



Learning Curve of Robot-Assisted Laparoscopy in Gynecologic Oncology Surgery: Team Training and Impact on Morbidity

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Abstract

Objectives: The aim of this study was to evaluate the learning curve of robot-assisted laparoscopy for gynecologic oncologic surgical procedures, regarding post-operative morbidity.

Methods: Between February 2007 and October 2010, 225 robot-assisted procedures has been performed by a single team specialized in gynecologic oncology. Dates were prospectively collected. Isolated and poorly reproducible procedures were excluded, so a total of 187 procedures were finally included to assess the learning curve. Three parameters have been used: overall rate of postoperative complications, operative time and number of lymph nodes.

CUSUM statistical analysis was used to investigate the learning curve. After determining the number of cases necessary for learning, a comparative analysis was conducted to compare the learning period to the efficiency period.

Results: Fifty cases were necessary to master postoperative complications. The operative time evolves in three phases: the learning phase, with a gradual decrease in operative time; the consolidation phase, steady; and the final phase, increasing, corresponding to the introduction of more difficult cases and to the beginning of training program. There was a growing trend in the number of nodes removed. Comparative analysis of the learning period (senior surgeons) and the efficiency period (with increasing involvement of juniors) showed a significant evolution of procedures, and did not reveal any difference in terms of complications (44% vs. 31%, non significant), or mean number of lymph nodes removed (12.3 vs. 13.2, non significant).

Conclusion: Team training of robot-assisted laparoscopy requires an average of fifty cases looking at per operative complications.

Keywords: Robot-assisted laparoscopy; Gynecologic; Oncology

Introduction

Conventional laparoscopy has demonstrated its interest in various gynecologic surgical procedures and particularly in oncology. But this minimally invasive approach presents several difficulties due to its relatively long learning curve, which can explain its slow development in our countries.

In this context, in order to overcome the difficulties, robotic assistance appeared in 1994, with the development of the first robotic arm holding a camera (AESOP, Computer Motion, California, 1994). Later, in the 2000s, the 3-armed Zeus robot (Computer Motion, California) and the Da Vinci robot (Intuitive Surgical, California) appeared. This new robot-assisted technique is currently being evaluated, both clinically and financially. This evolution of conventional laparoscopy has its own learning curve which should be evaluated.

Objective

The aim of our study was to evaluate the learning curve of a single surgical team, considering all gynecologic oncology procedures conducted by robot-assisted laparoscopy, since the beginning of our robotic program. The primary endpoint was postoperative morbidity, and secondary endpoints were operative time and number of lymph node removed.

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Table 1: Clinical and peroperative data.

	Overall series	colpoHTT+BO+PL for cervical cancer after RCT	colpoHTT+BO+PL after treatment	HTT+BO for benign, ICN, OC, cervical, or endometrial	Pelvic lymphadenectomy	Para-aortic lymphadenectomy
n	187	46	41	54	17	32
Median age (years)	52 (25 – 84)	46 (29 – 77)	64 (46 – 82)	50 (32 – 84)	49 (29 – 75)	46.5 (25 – 75)
Median BMI	23 (15 – 42)	23 (16 – 37)	25.5 (16 – 42)	24 (16 – 42)	21 (16 – 39)	23 (16 – 36)
Conversion rate	1.60% (n = 3)	0%	0%	3.70% (n = 2)	0%	3% (n = 1)
Operative time (median) (minutes)	165 (60 – 360)	180 (120 – 300)	210 (110 – 360)	120 (60 – 240)	97.5 (80 – 120)	160 (80 – 330)

Abbreviations: ColpoHTT + BO: Colpohysterectomy + bilateral oophorectomy; PL: Pelvic Lymphadenectomy; HTT + BO: Hysterectomy + Bilateral Oophorectomy; RCT: Radio Chemotherapy; ICN: Intraepithelial Cervical Neoplasia; OC: Ovarian Cyst

Materials and Methods

Patients

From February 2007 to October 2010, 193 patients underwent 225 robotic assisted laparoscopic procedures in our institution (Paoli-Calmettes Institute, Marseille, France). Six surgeons, three seniors and three fellows in training performed all the procedures.

Data collection

Socio-demographic, clinical, and intraoperative data were prospectively collected, including type of surgery, docking time, operative time, intraoperative complications, blood loss and transfusions, conversion to conventional laparoscopy or laparotomy, and definitive pathology.

Operative time was defined as the time elapsed between the first incision and the end of the skin suture. Thus, it also included robot docking time and surgeon console time.

The anatomopathological data collected were histological type and tumor size, margin status, number of lymph nodes removed, and lymph node involvement.

Postoperative complications were prospectively collected. Postoperative morbidity was graded according to the Clavien and Dindo’s classification [1]. Minor postoperative complications were defined by a grade 1 or 2, and severe postoperative complications by a grade 3 or 4.

Patient follow-up was ensured by a systematic visit at one month, six months, and then annually. Late post operative complications and recurrence rate has been recorded.

Learning curve analysis

We decided not to take into account exceptional or poorly reproducible interventions, such as pelvectomy, isolated lymph node removal, or ovarian cancer restaging. A total of 187 cases were analyzed and divided into 5 homogenous sub groups in terms of indications and surgical procedures (Table 1).

The effect of learning was studied by analyzing the following criteria: postoperative morbidity, severe postoperative morbidity, operative time, and number of pelvic lymph nodes removed. We chose the number of complications as a primary endpoint. The conversion to laparotomy was not included as a learning factor

because it was a rare event in our series. Intraoperative data were collected individually by each surgeon and were not exhaustive. Thus, in the data collected, blood loss information was too missing to be analyzed. The extent of bleeding during the intervention was then assessed by the rate of transfusion. Concerning oncological outcomes, we did not considered recurrence rate and overall survival in our analysis, because our robotic program only began 4 years ago. Our objective was to determine the learning curve of the surgical team, and not to study individual learning curve. Surgical procedures were analyzed according to whether they were performed by a senior surgeon, or a junior surgeon associated to a senior. The analysis was not performed in previously determined periods, but by observing the learning curve, defined by the complications rate. A shift in the curve was considered the end of the learning period. To define the learning period, we decided to follow the evolution of the complications rate.

Statistical analysis

To study the learning curve, a univariate analysis of factors deemed relevant *a priori* was first conducted on the rate of surgical complications, the operative time, and the number of pelvic lymph nodes removed. These factors were related to the patient (age, BMI), the intervention performed (indication, procedure, chemoradiotherapy antecedents), and the surgeon (intervention conducted by a senior surgeon, or “accompanied” intervention conducted in whole or in part by a junior surgeon, under supervision of a senior surgeon).

The cumulative sum technique (CUSUM) was used for continuous variables (operative time and number of pelvic lymph nodes removed), and for binary variables (overall postoperative morbidity and severe postoperative morbidity) [2-4]. It consists in expressing each case by the difference between the value of a measured parameter (operative time in minutes, or presence/absence of complications) and the mean of the entire series. The cases were first classified in chronological order, depending on the date of surgery.

Regarding continuous variables, the point representing the 1st case is the difference between the operating time of the 1st case and the mean operating time of the entire series. To represent the 2nd case, we calculated the difference between the operating time of the 2nd case and the mean operating time of the entire series, added to the previous value, and so on, until the last case, for which the CUSUM value is necessarily 0. Regarding binary variables such as complications, the curve moves upward for each complication, and

Table 2: Postoperative data.

	Overall series	colpoHTT+BO+PL for cervical cancer after RCT	colpoHTT+BO+PL after treatment	HTT+BO for benign, ICN, OC, cervical, or endometrial	Pelvic lymphadenectomy	Para-aortic lymphadenectomy
n	187	46	41	54	17	32
Length of stay (days)	3 (1 – 24)	3 (2 – 24)	3 (2 – 7)	3 (1– 8)	2 (2 – 6)	3 (1 – 9)
Overall postoperative morbidity	35 % (65)	60 % (28)	29 % (12)	24 % (13)	24 % (4)	25 % (8)
- severe	9 % (17)	19.5 % (9)	5 % (2)	5 % (3)	6 % (1)	6 % (2)
- lymphatic	20 % (37)	41 % (19)	15 % (6)	5 % (2)	24 % (4)	19 % (6)

Abbreviations: ColpoHTT + BO: Colpohysterectomy + Bilateral Oophorectomy; PL: Pelvic Lymphadenectomy; HTT + BO: Hysterectomy + Bilateral Oophorectomy; RCT: Radiochemotherapy; ICN: Intraepithelial Cervical Neoplasia; OC: Ovarian Cyst

downward for each case free of complications. The end of the learning process was defined as the point where the curve ceases to rise, and stabilizes or descends.

Finally, Fischer and X² tests were used to compare clinical data, type of procedure, complication rates, operative times, participation of surgeons in training, and number of lymph nodes removed between the so-called “learning period” and the so-called “efficiency period.”

Ethics statement

Prior to analysis, patients were anonymized. Neither their names nor their initials were recorded, but a number was assigned to each. At the time of the first admission, all patients provided written consent to the use of their clinical and histological data by anonymous way.

Our institutional review board (COS, Comité d’ Orientation Stratégique) approved the study and the consent procedure.

Results

Descriptive results

To analyze the learning curve of 187 surgical procedures we defined five homogenous sub groups as follow:

Group 1 (n=46): Adjuvant surgery for locally advanced cervical cancer after para-aortic lymph node staging (surgical in 85% of cases), concomitant chemoradiotherapy and brachytherapy. In this subgroup, patients underwent an extra facial hysterectomy + bilateral oophorectomy + pelvic lymphadenectomy, Most patients were treated for stage IB2 (48 %) or IIB (28 %).

Group 2 (n=41): Colpohysterectomy + bilateral oophorectomy + pelvic lymphadenectomy for endometrial or cervical cancer (less than 4 cm), before treatment, or after brachytherapy for cervical cancers.

Group 3 (n=54): Hysterectomy + bilateral oophorectomy without lymph node removal and without prior treatment (intraepithelial cervical neoplasia, fibromas, ovarian cysts, and endometrial or cervical cancers).

Group 4 (n=17): Pelvic lymphadenectomy.

Group 5 (n=32): Para-aortic lymphadenectomy (retroperitoneal or transperitoneal).

Clinical and intraoperative data are reported in Table 1.

Two intraoperative complications occurred during two para-aortic lymphadenectomies: an inferior mesenteric artery injury controlled by suture laparoscopically, and a bowel injury (duodeno-jejunal angle), with a conversion to open.

The median hospital stay in each group, as well as the rate

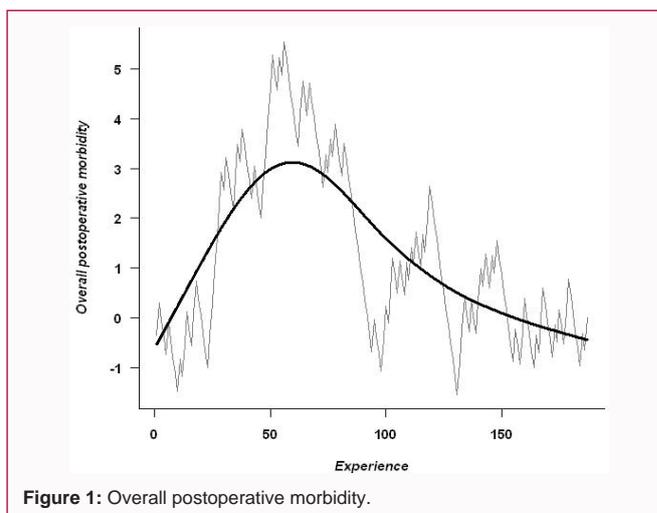


Figure 1: Overall postoperative morbidity.

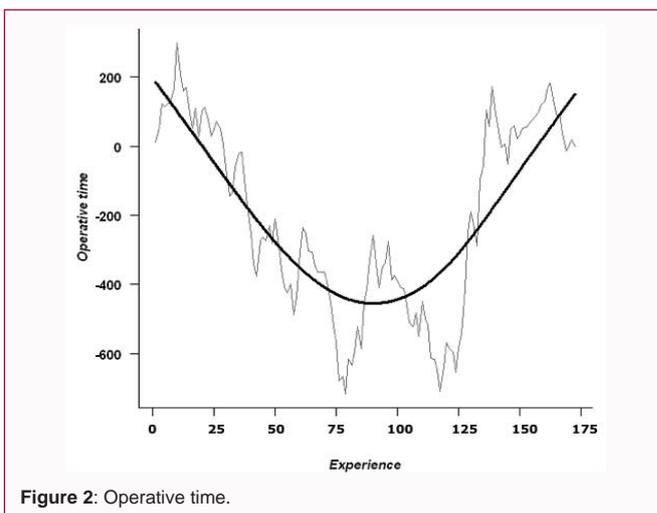


Figure 2: Operative time.

of postoperative complications, is summarized in Table 2. The overall postoperative complications rate was 35%, including lymphatic complications rate (20%). Seventeen severe postoperative complications were described (9%). They were mainly infected or symptomatic lymphoceles requiring radiological drainage.

In our series, the most important complications rate was observed in the sub group 1 (66%).

Postoperative morbidity

Regarding the overall rate of postoperative complications, the CUSUM curve revealed a significant decrease in the rate of

Table 3: Comparisons between the “learning period” and the “efficiency period”.

	Learning period: 50 first cases	Following period: 137 cases	P value
Age Years	52,3	52,6	NS
BMI Kg/m ²	24,1	24,7	NS
Indications			
<i>Benign diseases</i>	26 % (n = 13)	14 % (n = 19)	0,0465
<i>Cervical cancer</i>	58 % (n = 17)	55 % (n = 76)	
<i>Endometrial cancer</i>	16 % (n = 8)	31 % (n = 42)	
Operative time minutes	161,6	171,7	NS
Prior radiochemotherapy	28 % (n = 14)	22 % (n = 30)	NS
Trainees involvement	0%	36 % (n = 49)	< 0,0001
Overall postoperative morbidity	44 % (n = 22)	31 % (n = 43)	NS
Severe postoperative morbidity	12 % (n= 6)	8 % (n = 11)	NS
Pelvic lymph nodes	12.3 (5.1)	13.2 (5.3)	NS
Length of stay days	3,4	3,4	NS

complications beyond the 50th procedure (Figure 1).

Operative time

From the CUSUM curve representing the evolution of operative time, three phases were identified: a first phase going downward, corresponding to the learning stage; a consolidation phase, with a plateau phase; and an ascending phase, corresponding in our activities to the inclusion of more challenging cases and to the beginning of training program for our 3 fellows (Figure 2).

Number of pelvic lymph nodes removed

The mean number of lymph nodes removed during pelvic lymphadenectomies (104 procedures) was 12.8 (4 – 33) (Table 3), The CUSUM analysis showed an increase mean lymph node number, without reaching any specific threshold (Figure 3).

Comparisons between the “learning period” and the “efficiency period”

Looking at the curve representing the overall complications rate, we defined the point of inflection of the curve (50th case), as the end of the “learning period”. The following cases (n=137) represented the “efficiency period.” Comparative analysis of these two periods is reported in Table 3. There was no difference regarding age, BMI, and the patients’ history of radio- and chemotherapy. The indications and the integration of fellows were significantly different between these two periods. Indeed, during the learning period, all surgical procedures were performed by experienced surgeons in conventional laparoscopy, whereas 36% of subsequent procedures included fellows. We did not observe any significative difference concerning complications rate between the 2 periods (44% vs. 31%), the rate decreased by 44% during the learning period, to 31% thereafter (non-significant). The mean operative time was 161.6 and 171.7 minutes, respectively (non-significant). There was no significant difference in the number of pelvic lymph nodes removed. Two patients in the series were transfused: one during the learning period and one during the efficiency period. The length of stay was also similar in the two groups.

Discussion

The concept of minimally invasive surgery in gynecology emerged in the 1980s and has been progressively developed in gynecologic oncology surgery. Conventional laparoscopy is now validated for

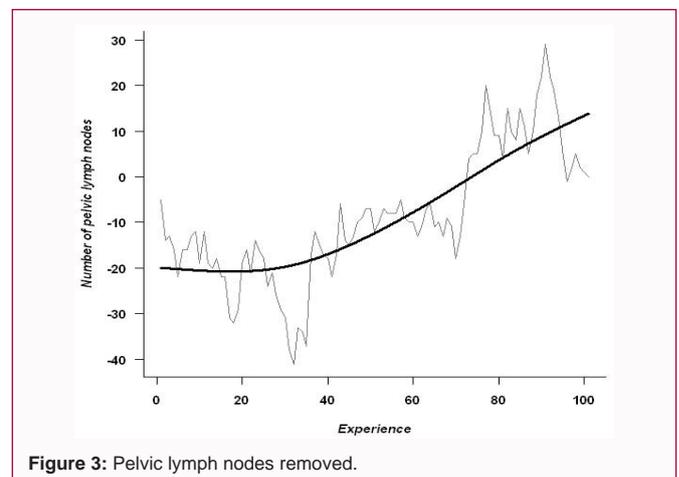


Figure 3: Pelvic lymph nodes removed.

various procedures, and its advantages compared to open surgery are now well described (less blood loss, less postoperative pain, and reduced hospital stay with a faster recovery, and better quality of life) [5-16]. However, laparoscopy has several limitations, such as the two-dimensional view, the image instability, and the instruments, which offer only four degrees of freedom. These limitations are associated with a specific and longer learning curve compared to open surgery, and may limit the development of this minimally invasive approach.

Robotic-assisted laparoscopy emerged in 2000, and has gradually expanded to the field of pelvic surgery. On July 11, 2000, the Food and Drug Administration approved robot-assisted laparoscopy for pelvic surgery, and specifically approved it for hysterectomy in 2005. It has been validated by numerous comparative studies [13,17-28]. Robotic assistance was developed to overcome the drawbacks of conventional laparoscopy, by allowing 3D visualization, tremor filtration, increased accuracy (thanks to motion scaling), ergonomics, allowing surgeon performance optimization; and low intra-abdominal pressure.

However, this new robotic tool requires specific training. Indeed, the surgeon must acquire a control on several elements associated with robot-assisted surgery: he must learn to incorporate the spatial relationships of the instruments outside the operative field to mobilize them while minimizing conflicts between the robot’s arms; master the operation of the robot by combining specific manual controls with pedal controls; and compensate for the loss of force feedback through

a visual assessment of the tension applied to the tissue.

Choice of statistical method

We chose the CUSUM method to express our results. This is a method adopted by the medical profession in the 1970s [2-4,33]. It allowed us to express our results in deviations from the mean, providing data non-identified by other approaches (such as the comparison of chronological cases split into predefined segments). Similarly, Bokhari et al. [34] in 2010 investigated robot-assisted laparoscopy learning curve in rectosigmoid and rectal surgery. Three phases of learning on a CUSUM curve representing the operative time was demonstrated: the learning phase, the consolidation phase, and the expertise phase. Duration of hospitalization was stable, setup time and blood loss decreased, and operative time increased (which they attributed to the management of increasingly difficult cases).

In our study, the curve representing operative time shows the same triphasic aspect: the first phase represent the learning stage, with an improvement in operative time throughout the procedures; the second phase correspond to the consolidation of this learning; and the third phase, going upward, correspond to the contribution of junior training surgeons and the inclusion of more challenging cases. Indeed, the majority of cervical and endometrial cancers were included during the second phase of the study (Table 4).

Choice of primary endpoint

Unlike most studies, which analyze preferentially operative time, we chose the rate of complications as the primary endpoint. This could be more relevant and more representative of mastery of surgical procedure, given the heterogeneity of our serie. This have been previously reported in conventionnal laparoscopy by Altgassen et al. [35] in 2004.

Learning curve

Several studies have been published concerning the learning curve in robotic surgery. Seamon et al. [38] in 2008, in a descriptive analysis of their 92 first interventions for endometrial cancer, noted a threshold at the 20th case (considering the evolution of operative time). They compared the learning phase to the next phase. They didn't find any difference in the number of lymph nodes removed or blood loss. No comparison was done considering the rate of complications. In 2009, the same authors reported a prospective analysis on 79 cases of endometrial cancer, carried out by two surgeons. Interventions were splited into chronological quartiles of 20 cases (because of the threshold observed in the preliminary study). There was a difference in terms of operative time when comparing the 20 first cases to the 20 next cases, which was not found in subsequent cases. There was a significant difference regarding blood loss, number of lymph nodes removed, and duration of hospitalization [39].

In 2009, Bell et al. [40] published a retrospective review of the first 100 robot-assisted laparoscopic hysterectomies performed by a single surgeon. Cases were analysed after division into quartiles of 20. No significant difference was noted in operative time. The rate of complications was 15% for the first 20 cases, and 5% for the following cases, although this difference was not significant. Lim et al. [41] in 2010 compared the 122 first robot-assisted procedures for endometrial cancer, to a historical cohort of the 122 first procedures by conventional laparoscopy. Learning curve was 24 cases for robotic assistance, against 49 cases for conventional laparoscopy. Comparisons before and after this threshold did not show any difference in conventional laparoscopy, and showed increased

operative time and blood loss during robot-assisted laparoscopy learning.

Robot-assisted laparoscopy was evaluated in other specialties, and notably in urology. Patel et al. [42] analyzed data from the 200 first prostate cancer procedures, managed by two surgeons. A progressive decrease was noted in operative time and blood loss, and they described a learning curve of 20 to 25 cases.

In our study, 50 procedures were necessary to observe a threshold in the rate of complications. This is reflecting a longer learning curve than most published studies. This may be due to the fact that we chose the rate of complications as our primary endpoint (instead of operative time), or because the patients carried out by our team were mainly affected by malignant tumors, with a majority of advanced stages of cervical cancer. Moreover, we analyzed the learning of a whole team, and not individual surgeons, and we analyzed several different procedures, including after preliminary treatment with concomitant chemoradiotherapy. Similarly, Lenihan et al. [36] reported the learning curve of a two gynecological surgeon's team by analyzing data from all procedures performed with robotic assistance and for various benign pathologies. They analyzed 113 procedures and concluded that the learning curve required 50 cases, in agreement with our results.

Junior's contribution

During the first phase of our study, there was no accompanied procedure. Our training program began at the sixty fourth procedures, according to a step by step learning method: the trainee performs one step of the procedure, and when this step is mastered, he performs the next one.

Comparative analysis of these two periods - learning and efficiency - is therefore similar to analyzing the effects of the training surgeons' involvement. However, we didn't find any difference regarding the rate of complications, transfusions, and number of lymph nodes removed. Operative time increased but this wasn't significant, and probably due, as mentioned before, to the inclusion of more challenging cases, but also to the implication of more junior surgeons (Table 4).

In our experience, robot-assisted surgery can thus be taught without risk and without impairing the quality of the procedures. The curve corresponding to the number of pelvic lymph nodes removed even showed an increasing trend. This suggests that there is a positive effect of the senior surgeons' experience on the performance of their students. Once the team training is achieved, fellowship is sufficient to train juniors without increased risk or decreased quality of surgery.

Ali et al. [37] have studied this, in 2007. Learning curve in robot-assisted laparoscopy was evaluated by analysis of the performance of the junior staff during bariatric surgery. Three phases were identified, and the junior was the main surgeon during the first phase, then for the two first phases, and then for all three phases. These procedures were compared to data from the original series on senior surgeons. There was no difference in total time for all three phases, no matter the junior's contribution. More importantly, there was no difference in operative time when the three phases were performed by the junior, in comparison with the original series. Similarly, during "accompanied" procedures, where a senior surgeon performs one or more phases, operative times were shorter than in the original series (seniors). Moreover, robot docking time was better than in the original series, reflecting the learning of the entire team, including

nurses, anesthesiologists, etc.

A prospective study of the learning curve in robot-assisted laparoscopy of training surgeons is currently in progress in our team. A standardization of procedures seems interesting to accelerate and evaluate learning. This standardization is an unavoidable step to teach robot-assisted laparoscopy (because of the impossibility to do “four hands surgery”), unlikely to conventional laparoscopy. This includes standardization of pre operative patient care, patient positioning, position of trocars, and surgical procedures. This standardization might be one of the reasons why there is no increase in morbidity when involving junior surgeons.

Reducing the learning curve would allow access to minimally invasive surgery to an increasing number of patients. Indeed, only 20% of patients eligible for this approach are actually supported by laparoscopy in France (data from the Program for Medicalization of Information Systems). Robotic assistance, once its cost is overcome, can be the answer to this too-limited access to minimally invasive approaches. The advantages of robot-assisted compared to conventional laparoscopy are currently under evaluation in France in a randomized trial (PHRC ROBO-GYN).

Conclusion

Robot-assisted laparoscopy appears to be an evolution of minimally invasive surgery, with an important place in gynecologic oncology. While some parameters, such as financial impact and oncologic follow-up remain to be evaluated, it appears that this technique is feasible in the majority of gynecologic oncology procedures, and could give access to minimally invasive surgery to an increasing number of patients.

This study suggests that team training needs 50 cases to master the rate of complications, and to allow integration of juniors and advanced procedures without negative impact on level of safety and quality of results. A prospective validation of this learning curve is necessary to confirm these data.

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