared with laparotomy. Therefore, a minimally invasive approach may be considered for procedures that might otherwise require laparotomy.

**Surgical Procedures**

Overall, the data on robot-assisted approaches for surgical procedures for noncancerous conditions (eg, hysterectomy, myomectomy, management of endometriosis) are of low quality or certainty, or both. When available, the data for robot-assisted surgery versus conventional laparoscopic surgery and robot-assisted surgery versus abdominal surgery are discussed below.

**Hysterectomy**

Although the use of robot-assisted approaches to hysterectomy has increased, data on operative time and perioperative outcomes are of low certainty. Additionally, assessments of the costs of robotic surgery are complex and dependent on factors such as usage and surgeon experience.
Robot-Assisted Surgery Versus Abdominal Surgery

Single-institution studies that compared robot-assisted hysterectomy with abdominal and laparoscopic approaches reported no mean difference in operative time (20–26). Studies that compared a robot-assisted approach with laparotomy reported less blood loss, lower complication rates, and shorter hospital stays with the robot-assisted hysterectomies (21, 22). A 2016 multicenter retrospective study that included 2,300 robot-assisted hysterectomies, 9,745 abdominal hysterectomies, 8,121 vaginal hysterectomies, and 11,952 laparoscopic hysterectomies performed by high-volume surgeons demonstrated that the robot-assisted cohort had higher rates of adhesive disease, morbid obesity, and larger uteri, but fewer intraoperative complications compared with laparotomy and vaginal approaches, as well as shorter hospital stays and fewer postoperative complications compared with abdominal, vaginal, and laparoscopic approaches (27). As noted in the study, interpretation of clinical outcomes is affected by the surgical volume. One limitation of these results is the definition of “high-volume” surgeons in the comparison group by their cumulative robotic experience (greater than 60 procedures in a 5-year period) as opposed to their annual surgical volume. The seven surgeons who performed the 2,300 robot-assisted procedures performed more than 80 robot-assisted hysterectomies per year during the study period (27).

Robot-Assisted Surgery Versus Conventional Laparoscopic Surgery

To date, there are four RCTs that compared robot-assisted hysterectomy with laparoscopic hysterectomy (12, 15, 17, 19). In three RCTs, no differences were found in perioperative outcomes, including blood loss, length of stay, type or number of complications, postoperative pain levels, analgesic use, or recovery time (15, 17, 19). Data on operative times were mixed. A 2012 study and 2013 study found significantly longer operative times for robot-assisted hysterectomy than laparoscopy (29 minutes and 77 minutes mean difference, respectively) (15, 17). Longer operative times in the robot-assisted group compared with the laparoscopic group potentially may be due to surgeons being early in their learning curve and to specimen weights being larger in the robot-assisted group (28). Conversely, a 2015 study and a 2016 study reported similar operative times when comparing robot-assisted hysterectomy with laparoscopic hysterectomy (12, 19).

The overall incidence of vaginal cuff dehiscence after any hysterectomy is reported to be 0.14–4.1%. Based on low-quality data, and only a few studies, the incidence of vaginal cuff dehiscence for robot-assisted hysterectomy is reported to be 0.4–2.61% (29–31). A retrospective study that compared robot-assisted hysterectomy with laparoscopic hysterectomy showed no difference in vaginal cuff dehiscence rate (30). However, a 2018 randomized trial reported a significant reduction in vaginal dehiscence and cuff complications with intracorporeal vaginal closure (32). Improvements in visual technology and surgical technique may partially explain the earlier conclusions of elevated cuff complication rates when compared with transvaginal closure (33, 34).

Myomectomy

In well-trained hands, all routes of myomectomy—open, laparoscopic, and robotic—are safe. However, the laparoscopic approach to myomectomy is challenging. The robot-assisted system may help overcome variables that limit the use of laparoscopic myomectomy, such as unfavorable myoma location (35). Also, robot-assisted myomectomy is safe in women with a wide range of body mass indices (36). Despite the purported benefits of robot-assisted technologies, evidence of its superiority is based on observational studies of varying quality and power with heterogeneous patient populations.

A 2016 systematic review attempted to summarize the available evidence regarding robot-assisted laparoscopic myomectomies as compared with open or laparoscopic approaches (37). Although robot-assisted laparoscopic myomectomies had longer operative times compared with abdominal approaches, blood loss, rates of transfusion, and length of hospital stays were substantially reduced (37–45). When compared with laparoscopic approaches, the robot-assisted laparoscopic myomectomy did not offer any advantage for operating time, blood loss, or length of hospital stay (37); however, a 4.5 times increased risk of conversion to an open approach was observed when laparoscopic myomectomy was used compared with robot-assisted cases (37). Data on long-term outcomes such as pain control, postoperative fertility, and myoma recurrences are needed.

Surgical Management of Endometriosis

Robot-assisted surgery has emerged as an additional surgical tool for the management of endometriosis. Retrospective and descriptive studies have reported feasibility of robot-assisted surgery for deep infiltrating endometriosis (46–49). A comparative study showed better detection of endometriosis lesions with the robot-assisted camera compared with the laparoscopic camera (50). Near-infrared technology is available on both laparoscopic and robotic platforms. However, this technology is built into the robotic system and readily available, and it has been reported to potentially help identify atypical endometriosis lesions (51, 52). This near-infrared technology can identify vascular islands surrounded by fibro-vascular tissue by detecting an injected tracer dye of indocyanine green in the blood stream. This dye binds to plasma proteins and becomes confined to the vascular system (53). This near-infrared technology may provide another tool for detection of endometriosis, but more data are needed to confirm its use for this procedure.
Robot-Assisted Surgery Versus Conventional Laparoscopic Surgery

In the few retrospective studies that compared robot-assisted surgery for endometriosis with laparoscopy, there was no difference in overall complication rates or estimated blood loss (54, 55). Data regarding operative time are conflicting. Some studies reported longer operative time (54) for robot-assisted surgery and others reported similar operative times between robot-assisted and laparoscopic groups (55). A clinical trial that investigated laparoscopy versus robot-assisted surgery for endometriosis demonstrated no difference between robot-assisted approaches and laparoscopic approaches in outcomes, including operative time, blood loss, intraoperative and postoperative complications, and rates of conversion. Both groups produced similar improvement in quality of life at 6 weeks and 6 months (13).

Sacralpexy

Traditionally, sacralpexy has been performed with an abdominal or laparoscopic approach. However, adoption of the laparoscopic approach has been limited by a steep learning curve.

Robot-Assisted Surgery Versus Abdominal Surgery

To date, there are two studies that compared robot-assisted surgery with abdominal sacrocolpopexy. Both studies found decreased lengths of stay for robot-assisted surgery compared with open techniques. A retrospective review of abdominal open or robot-assisted sacrocolpopexy operations over a 4-year period observed an overall 10% cost savings for robot versus open sacrocolpopexy, largely due to decreased costs per hospitalization day in the postoperative period (56). A review of robot-assisted vaginal vault suspension and open vaginal vault suspension observed lower postoperative wound, genitourinary, and vascular complications with the robotic approach compared with the open approach (57).

Robotic-Assisted Surgery Versus Conventional Laparoscopic Surgery

In 2016, researchers systematically reviewed nine papers of variable quality that compared robot-assisted sacrocolpopexy with laparoscopic sacrocolpopexy involving 1,157 patients. Seven of the studies were nonrandomized and there were only two RCTs. There were no significant differences between the different approaches in anatomic outcomes at the 1-month, 3-month, and 6-month intervals and no significant differences in recurrence rates at 1 year. In addition, there were no differences in mortality, length of hospital stay, and postoperative quality of life. In the two RCTs that compared robot-assisted sacrocolpopexy with laparoscopic sacrocolpopexy, operating time, postoperative pain, and cost were found to be significantly greater in the robot-assisted group (16, 18), but anatomical and functional outcomes 6 months to 1 year after surgery were similar. Ultimately, the surgical approach should take into account individual patient characteristics and surgical expertise of the physician.

Other Gynecologic Procedures

Patients scheduled for gynecologic procedures of short duration and low complexity are unlikely to benefit from robot-assisted surgery. Due to a lack of advantages and potential disadvantages, both ACOG and SGS recommend against (in most routine cases) the use of a robotic approach for the following procedures (if not performed as part of another surgical procedure):

- Tubal ligation
- Simple ovarian cystectomy
- Surgical management of tubal ectopic pregnancy
- Bilateral salpingo-oophorectomy
- Bilateral salpingectomy
- Diagnostic tubal or other surgeries when diagnosis is unknown

Special Patient Population Considerations

Further comparative studies are needed to assess long-term outcomes and patient safety, and to identify specific subgroups of patients who would benefit from a robot-assisted approach. Obesity is a well-documented risk factor for major and minor surgical complications regardless of route. However, data have demonstrated similar risks of complications with laparoscopic surgery compared with open surgery in this population (58). The incremental effect of robotic surgery on surgical adverse events is not clearly defined. Although low-quality data suggest that a robot-assisted surgical approach in gynecologic surgery has similar or decreased rates of surgical complications as compared with laparoscopy for patients with obesity and morbid obesity (59–62), these data are in higher risk patients with cancer. Further research in patients with noncancerous pathology is needed to verify extrapolation of these observations.

Learning Curve

Based on limited data, the combination of improved visualization and instrument control allow for a faster surgical learning curve on a robot-assisted device compared with conventional laparoscopy, which involves two-dimensional imaging and counterintuitive hand movements (1). Robot-assisted techniques may permit some procedures that previously would have required laparotomy to be performed using a minimally invasive approach. Data show that improvements in surgical technique with robot-assisted devices are seen continuously throughout the first 100 surgeries; efficiency in surgical times appeared to be attained after 20–30 cases (63).

Several studies have demonstrated the value of laparoscopic simulation in improving surgical skill and operating performance (64, 65). Although simulation has
Credentialing, Privileging, Certification, and Training

Credentialing and privileging are conducted at the local level by health care institutions, whereas boards (eg, the American Board of Obstetrics and Gynecology) provide certification after completion of resident training. Medical specialty organizations, other educational institutions, and the health care industry do not have the authority to certify, credential, or privilege, but may provide training for physicians and document their completion of training.

Currently, there are no standardized credentialing and privileging guidelines; guidelines vary across institutions and hospitals. Some medical specialty organizations, such as the American Association of Gynecologic Laparoscopists (AAGL), have developed guidelines for robot-assisted credentialing and privileging (69). A 2017 study described the experience of developing best practices for robot-assisted surgery over 7 years and provides guidelines for credentialing and privileging that can be applied to various surgical specialties, including gynecology (70). These guidelines may be used as templates and modified for each individual institution. See Box 1 for considerations that institutions may want to consider when developing credentialing and privileging guidelines for robot-assisted surgery.

Certification is required in order to use the robotic device; however, this does not confer proficiency. Training of the surgical team is essential and has been reported to decrease operative time and complication rates (71, 72). Although laparoscopic skills are used in the operation of robotic devices, they are not a surrogate for robotic training.

Although training in robot-assisted surgery increasingly is incorporated into obstetric and gynecologic residency programs, exposure to and training with robotic devices varies nationally. Individual programs may offer, and specific residents potentially may receive, training compatible with that outlined previously for the practicing physician, but this varies from institution to institution and certification is not yet standardized.

Obstetrician–gynecologists not previously trained in robot-assisted surgery can acquire the necessary skills through independent robot-assisted training programs and through courses offered and accredited by organizations such as ACOG, SGS, AAGL, the Society of Gynecologic Oncology, and the American Urogynecologic Society. Health care institutions often require surgeons’ initial robot use to be proctored by a surgeon experienced with this technology. Determination of competency for credentialing should be done at the local level (Box 1).

Box 1. Considerations for Institutions Developing Credentialing and Privileging Guidelines for Robot-Assisted Surgery

Establish pathways for surgeons’ varied experiences and training
- Current surgeons already credentialed at outside institution transferring from another institution
- Residency- or fellowship-trained surgeons
- Current surgeons who are new to robot-assisted surgery

Determine prerequisites for credentialing and privileging eligibility
- Verification of training in gynecologic surgery
- Verification of robot-assisted training (eg, formal training, clinical experience)

Determine general requirements for credentialing and privileging
- Competency assessment (eg, minimum case volume, simulation hours, video assessment, robotic surgery certification)
- Proctoring requirements (number of cases needed based on experience level versus standardized number)

Delineate requirements for types/levels of procedures (eg, simple vs complex procedures)

Determine objective requirements to support maintenance of privileges (eg, using assessment or metrics for competency and proficiency, minimum case volume, required continuing medical education, measurement of outcomes and complications, simulation hours, video or proctored review of surgical cases)

Both ACOG and SGS recommend that general robot-assisted training requirements for gynecologic surgery for obstetrician–gynecologists who have completed an accredited residency training and who are using robot-assisted surgery in their practices include the following components:

- The obstetrician–gynecologist must have completed a didactic educational program focused on robot-assisted surgery, such as approved online training modules. These programs may have been a part of residency or fellowship training and may be offered and accredited by organizations such as ACOG, SGS, AAGL, the Society of Gynecologic Oncology, and the American Urogynecologic Society.
- Individuals should have hands-on training using the new technology, including docking, bedside assisting, and sitting at the console. This experience may include inanimate, animate, cadaver laboratory setting, and virtual reality simulation (73). Standardized
and validated assessment tools such as Global Evaluative Assessment of Robotic Skills (or GEARS) (https://www.csats.com/gears) and Objective Structured Assessment of Technical Skills (or OSATS) may be used for evaluation in both simulation and intraoperative settings (74–76).

Conclusion

Robot-assisted surgical devices are tools for a minimally invasive approach. Appropriate training on robotic devices is necessary to ensure patient safety and appropriate use of technology. Robot-assisted cases should be selected based on the likelihood of improved outcomes compared with other surgical approaches due to the complexity of the case or patient factors, with appropriate consideration to costs. As with any procedure, informed consent should be obtained from patients before surgery with discussion of the surgeon’s experience with robot-assisted surgery, indications for surgery, and potential risks and benefits associated with the robot-assisted technique compared with alternative surgical approaches and other therapeutic options. Ongoing quality assurance is essential to ensure appropriate use of the technology and, most importantly, patient safety. Well-designed studies are needed to determine which patients are most likely to benefit from robot-assisted surgery over other minimally invasive approaches.

References

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