Research

### GYNECOLOGY

# Gynecologic robotic laparoendoscopic single-site surgery: prospective analysis of feasibility, safety, and technique

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OBJECTIVE: Multiple reports suggest that laparoendoscopic singlesite surgery is technically feasible, safe, and effective in treating a variety of gynecological disease processes. The study purpose was to assess the feasibility and safety of a novel robotic single-site platform (R-LESS) for the surgical treatment of benign and malignant gynecological conditions.

STUDY DESIGN: A single-institution, prospective analysis of 40 women treated with R-LESS on the gynecology and gynecological oncology services from June 2013 through March 2014. Women undergoing hysterectomy or adnexal surgery for either a benign or malignant gynecological condition were offered robotic single-site surgery during the study period of June 1, 2013, through April 1, 2014. Patients underwent surgery through a single 2.5-3.0 cm umbilical incision with a multichannel port and utilizing the da Vinci robotic single-site platform. Two surgeons with extensive laparoendoscopic single-site experience participated.

**RESULTS:** Forty patients had R-LESS performed. Procedures included total laparoscopic hysterectomy, laparoscopic supracervical hysterectomy, salpingo-oophorectomy, ovarian cystectomy, excision of endometriosis, and a combined case of total laparoscopic hysterectomy and cholecystectomy. Median age and body mass index were 42 years and 28.2 kg/m<sup>2</sup>, respectively. Median operating time, defined as the interval between incision start to closure, was 134 minutes (range, 84—311 minutes). Median vaginal cuff closure was 21 minutes (range, 9-77 minutes). Overall, there appeared to be a linear relationship between vaginal cuff closure time, console time, and operating time with number of cases performed. Procedures were successfully performed via R-LESS in 92.5% of cases; 2 cases required 1 additional port and there was 1 conversion to traditional multiport robotic surgery. There was 1 major postoperative complication (2.5%) and 1 readmission (2.5%). After a median follow-up period of 230 days (range, 61—256), there have been no postoperative hernias diagnosed.

CONCLUSION: We present one of the first series of robotic laparoendoscopic single-site surgery for the treatment of various gynecological conditions. When performed by experienced minimally invasive surgeons, R-LESS is feasible and safe in select patients. Further studies are needed to better define the ideal gynecological procedures to perform using robotic single-site surgery and to assess the benefits and costs of R-LESS compared with multiport robotic and conventional laparoscopic approaches.

**Key words:** laparoendoscopic single-site surgery, robotic surgery, single-port surgery

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inimally invasive surgery is the standard treatment for many gynecological disease processes. Multiple studies illustrate that laparoscopic and

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0002-9378/\$36.00 © 2015 Published by Elsevier Inc. http://dx.doi.org/10.1016/j.ajog.2014.07.057 robotic approaches to various gynecological conditions improve quality of life with comparable or improved surgical outcomes compared with standard open abdominal procedures. 1-6

Despite the potential for excellent outcomes with laparoscopic gynecological surgery, multiport laparoscopy is not without risks. Most gynecological procedures require 3-5 trocar incisions, including muscle-splitting incisions. Recent reports suggest that there is a greater risk of morbidity associated with multiple incisions, including pain, infection, and hernia. For instance, in a retrospective study by Shin and Howard<sup>7</sup> of 317 women who underwent total laparoscopic hysterectomies, a 5% risk of clinically significant neuropathic pain at the site of lower quadrant abdominal trocar incisions was reported.

In the last decade, laparoendoscopic single-site surgery (LESS; also known as single-port surgery) has emerged as a potentially less invasive alternative to multiport laparoscopy. 8-11 LESS, a procedure performed exclusively through a small incision in the umbilicus, is an attempt to enhance the cosmetic benefits of minimally invasive surgery while theoretically minimizing the risks of multiport laparoscopy described above. Many reports demonstrate that LESS is feasible and safe to perform for a variety of gynecological indications in the hands of experienced surgeons. 12,13

Several studies indicate improvement in pain scores and less need for narcotics in the postoperative setting when LESS patients are compared with conventional laparoscopy patients, although reports are conflicting.14 In a recent metaanalysis of existing randomized controlled trials, LESS is comparable with traditional laparoscopy in terms of efficacy and safety for treating gynecological conditions. Although improved cosmesis was validated in most trials, decreased pain has not been consistently demonstrated. 15

LESS presents unique surgical challenges, including instrument crowding and the need to manipulate a flexible camera and surgical instruments in a coordinated fashion through a small umbilical incision. This technique, known as in-line surgery, departs from the conventional triangulated technique and requires advanced laparoscopic skills.8-11 Information regarding how to transition LESS into surgical practice is scarce in the current literature.

Additionally, the expense and learning curves associated with the ports and instrumentation may be factors deterring universal adoption of LESS. Although the feasibility of LESS for complex surgical procedures is no longer in question, 12,13 the generalizability of this approach has been questioned, given the previously mentioned factors and the need for advanced laparoscopic skills.

To potentially overcome these challenges, single-site robotic surgical platforms have been developed recently. Robotic surgical platforms may shorten the minimally invasive learning curve for select surgeons compared with traditional laparoscopy. 16,17 A single-site robotic platform may also help overcome some of the technical limitations of LESS (learning curve, instrument crowding, lack of triangulation, and loss of depth of perception/instability with current 2dimensional flexible optics). Furthermore, it may play an essential role in the reproducibility and diffusion of LESS.

Therefore, the primary study purpose was to determine the feasibility and safety of robotic-assisted LESS (R-LESS) for the surgical treatment of various gynecological conditions through a novel robotic single-site platform. A secondary purpose was to describe techniques for successful platform set-up and performance of select gynecological procedures via the R-LESS platform.

## MATERIALS AND METHODS **Patient and surgical characteristics**

This prospective study was approved by the Institutional Review Board at the Johns Hopkins Hospital (Baltimore, MD). Women undergoing hysterectomy or adnexal surgery for either a benign or malignant gynecological condition were offered robotic single-site surgery during the study period of June 1, 2013, through April 1, 2014. During informed consent, patients were counseled that the robotic single-site platform was a novel, Food and Drug Administration-approved surgical tool and that the surgeons were well trained and experienced with conventional LESS and traditional robotic surgery. Surgical consent was obtained from all patients.

Inclusion criteria were women with a uterus size of 14 weeks or less, presumed benign or early malignant condition based on clinical evaluation and/ or preoperative imaging, 1 or less vertical midline incision, and a native umbilicus (ie, no previous panniculectomy) and were otherwise reasonable medical candidates for laparoscopic surgery. There were no restrictions by body mass index (BMI). Every patient received deep-vein thrombosis prophylaxis at the time of surgery and postoperatively, if admitted.

Peri- and postoperative data were collected prospectively. Operative times were recorded electronically and were defined as the interval between incision start to closure. Specifically, recorded was the time to perform the following: (1) umbilical incision and single-port placement, (2) robotic docking, (3) surgeon console time, and (4) vaginal cuff closure.

BMI was categorized by standard World Health Organization criteria. Data collection also included estimated blood loss, procedure type, conversion to multiport laparoscopy or laparotomy, pathology, uterine weight (in hysterectomy cases), length of hospital stay, and perioperative complications. All patients were seen and examined in the office 4-6 weeks after surgery. Patients were counseled regarding signs and symptoms of hernias and notified to contact the surgeon in that situation.

#### Surgeons

Cases were performed by a 2-surgeon team. The participating physicians (a gynecological surgeon and gynecological oncology surgeon) had extensive experience with both robotic surgery and laparoendoscopic single-site surgery. Collectively they have performed more than 1500 robotic cases and 1000 LESS cases prior to conduction of this study as well as some experience with R-LESS using more conventional instrumentation and ports (approximately 20 cases collectively). Gynecological oncology fellows or upper-level residents assisted the surgeons at the bedside in all cases. The technique for the single-site cases using conventional robotic platforms have been previously described by members of our surgical research group. 18-20

#### **Instrumentation and techniques**

Patients underwent surgery through a single 2.5-3.0 cm vertical umbilical incision (as measured by a sterile ruler) performed via an open Hasson approach. The da Vinci (Intuitive Surgical, Sunnyvale, CA) single-site port was positioned at the incision in 39 of 40 cases. In one case, a single-channel Gelport (Applied Medical, Rancho Santa Margarita, CA) was used. Prior published work with single-incision robotics utilized the Gelport. 18-20 The Gelport would potentially allow for better placement of the accessory port and to determine whether the da Vinci single-site port was required.

Easier port placement was made possible by either the use of an Army-Navy retractor at the caudad region of the incision or tagging the fascia with an interrupted 0-vicryl suture on each side of the incision and providing upward countertraction on the incision. The lubricated port was delivered into the incision in a cephalad-to-caudad direction using 1 or 2 large Kelly clamps. Marked regions on the port assist the surgeon in proper orientation of the

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