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Updates and Controversies of Robotic-Assisted Surgery in Gynecologic Surgery

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Abstract

minimally invasive surgery (MIS) is the standard approach to performance of several gynecologic procedures, including hysterectomy, gynecologic cancer staging procedures, myomectomy, pelvic organ prolapse repair, and select adnexal procedures. Robotic-assisted surgery, a computer-based MIS approach, has been adopted widely in the United States and several other countries. Robotics may offer technological and ergonomic benefits that overcome limitations associated with conventional laparoscopy; however, it is not clear that reported claims of superiority translate into improved gynecologic patient outcomes compared with other MIS approaches. This review critically appraises the evolving role, benefits, limitations, and controversies of robotic-assisted surgery utilization in benign and oncologic gynecology settings.

Keywords

robotic surgery; gynecology; minimally invasive surgery; controversies; MIS utilization; MIS costs

Introduction

Gynecologic surgeons have increasingly integrated minimally invasive surgery (MIS) into their surgical repertoire over the last 3 decades. For women undergoing hysterectomy, myomectomy, sacrocolpopexy, adnexal procedures, and select gynecologic cancer staging surgeries, randomized controlled trials (RCTs) and select retrospective studies demonstrate the association of MIS with less estimated blood loss (EBL), shorter hospital length of stay (LOS), fewer perioperative and postoperative complications, and increased quality of life (QoL) compared with open procedures.¹⁻⁵ Robotic surgery is one of the latest surgical innovations that gynecologic surgeons have widely adopted in the United States and in many countries worldwide.^{6,7} Certainly, Intuitive Surgical's 16% revenue growth from \$2.7 billion to \$3.1 billion throughout the 2017 fiscal year exemplifies the widespread dissemination of the da Vinci Surgical System, primarily within US hospitals.⁸ Using a computer-assisted platform, robotic surgery is a technologically more sophisticated extension of traditional laparoscopy that is described to overcome the purported limitations of conventional

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laparoscopy, including 2-dimensional (2D) visualization, limited instrument range of motion, and ergonomic challenges for the surgeon. Advancements such as joint-wristed instrumentation, tremor-control, and 3D stereoscopic vision for intricate tissue visualization and manipulation are among the putative benefits of robotic-assisted surgery. The most widely used platform, the da Vinci Surgical System (Intuitive Surgical Inc., Sunnyvale, CA), received approval from the United States Food and Drug Administration (FDA) for select gynecologic procedures in 2005.⁸ The system is currently the only FDA-approved robotics platform on the market.⁶ Reported advantages of this particular platform compared with conventional laparoscopy include less postoperative pain, improved surgeon ergonomics, faster learning curve, facilitation of 7 degrees of freedom within the instrumentation, elimination of the fulcrum effect, and a more seamless integration of fluorescence technology for lymphovascular assessment.^{7,9,10}

Level 1 evidence comparing robotic surgery to vaginal or laparoscopic approaches in gynecologic procedures exist, but are sparse compared with retrospective studies. It is, therefore, unclear that industry claims of robotic surgical superiority over other MIS approaches are sound. Is widespread adoption of the robotics platform justified in this setting? Herein, we critically analyze the literature regarding the utilization of robotic surgery in modern-day gynecology practice and examine the controversies associated with its use. Concepts discussed in the review include evidence evaluating the use of robotic surgery for various gynecologic procedures, operational costs, robotics operating room staffing, national trends in utilization, marketing and patient disparities, and future innovations.

Evolution of the da Vinci Surgical System

The da Vinci Surgical System is the first widely implemented and FDA-approved telesurgical system.⁹ The tilt and height of the console headrest, positioning of the armrest, and foot-pedal placement are electronically adjusted by the surgeon according to height and comfort level. The 3D camera provides a precise panoramic view of the surgical site along with motion scaling.¹¹ There have been 4 generations of this robotic system introduced into the marketplace with a variety of enhancements: the original system with 3-arm to 4-arm iterations, the da Vinci S with visual (3D high definition) and less bulky architectural improvements, the da Vinci Si with a second console for teaching and near-infrared fluorescence imaging capabilities, and the da Vinci Xi with laser instrument targeting and more ergonomic overhead mounted arms alongside the anticipated da Vinci SP for single-port applications.¹² The Firefly near-infrared fluorescence technology associated with the da Vinci surgical system received FDA approval in August 2014.¹³ Indocyanine green, a fluorophore that emits light upon excitation at around 780 nm, accumulates in tumor cells and provides a clear signal-to-background ratio during surgical exploration.¹⁴ Rossi et al¹⁵ validated the use of indocyanine green for sentinel lymph node biopsy for endometrial cancer in a prospective cohort trial with a sensitivity to detect node-positive metastatic disease of 97.2% and a negative predictive value of 99.6%.

The updated iterations of computer software, immersive panoramic imaging, increased ergonomics of systems architecture, and the addition of trainee didactic capabilities provided

opportunities for increasingly complex surgical procedures in more confined surgical spaces and revolutionized the robotic system's role in residency and fellowship training programs. The system's ability for automated troubleshooting decreased the number of ancillary staff needed in the operating room and minimized surgeon interruptions.

Operating Room Efficiency and Learning Curve

Many hospitals employ a dedicated operating room team that play a factor in surgery time and operating room usage costs. A retrospective series revealed that improvement of robotic assembly timing from 45 to 35 minutes required 20 and 50 cases, respectively.¹⁶ The experience of a patient-side surgical assistant has a role in the procedural efficacy and perioperative outcomes as demonstrated by a study that revealed higher conversion rates (9.1% vs. 1.1%, $P < 0.01$) and perioperative complications (18.2% vs. 7.9%, $P = 0.05$) between a resident physician and co-surgeon, respectively.¹⁷ Given that operating room costs increase with prolonged operating room times, such data highlight the benefit of an experienced table-side assistant and surgical staff to potentially streamline robotic procedure times and cost.

A surgeon's learning curve can be quantified in either patient-oriented (postoperative complications, optimal resection of disease) or procedure-oriented terms (robot set-up time, operating time). Procedural performance certainly improves with repetition and experience, but surgeons may plateau with more complex cases that would not have previously been undertaken with traditional laparoscopy.¹⁸ Lenihan et al¹⁶ concluded in a case series composed of 86.7% robotic hysterectomies that it took 50 cases to optimize operating time at 95 minutes. Lim et al¹⁹ revealed a shorter robotics learning curve (24 vs. 49 cases) compared with laparoscopic hysterectomy and lymph node dissection for the treatment of endometrial cancer. The integration of robotics into gynecologic training, development of new techniques from pioneering surgeons, and technological advancements will continue to impact surgeon learning curves, but the retrospective literature suggests that robotics technology may indeed facilitate more efficient MIS learning and adoption in novice surgeons compared with laparoscopic or vaginal techniques.

Costs of the Robotics System

The previous decade has witnessed the most expansive dissemination of robotic surgery platforms, especially in the United States. Gynecology ranked the highest among specialties in robotic procedure volume with an accumulated case load of 252,000 in the 2017 fiscal year.²⁰ In 2010 US dollars, the da Vinci Si platform was \$2,600,000, disposable equipment per case was \$2500 at baseline, and training of a single surgeon was \$6000.²¹ Supply and demand economics apply to robotics since patent-protected technology is prone to higher market prices. Factors for cost include care providers (surgeons, hospitals), care payers (insurance companies, government), and robotics manufacturers.²² Cost model studies involving robotic hysterectomy for benign/malignant conditions, sacrocolpopexy, and myomectomy show statistically significant elevation of costs and operating room times compared with laparoscopic surgery.²³⁻²⁶ Analyses of cost-effectiveness in MIS include various models: (1) hospital costs with or without amortization of initial capital investment

in the robotic device, (2) societal costs that include lost wages, employer costs, and the requirement of a caretaker at home.^{23,26-28}

A database study encompassing 36,188 patients showed that robotic hysterectomy cost more than laparoscopic hysterectomy in the inpatient (\$9640 vs. \$6973, $P < 0.01$) and outpatient settings (\$7920 vs. \$5949, $P < 0.01$).²⁹ A cost-decision model analysis among laparoscopic, robotic, and open hysterectomy for endometrial cancer patients revealed societal costs to be \$10,128, \$11,476, and \$12,847, respectively. Laparoscopy was the least expensive option in regards to hospital costs with or without initial capital.²³ A high-volume cancer institution's study showed that the amortized cost of initial capital was \$3157 higher for robotic surgery compared with laparoscopy (\$23,646 vs. \$20,489, $P < 0.05$).²⁷ Despite this data, select experts indicate that the more rapid adoption of robotic techniques compared with conventional laparoscopic techniques correlates with the decrease in laparotomy rates over the previous decade, especially at institutions with nonsubstantial laparoscopy rates in the prerobotics era. The diminished laparotomy rate would theoretically neutralize robotic costs.^{27,30} The evidence put forth is clear that robotics is more expensive than laparoscopy, but despite these differences, MIS in general can contribute to \$280 to \$340 million in health care savings, largely through prevention of perioperative complications and reduced hospital stays compared with laparotomy surgery.³¹

Trends in Robotics Utilization and Surgical Curricula

Analyses of nationwide databases for benign hysterectomy corroborate the surge in MIS during the past decade, with a higher increase in robotics as compared with conventional laparoscopy. During 2007-2010, robotic surgery increased 0.5% to 9.5%, conventional laparoscopy increased from 24.3% to 30.5%, vaginal surgery decreased from 21.7% to 19.8%, and open hysterectomy decreased from 53.6% to 40.1%.³² MIS cohorts include more patients with obesity, adhesive disease, and associated comorbidities compared with laparotomy cohorts and reinforce the current advocacy to provide surgical care to these patient subgroups on an outpatient basis.³²⁻³⁴ Table 1 lists studies regarding the trends of MIS techniques in the US. Surgeon preferences also play a substantial role in nationwide trends, as indicated in a survey of fellows from the American Association of Gynecologic Laparoscopists (AAGL) in which 96% of participants expressed desire to practice in a hospital that offered robotic surgery.³⁷

A standardized and validated curriculum in surgical robotics training does not exist. Intuitive Surgical's da Vinci Training Passport program provides a progressive, 5-tiered curriculum that involves tissue lab, complex anatomy review, and peer-to-peer assessment.³⁸ However, the framework of robotics training should be free of industry's influence and marketable across all types of robotics platforms. This process entails multiple consensus meetings to provide the foundation for course objectives, theory, and outcomes measures.³⁹ A multi-institutional RCT by Satava et al⁴⁰ validated the noninferiority of the Fundamentals of Robotic Surgery (FRS) curriculum when compared with the da Vinci Skills Simulator (DVSS) and dV-Trainer (Mimic Technologies Inc., Seattle, WA). Residents and fellows were noted to exhibit increased speed at completion of tasks with fewer errors ($P < 0.01$). As experienced surgeons are involved in such peer-to-peer training, there is limited dedication

of time when clinical practice and personal matters are taken into consideration. Polin and colleagues assessed the feasibility of “crowdsourcing” where nonmedical individuals from the general public were requested to score dry lab robotic surgical skills. The authors concluded there was high correlation (correlation coefficient r ranging 0.75 to 0.91) between the scores provided by expert surgeons and the crowdworkers.⁴¹ The surgeon’s acquirement and demonstration of procedural skill is needed with technological advances, and curricula such as those mentioned provide the standard of surgical care for the international community.

Marketing, Patient Perceptions, and Disparities

The historical background of the robotics platform is rooted in the AESOP and ZEUS systems (Computer Motion Inc., Goleta, CA) in the 1990s. The merger between Computer Motion Inc. and Intuitive Surgical Inc. marked the end of a litigious era between the 2 companies for copyright infringement and eventually led to the mainstream marketing of the da Vinci system.⁴² Marketing of new surgical technology is controversial and complex, as it is not under the jurisdiction of a regulatory body and has the potential for great bias when introduced to hospital systems, physicians, and patients. In addition, the FDA’s medical device approval process does not include evidence-based comparative trials by the medical community. A study of 400 randomly selected hospital websites in the United States highlighted 164 medical centers with a description of robotic surgery in their respective advertising. Approximately 73% of these centers used manufacturer materials such as image and text. In addition, 89% provided a qualitative statement of superiority that included less pain, scarring, EBL, and shorter recovery compared with any other surgical approach.⁴³ Such marketing can also have an impact on patients’ perceptions of robotic surgery. A MIS questionnaire study by Khalil et al⁴⁴ of 103 patients showed that the dissemination of information originated from physicians (12%), the Internet (41%), print media (30%), television/radio (37%), and friends (48%). It is evident that the physician’s role in patient counseling regarding the role of robotic surgery may not be as impactful as various forms of media.

Despite a growing trend in robotic surgery, there are also existing disparities regarding patient access to MIS. Mehta et al⁴⁵ studied hysterectomy trends from 2012 to 2014 in Maryland by general gynecologists and showed a lower likelihood of MIS associated with older age, black race, Hispanic ethnicity, and smaller hospitals (< 100 beds) along with a higher rate of postoperative complications among low-volume surgeons (1 to 5 hysterectomies per year), laparotomy, and Medicaid/Medicare/noninsured patients. Fader and colleagues identified 32,560 patients who underwent hysterectomy for early-stage endometrial cancer and concluded that patients who were treated at teaching hospitals [odds ratio (OR): 1.58], living in urban locations (OR: 1.35), nonobese (OR: 0.88 for obesity), or diagnosed after 2008 (OR: 1.23) were more likely to receive a MIS hysterectomy than obese patients and those treated at community-based or rural hospitals.³⁵ These discrepancies of MIS utilization among select patient populations underscore the need for a clinical model where MIS-eligible patients can obtain easier access to advanced laparoscopic surgeons.

SPECIFIC DISEASE-BASED GYNECOLOGIC OUTCOMES WITH ROBOTIC SURGERY

Extrafascial Hysterectomy for Benign Indications—Hysterectomy is one of the most common gynecologic procedures in the United States. Since the introduction of laparoscopic hysterectomy by Reich in 1988, MIS advancements have allowed the surgeon to operate in increasingly confined spaces and manipulate tissue at various angles for procedural optimization.⁴⁶ Select studies suggest a benefit for robotic surgery utilization in the setting of complex benign hysterectomy. A study involving 32,118 cases compared the outcomes of robotic, laparoscopic, vaginal, and open hysterectomies. Despite the robotic cohort's higher rate of adhesive disease, uteri > 250 g, and morbid obesity ($P < 0.01$ in comparison to laparoscopic/vaginal), this patient cohort had the shortest hospital LOS of 1.37 days ($P < 0.001$). It is not clear, however, that this improvement was clinically significant, given that the laparoscopic cohort of patients also had a relatively short LOS. In addition, no significant differences in intraoperative complications were noted between robotic and laparoscopic groups ($P = 0.077$).³³ Surgical volume history is unknown for the surgeons involved in this study and presents as a study limitation that should be taken into consideration.

Furthermore, a retrospective analysis of 804,551 robotic and laparoscopic benign hysterectomies revealed no significant differences in patient outcomes (respiratory, cardiovascular, gastrointestinal, renal) between the 2 groups, except for an increased risk of postoperative pneumonia in the robotics cohort ($P = 0.005$).⁴⁷ A Cochrane analysis of hysterectomy techniques highlighted the fewest intraoperative complications, quickest return to baseline activities, and the fewest number of urinary/bowel dysfunction and dyspareunia issues with the vaginal approach. There were no significant differences in adverse events between the traditional laparoscopic and robotic cohorts, but the low numbers between the groups contributed to low statistical power.⁴⁸

Randomized trials of robotic hysterectomy provide comparative insight to other techniques of hysterectomy with the intent to minimize bias. Sarlos et al⁴⁹ revealed a significantly higher operating time with robotic-assisted surgery compared with laparoscopy (106 vs. 75 min, $P < 0.001$) and higher pre to postoperative QOL scores (EuroQol ED-5D score interval 13 vs. 5, $P < 0.001$). Lonnerfors et al⁵⁰ demonstrated a significant decrease in perioperative EBL (50 vs. 100 mL, $P < 0.05$) and postoperative complications (4 vs. 12, $P < 0.01$) between the robotic and laparoscopic cohorts, respectively, while Paraiso et al⁵¹ found no difference in QoL between robotics and laparoscopy up to 6 months postprocedure.

In summary, retrospective and prospective studies underscore the comparative similarities between robotic and traditional laparoscopic approaches for benign hysterectomy (Table 2). Although skilled robotic surgeons demonstrate excellent clinical and perioperative outcomes in the literature, it is not clear whether there is a significant advantage to performing this approach in women with benign, straightforward conditions requiring hysterectomy. Conventional laparoscopic hysterectomy should likely be offered as the standard in this setting given the superior outcomes and cost-effectiveness. However, surgeon skills and experience as well as hospital surgical resources should ultimately influence the plan of care for each patient.

Myomectomy—The incidence of uterine leiomyomas in reproductive-aged women is difficult to decipher because many are asymptomatic, but 25% of women have significant clinical symptoms warranting intervention.⁵² A retrospective comparison between robotic-assisted laparoscopic myomectomy (RALM) and abdominal myomectomy (AM) highlighted lower mean EBL (195.7 vs. 354.7 mL, $P < 0.05$), shorter LOS (1.48 vs. 3.62 d, $P < 0.05$), and longer operating times (231.38 vs. 154.41 min, $P < 0.05$) for the RALM cohort. RALM and laparoscopic myomectomy (LM) showed no difference in EBL (370 vs. 420 mL, $P = 0.2$), hospital stay (1.00 vs. 1.05 d, $P = 0.12$), number/maximum diameter of leiomyomas, and postoperative complications.⁵³ However, a meta-analysis of all 3 forms of myomectomies demonstrated significantly lower EBL (68.2 to 138.42 vs. 85.3 to 420, $P = 0.02$), less postoperative bleeding (2 vs. 10, $P = 0.03$), and fewer intraoperative complications (30 vs. 46, $P = 0.009$) with RALM compared with LM.⁵⁴ There were no differences in fertility outcomes between the 2 modalities of MIS.^{55,56} A retrospective analysis enumerating 872 patients undergoing RALM resulted in 127 pregnancies with a 21% pregnancy loss rate at 14 weeks or less and a spontaneous conception rate of 60.6%.⁵⁷ The available data provides categorical evidence of RALM's benefits compared with AM and LM (Table 3). However, there is a dearth of published reports regarding long-term obstetrical and clinical outcomes of RALM versus other surgical approaches and further studies are needed.

Sacrocolpopexy—The incidence of pelvic organ prolapse (POP) increases with age and parity. A population analysis indicated that the highest prevalence of POP occurs in women 70 to 74 years.⁶¹ Surgeons have refined sacrocolpopexy, defined as the suspension of the vaginal apex to the sacral anterior longitudinal ligament, since the beginning of the 20th century. Experts considered the abdominal approach (ASC) as the gold standard, but MIS paved the way for the procedure's evolution. A bi-institutional study of 73 robotic-assisted laparoscopic sacrocolpopexy (RA-LSC) and 105 ASC patients by Geller and colleagues revealed less EBL (103 ± 95 vs. 255 ± 155 mL, $P < 0.001$), longer operative times (328 ± 55 vs. 225 ± 61 min), shorter hospital stay (1.3 ± 0.8 vs. 2.7 ± 1.4 d, $P < 0.001$), and higher incidence of postoperative fever (4.1% vs. 0.0%, $P = 0.04$) in the RA-LSC group. Both groups had similar Pelvic Organ Prolapse Quantification System (POP-Q) scores.⁶²

A perioperative outcomes analysis showed the same number of anatomic or symptomatic failures between ASC and laparoscopic cohorts, with few patients requiring additional procedures.⁶³ A RCT performed at the Cleveland Clinic comparing laparoscopic (LSC) and RA-LSC revealed longer operative/anesthesia times, higher operating room costs, and higher pain scores in the robotic-assisted group.⁶ Surgeons involved in the study were highly skilled in both conventional laparoscopy and robotic surgical techniques. POP-Q scores up to one year postsurgery exhibited no significant differences.⁴ It is clear that minimally invasive sacrocolpopexy has many benefits compared to the open approach. However, a surgeon trained in conventional laparoscopic techniques may not necessarily benefit from utilizing robotic surgery in this setting, whereas those without this training may wish to adopt the robotic-assisted approach that is theorized to allow for greater ease with tissue manipulation and complex suturing. Further urogynecologic prospective trials are needed to help define the role of robotics for this procedure.

Endometrial Cancer—Gynecologic oncologists have traditionally approached endometrial cancer, the most common gynecologic cancer in the United States, with open surgical staging for pathologic evaluation and treatment planning. Concerns for MIS in endometrial cancer included the lack of tactile feedback in the abdomen, adequacy of para-aortic lymph node retrieval, and theoretical seeding of tumor with intrauterine manipulator placement. However, those concerns have been dispelled with multiple studies demonstrating the safety of MIS in this setting and equivalency of oncologic outcomes between MIS and laparotomy in early stage endometrial cancer.^{2,64-68} A retrospective study by Boggess et al⁶⁹ allocated 322 patients to robotics, laparoscopy, or laparotomy and revealed that robotics yielded the highest lymph node count (32.9 vs. 23.1 vs. 14.9, $P < 0.0001$), shortest hospital stay (1.0 vs. 1.2 vs. 4.4, $P < 0.0001$), lowest overall complication rate (5.8% vs. 13.6% vs. 29.7%, $P < 0.0001$), and lowest EBL (74.5 vs. 145.8, vs. 266.0, $P < 0.0001$). The LAP2 study was a RCT that compared traditional laparoscopy and laparotomy in patients with early stage (FIGO stage I to IIA) uterine cancer (1988 FIGO criteria). Despite a 25.2% conversion rate to laparotomy, the authors demonstrated that laparoscopy had lower postoperative complication rates (21% vs. 14%, $P < 0.001$) and fewer patients with postoperative hospital LOS > 2 days (52% vs. 94%, $P < 0.0001$).⁷⁰ A subsequent analysis by the LAP2 study authors showed that recurrence rates at 3 years were not significantly different between the laparoscopy and laparotomy arms [11.39% vs. 10.24%, respectively; laparoscopy hazard ratio (HR): 1.14, 95% confidence interval (CI): 0.92-1.46]. Although the 95% CI exceeded the predetermined HR threshold of 1.4, the recurrence rate was lower than the a priori value of 15%.⁶⁸

Epidemiologic analysis of early-stage endometrial cancer cases during 2012-2013 from the National Inpatient Sample database showed that patients were less likely to undergo MIS in rural compared with urban areas (OR: 14.34, 95% CI: 9.66-21.27), government compared with nonprofit hospitals (OR: 1.66, 95% CI: 1.15-2.39), and black race (OR: 1.46, 95% CI: 1.30-1.65).⁷¹ Fader et al³⁵ showed an increase in MIS utilization from 22.0% in 2007 to 50.8% in 2011 ($P < 0.00$) and a higher number rate of intraoperative complications (OR: 2.08, 95% CI: 1.98-2.18), surgical site infection (OR: 6.21, 95% CI: 5.11-7.54), pneumonia (OR: 2.36, 95% CI: 2.06-2.71), venous thromboembolic disease (OR: 3.65, 95% CI: 3.12-4.27), and > 2 days hospitalization (OR: 34.49, 95% CI: 37.72-41.35) with laparotomy.

Despite higher costs of robotic surgery on a single case level, long-term cost reductions from the decrease in laparotomy rates and associated postoperative complications are beneficial in this population that is already characterized by obesity and other comorbidities. The published data signifies that MIS is safe and clinically effective for the treatment of early-stage endometrial cancer and should also be considered for patients with high-risk histology. Widespread dissemination of robotic-assisted surgery in the United States have given rise to an increasing number of endometrial cancer cases performed with robotic-assistance.

Cervical Cancer—Although cervical cancer screening with the Papanicolaou (Pap) smear and human papilloma virus vaccination is widely employed in the United States, this cancer remains a significant cause of morbidity and mortality globally. Cervical cancer is the fourth most commonly diagnosed cancer and the fourth leading cause of death in women worldwide.⁷² Total abdominal radical hysterectomy (TARH) is the standard of care for

FIGO stage IA2 to IB1 cancers.^{73,74} Encouraging results from endometrial cancer studies provided plausible validation of total laparoscopic radical hysterectomy and total robotic radical hysterectomy with cervical cancer. Specifically, the high definition, panoramic vision and 7-way wristed motion of robotics purportedly allows for precise, radical dissection of the parametria and retroperitoneal structures en bloc with the uterus and cervix. A handful of retrospective studies have emphasized improved EBL, hospital LOS, transfusion rates, postoperative complications, and equivalent survival outcomes of laparoscopic and robotic compared with open radical hysterectomy.⁷⁵⁻⁷⁸ However, the recently published Laparoscopic Approach to Carcinoma of the Cervix (LACC) trial, a phase 3, multicenter noninferiority study that investigated patients with FIGO stage IA1 with lymph vascular space invasion, IA2 or IB1 cervical cancer (squamous or adenocarcinoma histologies) undergoing total laparoscopic radical hysterectomy/total robotic radical hysterectomy versus TARH called into question the utilization of MIS in this setting. Despite the Data Safety Monitoring Committee's early discontinuation of patient recruitment at 85% for an increased risk of progression and death in the MIS cohort, results demonstrated a dramatically different 4.5-year disease-free survival (DFS) (86.0% vs. 95.5%) and overall survival (93.8% vs. 99%) between the MIS and laparotomy cohorts, respectively. DFS between MIS and TARH exceeded the -7.2% inferiority boundary.⁷⁹ The findings concur with those of a US epidemiologic study of 2461 women undergoing radical hysterectomy for stage IA2/IB1 cervical cancer that delineated a propensity-score matched 4-year risk of death of 9.1% with MIS versus 5.3% with TARH (HR: 1.65, $P = 0.002$).⁸⁰ Previous retrospective studies demonstrating favorable survival outcomes with MIS were underpowered and had shorter follow-up intervals. Some experts report that the exceptionally impressive TARH DFS from the LACC trial (96.5%) differs from that of previous GOG studies (80% to 95%) of early-stage cervical cancer, but these latter studies targeted patients at higher risk for recurrence as opposed to the population-based recruitment for the LACC trial.⁸¹⁻⁸⁵ At the present time, surgeons should proceed with caution with the robotic-assisted radical hysterectomy approach and counsel their patients with cervical cancer on the results of the LACC trial. This will allow women to make the most informed decision about surgical approach to treat their cervical cancer.

Future Directions—Surgical innovations are generally embraced by the medical community and patients alike. Research and development groups of various surgical technology companies have a special duty to collaborate with clinicians and regulatory agencies to optimize products and promote innovation in order to improve patient safety and outcomes. Recently, the launch of other companies specializing in MIS innovations have challenged the dominating presence of Intuitive Surgical Inc. Surgeons exhibited the safety and efficacy of the quad-arm REVO-I robotic platform (Meerecompany Inc., Seongnam, South Korea) in porcine models for fallopian tube reanastomosis with a mean operating time of 66 minutes.⁸⁶ The unique feature of reusable instruments associated with this system can potentially decrease costs compared with the da Vinci platform.⁸⁷ The TELELAP ALF-X platform (TransEnterix Inc., Morrisville, NC), rebranded as the Senhance surgical robotic system in 2016, provides haptic feedback and allows camera control by tracking the surgeon's eye movements, 2 features that are lacking in the current generation of the da Vinci surgical system.⁸⁸ Fanfani and colleagues demonstrated the feasibility of this system

in 146 gynecologic procedures with a MIS completion rate of 95.2%.^{89,90} A retrospective case-control study between the TELELAP ALF-X and conventional laparoscopy demonstrated significantly fewer instances of postoperative ileus (23 vs. 21 h, $P=0.050$) and intraoperative complications (2.5% vs. 4.3%, $P=0.040$) with the first cohort. Differences in OR times and EBL did not reach statistical significance.⁹¹ The Versius surgical robotic system (CMR Surgical Inc., Cambridge, UK) provides a modular design that allows individuals arms to be placed at the most optimal locations around the operating table.⁹² This differs from the conjoined overhead and pivoting arm architecture of the da Vinci system. The British-based company is anticipated to launch its product after FDA approval in the 2019 fiscal year. The end of the monopoly and the expansion of the robotics market will continue to drive new ideas that will benefit patients, surgeons, and hospital systems alike.

Conclusions

Robotic-assisted surgery is a revolutionary step in surgical innovation with its features of 3D panoramic vision, joint-wristed instrumentation, tremor filtration, and motion scaling. Level 1 and epidemiologic evidence validates the use of robotics in complex benign hysterectomy and endometrial cancer staging, and various retrospective and prospective studies demonstrate its potential benefits in myomectomy and sacrocolpopexy, especially for surgeons who do not have advanced conventional laparoscopic skills. Robotic-assisted surgery is not necessarily as useful for simple benign hysterectomies or adnexal surgery. At the present time, it is advised to proceed with caution when using robotic-assisted radical hysterectomy to treat cervical cancer, given recent level 1 data suggesting worse survival outcomes in the MIS compared with the open cohort. Despite the higher cost of robotics on a single case basis, it provides significant overall cost savings with concomitant laparotomy downtrend nationwide, due largely to a significant reduction in perioperative complications and hospital LOS. Robotic costs will surely decrease with market competition and platform refinement. Gynecologic societies have yet to establish a standardized credentialing process, and this role is currently overseen by the Robotics Training Network, the AAGL, and other national societies and hospitals around the country. The FRS curriculum is independent of any particular robotic company's platform and allows for establishment of psychomotor skills and robotic didactic education for burgeoning clinicians. There is integration of robotics in training programs, but individual graduates must determine when utilization of robotic-assisted techniques is most advantageous to their patients. Despite the controversies, robotic-assisted surgery will continue to evolve in a society with shifting demographics and gynecologic issues, and we await the arrival of newer robotics platforms to continue to inform this evolution.

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TABLE 1.
Select Literature of Minimally Invasive Surgery (and Robotics) Trends in the United States

References	Study Design	Time Period	Database	Cohort	Findings
Wright et al ³²	Retrospective cohort	2007-2010	Premier—benign hysterectomy	AH: n = 123,288 LH: n = 75,761 RH: n = 10,797 VH: n = 54,912	Rate of decline: VH 21.7%-19.8%; AH 53.6%-40.1% Rate of increase: LH 24.3%-30.5%; RH 0.5%-9.5% When data stratified for patients treated at hospitals offering RH, only difference was decrease in LH (28.9%-24.5%) in robotic-equipped hospitals vs. increase in LH (24.2%-34.7%) in robotic nonequipped hospitals
Moawad et al ³⁴	Retrospective cohort	2008; 2014	Premier—benign hysterectomy	AH: n = 32,479; 15,080 LH: n = 23,059; 18,700 RH: n = 2057; 17,841 VH: n = 15,327; 8367	All procedures had a 44.2% transition from inpatient to outpatient status. Proportion of African American and Medicaid patients undergoing MIS increased in 2014 ($P < 0.0001$) Rate of decline: VH 21.2%-13.5%; AH 47.8%-25.9% Rate of increase: LH 29.4%-31.2%; RH 1.7%-29.3%
Fader et al ³⁵	Retrospective cohort	2007-2011	National (Nationwide) Inpatient Sample—endometrial cancer	AH: 21,717 MIS (LH/RH/VH): 10,843	Increase in MIS from 22.0%-50.8% ($P < 0$). Increased likelihood of undergoing MIS at teaching hospitals (OR = 1.58, 95% CI = 1.12-2.23), high-volume cancer centers (OR = 4.22, 95% = 2.15-8.27), and areas of higher income zip codes (OR = 1.08, 95% CI = 1.02-1.13)
Wright et al ³⁶	Retrospective cohort	2008-2010	Premier—endometrial cancer	LH: n = 1027 RH: n = 1437	RH increased from 46.2% of MIS to 61.1%. Single women (OR 1.27; 95% CI 1.02-1.58), treatment at large hospitals (OR 2.89, 95% CI 2.21-3.78), treatment at non-academic hospitals (OR 1.28; 95% CI 1.04-1.59), and treatment outside the northwest were more likely to undergo RH. Rates of intraoperative (LH 4.0% vs. RH 3.0%, $P = 0.18$) and surgical site complications (LH 1.8% vs. RH 2.9%, $P = 0.08$) were similar

AH indicates abdominal hysterectomy; LH, laparoscopic hysterectomy; MIS, minimally invasive surgery; OR, odds ratio; RH, robotic hysterectomy.

TABLE 2.
Select Studies Comparing Robotics to Other Surgical Modalities for Treatment of Benign Gynecologic Conditions

References	Study Design	Cohort	Findings
Kluiters et al ³	Randomized controlled trial	AH: n = 32 LH: n = 27	QoL measurement (RAND-36 scores) 49.6 units higher for LH cohort. Longer OR time (121 vs. 78 min, $P = 0.01$) and fewer patients received opioids (10 vs. 22, $P = 0.01$) for LH
Lim et al ³³	Retrospective cohort	AH: n = 9745 LH: n = 11,952 RH: n = 2300 VH: n = 8121	RH cohort with higher rate of adhesive disease ($P < 0.001$), morbid obesity ($P < 0.001$, 0.074), and uteri > 250 g ($P < 0.001$, 0.017) compared with other cohorts. RH fewer intraop complications than AH/VH ($P < 0.001$)
Lonnerfors et al ⁵⁰	Randomized controlled trial	VH: n = 25 LH: n = 36 RH: n = 61	RH less EBL than LH (50 vs. 100, $P < 0.05$) and fewest postoperative complications ($P = 0.01$). Mean hospital cost was \$993 less for VH/LH compared with RH
Sarlos et al ⁴⁹	Randomized controlled trial	LH: n = 50 RH: n = 50	RH with longer OR time (106 vs. 75 min, $P < 0.001$. EBL (RH 87 vs. 79 mL, $P = 0.38$), opiate use ($P = 0.195$), and complication rate (RH 15 vs. 11, $P = 0.364$) not significantly different
Paraíso et al ⁵¹	Randomized controlled trial	LH: n = 27 RH: n = 26	RH with longer OR time (+72 min, 95% CI, 14–130; $P = 0.016$. No difference in QoL (SF-36 scores) up to 6 mo after surgery, $P > 0.30$

AH indicates abdominal hysterectomy; EBL, estimated blood loss; LH, laparoscopic hysterectomy; OR, operating room; QoL, quality of life; RH, robotic hysterectomy; VH, vaginal hysterectomy.

TABLE 3.

Select Studies in Myomectomy: Surgical Approach and Outcome Characteristics

References	Study Design	Cohort	Findings
Bedient et al ⁵⁵	Retrospective cohort	RALM: n = 41 LM: n = 40	No significant differences between RALM vs. LM for short-term operating room times ($P = 0.61$), LOS >24 ($P = 0.81$), and postoperative complications ($P = 0.45$). Significantly higher intraoperative bleeding complications in LM cohort ($P = 0.01$)
Wang et al ⁵⁴	Meta-analysis	RALM vs. AM: n = 773 vs. 1079 RALM vs. LM: n = 510 vs. 490	RALM vs. LM: RALM had significantly fewer complications (OR = 0.52, $P = 0.009$), less EBL (WMD = -33.03, $P = 0.02$), fewer conversions (OR = 0.34, $P = 0.03$), and fewer postoperative bleeding (OR = 0.18, $P = 0.03$) RALM vs. AM: RALM had significantly fewer complications (OR = 0.56, $P = 0.03$), shorter LOS (WMD = 1.74, $P < 0.00001$), less EBL (WMD = 77.74, $P < 0.00001$), and fewer numbers of transfusions (OR = 0.25, $P < 0.0001$). Cohort did have longer operating room times (WMD = 84.88, $P < 0.00001$)
Flyckt et al ⁵⁶	Retrospective cohort	RALM: n = 25 LM: n = 28 AM: n = 81	No significant differences in spontaneous conception rate ($P = 0.39$), miscarriage rate ($P = 0.12$), pregnancy complications ($P = 0.52$), and live birth rates ($P = 0.30$) among all cohorts
Nezhat et al ⁵⁸	Retrospective cohort	RALM: n = 15 LM: n = 35	Total operating room time higher for RALM vs. LM (234 vs. 203 min, $P = 0.03$). EBL ($P = 0.20$), LOS ($P = 0.12$) not significantly different
Advincula et al ⁵³	Retrospective cohort	RALM: n = 29 AM: n = 29	EBL (196 vs. 364 mL, $P = 0.0112$) and LOS (1.5 vs. 3.6 d, $P < 0.0001$) lower for RALM. Operating room time (231 vs. 154 min, $P < 0.0001$) and costs (\$5946 vs. \$4664, $P = 0.0002$) higher for RALM
Göçmen et al ⁵⁹	Retrospective cohort	RALM: n = 15 LM: n = 23	Mean operating room time ($P = 0.887$), LOS ($P = 0.369$), EBL ($P = 0.549$), myoma number ($P = 0.573$), and myoma size ($P = 0.307$) not statistically different
Barakat et al ⁵	Retrospective cohort	RALM: n = 89 LM: n = 93 AM: n = 393	AM/LM/RALM: Median diameter of removed myoma 7.50, 6.70, and 7.70 cm, respectively. Significantly larger myomas removed in AM/RALM cohorts ($P = 0.036$). Median operating room time 126, 155, and 181 min, respectively. Significantly less time for AM cohort ($P < 0.001$)
Gargiulo et al ⁶⁰	Retrospective cohort	RALM: n = 174 LM: n = 115	Operating room time (195 vs. 118 min, $P < 0.001$) and EBL (110 vs. 86 mL, $P = 0.04$) longer for RALM vs. LM but postoperative complications not statistically different

AM indicates abdominal myomectomy; CI, confidence interval; EBL, estimated blood loss; LM, laparoscopic myomectomy; LOS, hospital length of stay; OR, odds ratio; RALM, robotic-assisted laparoscopic myomectomy; WMD, weighted mean difference.