





## **Original Article**

# The Feasibility and Safety of Adopting Single-Incision Laparoscopic Surgery into Gynecologic Oncology Practice

Ashley J. Jennings, MD, Ryan J. Spencer, MD, Laura Hanks, MD, Lisa Barroilhet, MD, David Kushner, MD, Stephen Rose, MD, Laurel Rice, MD, and Ahmed Al-Niaimi, MD\*

From the Division of Gynecology, Department of Obstetrics and Gynecology, University of Wisconsin, Madison, Wisconsin (all authors).

**ABSTRACT** Study Objective: To determine the complications associated with single-incision laparoscopy in gynecologic oncology surgery.

**Design:** A retrospective cohort (Canadian Task Force classification II-3).

**Setting:** A single academic institution.

Patients: One hundred fifteen consecutive patients undergoing single-incision laparoscopy with suspected gynecologic oncology conditions.

**Interventions:** Single-incision laparoscopy.

Measurements and Main Results: One hundred fifteen patients underwent single-incision laparoscopy. The mean age was  $55.3 \pm 13.1$  years. For procedures completed via single-incision laparoscopy (102/115 [88.7%]), the mean operative time was  $130.7 \pm 55.5$  minutes. The average blood loss was  $63 \pm 111$  mL. The conversion to open rate was 13 of 115 (12.17%). The conversion rate of the 55 patients with benign conditions was lower (2/55 [3.64%]) compared with the 60 patients with malignant conditions (11/60 [18.33%]). The hernia rate was 2 of 115 (1.80%), 1 of which was a recurrent hernia. The median time for follow-up was 30 days (range, 5–653 days).

**Conclusion:** Single-incision laparoscopy provides a feasible, safe, and promising minimally invasive modality for treating gynecologic oncology patients. Journal of Minimally Invasive Gynecology (2016) 23, 358–363 © 2016 AAGL. All rights reserved.

Keywords:

Gynecology oncology; LaparoEndoscopic Singe Site Surgery; Single incision; Single port

Single-incision laparoscopic surgery is a surgical technique that involves the use of a single incision through the umbilicus. Preliminary advances in this technique were made during the early 1990s in urologic and gastrointestinal surgery [1]. Initially, single-incision surgery was not well received by the medical community because of difficulties in learning the technique and a longer operative time [2]. Advancements in trocars and instruments have increased the ability for more surgeons to use the modality. However, comparable studies have shown that more complicated cases

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Corresponding author: Ahmed Al-Niaimi, MD, FACOG, FACS, Department of Gynecology Oncology, 600 Highland Avenue, Office H4/636, Madison, WI 53792.

E-mail: alniaimi@wisc.edu

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1553-4650/\$ - see front matter © 2016 AAGL. All rights reserved. http://dx.doi.org/10.1016/j.jmig.2015.11.002 have been associated with increased surgical time and complications [3]. Data from other surgical specialties have not shown an increased hernia rate or patient-reported chronic pain after single-incision surgery [4–6].

Gynecologic surgeons led the way in single-incision surgery between 1968 and 1972 when they performed thousands of laparoscopic tubal ligations via a single-incision technique [7]. Throughout the 1970s, many gynecologists continued to use laparoscopic tubal sterilization through a single umbilical incision. Pelosi and Pelosi [8] reported the first single-incision laparoscopic hysterectomy in 1991. The first publication on single-incision laparoscopic surgery regarding specific instrumentation in gynecology was published in 2010. Since that time, the research on single-incision surgery has increased dramatically with the majority of the research focused on benign indications [9].

The literature regarding single-incision surgery in gynecology oncology is limited but growing. There are publications describing the use of single-incision laparoscopy for endometrial cancer staging, with the largest study reporting on 100 patients with early endometrial cancer [10]. Results from this cohort showed a low conversion rate and minimal complications. There is also a case series looking at lymph node dissection and ovarian cancer [11].

In terms of complications, there is a meta-analysis showing that single-incision laparoscopic surgery has equivalent complication rates when compared with multiple-port surgery [12]. However, this report included a small number of participants and used a composite outcome measure. Post-operative hernia remains a concern for single-site laparoscopic surgery. A recent meta-analysis in single-incision cholecystectomy showed no difference in hernias when compared with multiple-port surgery [13]. Literature regarding the hernia rate for single-incision laparoscopic surgery in gynecologic oncology is lacking.

The aim of this study was to describe the surgical outcomes from consecutive single-incision laparoscopic gynecologic surgeons at a high-volume single academic institution. The secondary outcome was to report the rate of hernias in this patient population.

### **Materials and Methods**

This is a retrospective cohort study looking at surgical outcomes for 115 consecutive patients who underwent single-incision laparoscopic surgery from the time of adoption in May 2012 until April 2014 at our institution. Four gynecologic oncologists performed the surgeries. The majority of the procedures were performed by 1 surgeon (110/118 surgeries). All surgeons used the same single-incision platform and the same instruments (GelPOINT; Applied Medical, Rancho Santa Margarita, CA). University of Wisconsin Institutional Review Board approval was obtained. Cases were identified by querying an institutionally approved prospective database maintained by the Division of Gynecology Oncology (Gynecology Oncology Longitudinal Data Collection and Utilization Program).

Inclusion criteria included any single-incision surgery performed in the time period noted previously. We excluded patients who underwent a planned cosurgery with another surgical team. Data collection included age, body mass index, race, medical comorbidities, surgical history, and surgery indication. Operative data included length of surgery in minutes, estimated blood loss in milliliters, length of hospital stay in days, postoperative complications, and the conversion rate to laparotomy. The surgical time was defined as the time from skin incision to the time of skin closure. The estimated blood loss was taken directly from the operative report. The incisional hernia rate was defined as any hernia that was detected clinically or via imaging up to 2 years after surgery. Patients who did not follow up as outpatients were excluded from the analysis of the hernia rate but were included in the surgical outcomes data.

Statistical analyses were performed using SAS 9.1 software (SAS Institute Inc, Cary, NC). Continuous variables are reported as means with standard deviations. Descriptive data are shown as the percentage of the total as related to the variable of interest.

#### Results

After excluding 3 patients who had a planned combined surgery, 115 patients were available for analysis. Preoperative characteristics are listed in Table 1. The majority of patients are postmenopausal, with a mean age of  $55.3 \pm 13.1$  years. The mean body mass index was  $31.9 \pm 9.5$ . Prior abdominal surgery was noted in 62% of cases.

The types of laparoscopic procedures performed are listed in Table 2. A total of 192 distinct procedures were performed among the 115 patients. The most common surgery was bilateral salpingo-oophorectomy (n = 66/192, 34.4%) followed by hysterectomy (n = 51/192, 26.6%) and unilateral salpingo-oophorectomy (n = 23/192, 12.0%).

Surgical outcomes are described in Table 3. The mean operative time for surgeries completed with single-incision laparoscopy was  $130.7 \pm 55.5$  minutes. The median blood loss was "minimal" with a range of 0 to 600 mL. The mean blood loss was  $63 \pm 111$  mL. The most common indication for surgery was the removal of an adnexal mass. The mean size of adnexal masses was 9.38 cm.

We also reported complications in Table 3. Surgeries converted to open surgery were excluded in this analysis, except

Table 1			
Preoperative characteristics			
	Number of patients		
Variable	(%) (N = 115)		
Age (mean $55.3 \pm 13.1$ years)			
Younger than 65	88 (76.5)		
65 or older	27 (23.5)		
Body mass index (kg/m <sup>2</sup> ) (mean 31.9 $\pm$ 9.5	)		
Not obese (<30)	56 (48.7)		
Obese (30 or higher)	59 (51.3)		
Race			
White	105 (91.3)		
Other	10 (8.7)		
Diabetes	11 (9.6)		
Hypertension	38 (33)		
Prior abdominal surgery	71 (61.7)		
Preoperative indication for surgery			
Adnexal mass	52 (45.2)		
Endometrial cancer	33 (28.7)		
Endometrial hyperplasia	7 (6.1)		
Risk reducing for genetic mutation	7 (6.1)		
Cervical cancer	4 (3.5)		
Ovarian transposition	2 (1.7)		
Completion staging of endometrial cancer	2 (1.7)		
Other	8 (7.0)		

Table 2

Table 2	
Laparoscopic procedures performed: Total patients	of 192 procedures for 115
Laparoscopic procedures	Number of patients $(\%)$ $(N = 192)$
Appendectomy	3 (.02)
Bilateral salpingo-oophorectomy	66 (34.4)
Hernia repair without mesh	10 (5.2)
Hysterectomy	51 (26.6)
Lysis of adhesions	1 (.01)
Omentectomy	6 (.03)
Ovarian cystectomy	2 (.01)
Ovarian transposition	2 (.01)
Para-aortic lymphadenectomy	12 (.06)
Pelvic lymphadenectomy	15 (.08)
Salpingectomy	1 (.01)
Unilateral salpingo-oophorectomy	23 (12.0)

for the injury to the inferior vena cava that occurred before converting to laparotomy.

The number of patients who experienced complications after single-incision laparoscopy was 8 of 103 (7.77%). These 8 patients experienced a total of 17 complications. Of the 7 patients readmitted, 3 required a blood transfusion for anemia. Three patients developed abdominal or pelvic abscesses (deep organ space surgical site infection) requiring drainage with interventional radiology and antibiotics. One patient had a cerebral vascular accident. The patient who did not require readmission presented with a superficial surgical site infection and was treated with oral antibiotics.

Table 3					
Postoperative outcomes of procedures completed via single-incision					
laparoscopy					
Parameter	Number (n = 102)				
Farameter	Number $(n = 102)$				
Surgery length (min)	$133.09 \pm 60.00$				
EBL (mL)	$63.75 \pm 111.60$				
Hospital stay (d)	$1.01 \pm 0.74$				
Complications	Number (%) $(n = 8)$				
Readmission	7 (6.8)				
Injury of inferior vena cava	1 (0.9)				
Blood transfusion	3 (2.9)				
Retroperitoneal hematoma	1 (0.9)				
Superficial surgical site infection	1 (0.9)				
Abdominal/pelvic abscess	3 (2.9)				
(deep organ space surgical site					
infection)					
Cerebral vascular accident	1 (0.9)				
EBL = estimated blood loss.					

Table 4 includes information regarding rates and reasons for conversion to laparotomy (n = 13/115, 12.2%). For patients with malignancy on final pathology, the conversion rate was higher at 18.3% (n = 11/60). The most common reasons for conversion were suspected advanced pathology and a technical difficulty of the surgery.

A more in-depth analysis revealed that 4 of the 13 conversions were caused by the presence of ovarian cancer on frozen pathology. These patients underwent full surgical staging via laparotomy. An additional 5 conversions were caused by the technical difficulty associated with extensive adhesive disease. The other conversions were unsafe patient position after sliding up the table, an enlarged uterus that required a Pfannenstiel incision for removal, an inferior vena cava injury unable to be controlled laparoscopically, and the surgeon's suspicion of advanced cancer.

The distribution of pathologic diagnoses and stages are listed in Table 5. Malignancy was diagnosed in 60 of 115 (52.2%) patients on final pathology. The most common cancer site was the uterus. Only 12 of 36 patients with endometrial cancer underwent lymphadenectomy because at our institution low-risk endometrial cancer patients do not undergo lymphadenectomy according to an institutional quality assurance protocol. In order to meet criteria to forgo lymph node dissection, a patient must have grade 1 endometrial cancer without evidence of greater than 50% myometrial invasion on preoperative magnetic resonance imaging, no lymphadenopathy, and a normal cancer antigen 125 level.

For the secondary outcome of incisional hernia, a total of 111 patients were available for analysis. Four patients did not follow up after surgery and were excluded. The median follow-up time was 30 days with a range of 5 to 653 days. The postoperative rate of hernia formation was determined by reviewing outpatient records and physical examination

Table 4					
Rates and reasons for conversion to laparotomy					
Conversion	Cause	Total number (%) (N = 115)			
All		13/115 (12.2)			
Benign		2/55 (3.64)			
	Technically difficult	1			
	Suspected advanced pathology	1			
Malignancy		11/60 (18.3)			
	Technically difficult	4 (36.4)			
	Suspected advanced pathology	4 (36.4)			
	Patient intolerance of	1 (9)			
	Trendelenburg position				
	Pfannenstiel incision to remove uterus	1 (9)			
	Inferior vena cava injury	1 (9)			

Table 5			
Final pathology			
Pathology	Number $(N = 115)$		
Benign	55 (47.8%)		
Malignancy	60 (52.2%)		
Borderline	8		
Incomplete staging	4		
Stage I	0		
Stage II	3		
Stage III	1		
Ovarian	11		
No stage	2		
Incomplete staging	3		
Stage I	2		
Stage II	1		
Stage III	3		
Uterine	36		
Stage I	29		
Stage II	1		
Stage III	5		
Stage IV	1		
Cervical	5		
Stage I	3		
Stage II	2		

findings specific for hernia. The overall postoperative hernia rate was 2 of 111 (1.8%). There were 10 patients who underwent repair of a preexisting hernia during single-incision surgery with 1 of those 10 (10%) recurring after surgery. This recurrence was included in the overall hernia rate calculation.

#### Discussion

Our study shows that single-incision laparoscopy provides a safe surgical option for patients with gynecologic oncology conditions. Although there are some data for single-incision laparoscopy in benign gynecology, there are limited data for oncology patients. Table 6 shows the summary of available studies to date for single-incision laparoscopic surgeries in gynecologic oncology patients, excluding single-incision robotic surgery [10,11,15–21].

Simulation studies have shown an increased level of difficulty to learn single-incision surgery [22]. However, new instruments and platforms have decreased the challenges associated with the limited space. Comparative studies have not shown a difference in postoperative complications, cosmetic results, hospital stay, or pain [3]. Despite the use of single-incision laparoscopy for nearly 25 years, there are limited large studies available. In particular, more studies are needed to compare surgical outcomes in gynecologic oncology procedures.

The conversion rate from laparoscopy to laparotomy in our study was 12.17%. Although this rate of conversion seems high, it is similar to the LAP-2 randomized trial for

staging of endometrial cancer by minimally invasive techniques (14.6%) [23]. In 6 of the patients in this study, the conversion to open surgery was primarily caused by the limitations of laparoscopic surgery in general, not specifically because of the single-incision approach. The 5 conversions made because of the technical difficulty of the surgery may highlight the challenges associated with single-incision surgery. During these technically challenging surgeries, the option of adding an extra trocar should be considered. The injury to the inferior vena cava required grafting, which could not be performed laparoscopically.

We have found many distinct advantages of single-incision surgery in gynecologic oncology surgeries. The first advantage is that larger adnexal masses can be removed through the single, larger incision easier than with a conventional 5-mm trocar. The mean size of the adnexal masses was 9.38 cm with the largest mass measuring 40 cm. Second, the umbilical incision can quickly be extended to a laparotomy if the pathology is malignant and more extensive surgery is required. This can potentially increase the number of surgeries completed via laparoscopy. Single-incision laparoscopy uses fewer ports, which has the potential to produce a better cosmetic outcome [12,24]. Finally, the single-incision platform can be rotated in a 360-degree manner, allowing the surgeon to operate in all quadrants of the abdominal cavity.

Strengths of this study include the number of patients with oncologic conditions. All of the cases are consecutive, thus decreasing the opportunity for selection bias. The highest-volume surgeon did not perform surgeries via any other laparoscopic modality during the time frame, further decreasing the selection bias. In addition, we were able to definitively determine the reasons for conversion to open surgery. The weaknesses are the retrospective nature and the wide range of postoperative follow-up time. In addition, the study does not provide the opportunity for comparative analysis.

Our study included a variety of benign and malignant conditions treated by gynecologic oncologists at our institution. Although the variability of procedures reported poses a limitation in extrapolating the data to other populations, it potentially provides a realistic reflection of daily practice for gynecologic oncologists. Because the procedures ranged from risk-reducing bilateral salpingooophorectomies to larger adnexal masses suspicious for ovarian cancer, it is possible that the conversion rate would be different in a lower-risk population. Future research should focus on direct comparisons of oncology procedures completed via single-incision laparoscopy to robotically assisted or conventional multiport laparoscopy to determine if the surgical outcomes and complications are equivalent. Furthermore, more data are needed to evaluate the learning curve needed to decrease complications and operative time. The authors are currently reviewing a comprehensive analysis on the learning curve of a surgeon using this surgical modality.

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Table 6								
Summary of current single-incision laparoscopy in gynecologic oncology								
Study	Year	Study type	N	Single incision	Comparison	Cancer	Procedure	Outcomes
Fader et al [14]	2009	Retrospective descriptive	13	9	None	Variable	Variable	Median operative time 65 min, no postoperative complications
Escobar et al [11]	2010	Pilot	21	20	None	Variable	Pelvic and para-aortic lymphadenectomy	90.5% completed via single-incision laparoscopy
Fader & Escobar [15]	2010	Retrospective descriptive	58	58	None	Risk reducing/ breast	Bilateral salpingo- oophorectomy ± hysterectomy	Mean operative time 38.1 min, no surgical complications
Escobar et al [16]	2012	Retrospective cohort	90	30	Robotic, conventional laparoscopic	Endometrial	Hysterectomy, bilateral salpingo- oophorectomy, ± lymphadenectomy	No differences in hospital stay, comorbid conditions, complication rates, or operative times
Escobar et al [17]	2012	Multicenter retrospective cohort	150	75	Robotic	Endometrial	Hysterectomy	Single incision had statistically significant shorter operative time (122 vs 175 min) and blood loss (50 vs 80 mL)
Fagotti et al [18]	2012	Retrospective descriptive	100	100	None	Endometrial	Hysterectomy with bilateral salpingo-oophorectomy	Median operative time 129 min, blood loss 70 mL, complication rate 8%
Fanfani et al [19]	2012	Prospective descriptive	20	20	None	Endometrial	Hysterectomy	Median operative time 105 min, blood loss 20 mL, no conversions
Boruta et al [20]	2014	Retrospective cohort	46	19	Mini laparoscopic	Cervical	Radical hysterectomy	Conversion to open 5.3% (1/19)
Park et al [21]	2014	Prospective cohort with historic controls	74	37	Conventional laparoscopic	Endometrial	Hysterectomy, bilateral salpingo- oophorectomy, ± pelvic lymphadenectomy	Comparable surgical outcomes, less pain in single incision

In conclusion, single-incision laparoscopy provides a feasible, safe, and promising minimally invasive modality for treating gynecologic oncology patients. A variety of procedures performed by a gynecologic oncologist are able to be completed using this surgical modality.

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