

# Criteria for Selection of Laparoscopy for Women with Adnexal Mass

Amilcar Barreta, MD, Luis Felipe Sallum, MD, Luis Otávio Sarian, MD, PhD,  
Joana Fróes Bragança Bastos, MD, PhD, Sophie Derchain, MD, PhD

## ABSTRACT

**Objectives:** We compared the indication of laparoscopy for treatment of adnexal masses based on the risk scores and tumor diameters with the indication based on gynecology-oncologists' experience.

**Methods:** This was a prospective study of 174 women who underwent surgery for adnexal tumors (116 laparotomies, 58 laparoscopies). The surgeries begun and completed by laparoscopy, with benign pathologic diagnosis, were considered successful. Laparoscopic surgeries that required conversion to laparotomy, led to a malignant diagnosis, or facilitated cyst rupture were considered failures. Two groups were defined for laparoscopy indication: (1) absence of American College of Obstetrics and Gynecology (ACOG) guideline for referral of high-risk adnexal masses criteria (ACOG negative) associated with 3 different tumor sizes (10, 12, and 14 cm); and (2) Index of Risk of Malignancy (IRM) with cutoffs at 100, 200, and 300, associated with the same 3 tumor sizes. Both groups were compared with the indication based on the surgeon's experience to verify whether the selection based on strict rules would improve the rate of successful laparoscopy.

**Results:** ACOG-negative and tumors  $\leq 10$  cm and IRM with a cutoff at 300 points and tumors  $\leq 10$  cm resulted in the same best performance (78% success = 38/49 laparoscopies). However, compared with the results of the gynecology-oncologists' experience, those were not statistically significant.

**Discussion:** The selection of patients with adnexal mass to laparoscopy by the use of the ACOG guideline or IRM

associated with tumor diameter had similar performance as the experience of gynecology-oncologists. Both methods are reproducible and easy to apply to all women with adnexal masses and could be used by general gynecologists to select women for laparoscopic surgery; however, referral to a gynecology-oncologist is advisable when there is any doubt.

**Key Words:** Laparoscopy, Adnexal diseases, Patient selection, Conversion to open surgery.

## INTRODUCTION

Approximately 10% of women will need surgery to treat an adnexal mass during their lifetime.<sup>1</sup> Minimally invasive techniques such as laparoscopy have well-established advantages over traditional laparotomy in reducing surgical morbidity.<sup>1-3</sup> Laparoscopy is becoming the preferred surgical approach to treat adnexal masses because, compared with laparotomy, it has been shown to be associated with reduced pain, incidence of febrile morbidity, and wound dehiscence; improved recovery times; and earlier return to work.<sup>3-5</sup>

Although the benefits of laparoscopic surgery are well known for the treatment of benign adnexal masses, there are still concerns about its safety and efficacy for the treatment of malignant adnexal tumors.<sup>4,5</sup> For this reason, most gynecologic surgeons refrain from using laparoscopy as the prime approach to malignant tumors or those that are highly suspicious for malignancy. The most recent International Federation of Gynecology and Obstetrics staging guidelines for gynecologic cancer also recommend that laparoscopy be used only to treat adnexal masses with a low suspicion for malignancy.<sup>6</sup> Up to the present date, there is no single examination or screening method capable of discerning benign from malignant adnexal masses.<sup>7-9</sup> Thus, approximately 1% to 20% of women with adnexal masses, selected based on surgeons' experience and operated by laparoscopy, will be found to have a malignant tumor during surgery,<sup>10,11</sup> or the surgeon will face technical difficulties, resulting in the need to convert to laparotomy.

Department of Obstetrics and Gynecology, Faculty of Medical Sciences, State University of Campinas-UNICAMP, Campinas, Brazil (all authors).

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Address correspondence to: Amilcar Barreta, Department of Obstetrics and Gynecology Faculty of Medical Sciences, PO Box 6111 State University of Campinas-UNICAMP, 13083-970, Campinas, SP, Brazil. Telephone/Fax: (+55) 19-3521-9305, E-mail: abarreta@yahoo.com.br

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Many risk score indexes have been studied to increase the accuracy of the diagnosis of malignant adnexal masses, with limited usability.<sup>12,13</sup> Some of those indexes are in use for the referral of women to gynecology-oncology centers or specialists. In the United States, the American College of Obstetrics and Gynecology (ACOG) developed a guideline based on the CA-125 antigen and clinical characteristics for referral of women at high risk for malignant adnexal mass to gynecology-oncologists.<sup>14,15</sup> In the United Kingdom, the Index of Risk of Malignancy (IRM), developed by Jacobs et al, is used for the referral of women suspected to have adnexal masses.<sup>16</sup>

A common cause of laparoscopy failure for the treatment of benign adnexal masses is the size of the tumor.<sup>17,18</sup> Larger masses seem to increase the rate of conversion to laparotomy, reducing the benefits of a surgery initially begun by laparoscopy<sup>19,20</sup>; also, larger masses appear to hamper intraoperative manipulation and to be associated with a higher rate of tumor rupture.<sup>17</sup> Because the rupture of an adnexal tumor upstages a malignant tumor,<sup>21</sup> many gynecologic surgeons tend to avoid manipulating large masses by laparoscopy.

In this study, we evaluated whether ACOG's guidelines and IRM, associated with tumor diameter, can help in selecting women with an adnexal mass for successful laparoscopic surgery. We considered that laparoscopy failed if the diagnosis of a malignant adnexal mass was made during or after surgery, the tumor ruptured intraoperatively, and/or the procedure had to be converted to laparotomy.

It was our hypothesis that a few of the patients' characteristics and disease features can guide an a priori determination of laparoscopy feasibility at a semispecialized center. In other words, our study aimed to answer the question of whether ACOG's guidelines and/or IRM guidelines can guide surgeons' selection of laparoscopy over laparotomy. This could decrease the incidence of malignant tumors being removed via laparotomy when a less aggressive procedure could have been performed. Because specialized treatment is usually performed by gynecologist-oncologists, the correct procedure indication can potentially obviate the need for referral to specialized centers.

## **MATERIALS AND METHODS**

### **Study Design**

This was a prospective study conducted at the Department of Obstetrics and Gynecology, Faculty of Medical Sciences, University of Campinas (UNICAMP), between

January 2010 and June 2012. During this period, 174 women who underwent surgery for the presence of adnexal tumors at the 2 hospitals of our institution—Pinotti Women's Hospital, CAISM, State University of Campinas (a tertiary oncology center) and State Hospital of Sumaré, State University of Campinas (a general hospital with surgical gynecology service)—were invited to participate. Before surgery, we conducted an initial interview and explanation about the methods and purpose of the study; all women who enrolled gave written informed consent. The study was approved by the Research Ethics Committee of the State University of Campinas—UNICAMP (CEP 006/2010).

The decision in choosing laparoscopy or laparotomy as the initial surgical approach was based on the surgeon's preoperative assessment (subjective assessment) because this is the standard method of selection of women with adnexal masses for laparoscopy at our service. The study protocol did not mandate one approach over the other, and there were no established protocols at our institution to guide the surgeons during selection. During the study period, surgeons performed 116 laparotomies and 58 laparoscopies for treatment of adnexal masses. Surgeries were performed by an expert gynecologic-oncologist assisted by one or more trainees with fellow or resident level. Our group of experts was composed of 6 surgeons at different levels of laparoscopy skills, and we used this to simulate real-world performance. Laparoscopy was performed with the patient under general anesthesia. Initial access for laparoscopy was made with a Veress needle. In a few cases, the surgeons opted for the open-access technique. After the establishment of a pneumoperitoneum, 1 to 4 accessory 5- to 10-mm trocars were placed into the peritoneal cavity. In cases of conversion, laparotomy was performed by midline or Pfannenstiel's abdominal incision under general or regional anesthesia. Specimens obtained during surgery were sent for frozen sectioning, and all specimens were further sent for confirmatory paraffin pathologic examination. All histopathologic examination was performed following the guidelines of the World Health Organization International Classification of Ovarian Tumors.<sup>22</sup> For statistical analysis, borderline tumors were classified as malignant. All surgeries initiated by laparoscopy that ended as laparoscopy and with final pathology diagnosis of a benign condition were considered a successful laparoscopic procedure. All surgeries that required conversion to laparotomy and/or had a diagnosis of malignant tumor

and/or facilitated a cyst rupture were considered as a laparoscopy failure.

## Objective Selection Criteria

### ACOG Guidelines

The ACOG guideline for referral of women with adnexal tumors to a gynecologic oncologist includes simple criteria associated with an increased risk of malignancy before and after menopause.<sup>14</sup> When a woman with an adnexal mass documented at imaging examination meets one or more of the criteria (considered positive for high risk), she should be referred to a gynecologic oncologist.

### Index of Risk of Malignancy

The IRM is obtained by multiplying the score of ultrasonography (US) findings by the CA-125 value by 1 if the woman is premenopausal or 3 if the woman is postmenopausal (M), according to the formula ( $IRM = US \times CA-125 \times M$ ). We used the IRM as previously studied in our population by Torres et al.<sup>23</sup>

Next, two cutoff points for laparoscopy indication based on the risk scores and tumor diameter were defined: (1) The absence of ACOG guideline criteria (ACOG negative) associated with 3 different tumor sizes (10, 12, and 14 cm); and (2) IRM with cutoffs at 100, 200, and 300, associated with the same tumor sizes (10, 12, and 14 cm).

### Data Analysis

Data were stored in Microsoft Excel (Microsoft Corp., Redmond, Washington) spreadsheets and analyzed with the R Environment for Statistical Computing software.<sup>24</sup> All statistical calculations were performed using 95% confidence intervals, with  $P < .05$  considered to be significant. Women were classified into failure and successful groups according to laparoscopy outcomes (ie, laparoscopies converted to laparotomies for any reason or encountering a malignant tumor during laparoscopy = failure). For estimating the sample size required in this study, the major parameter was the difference in probability of failure between women (20%), grouped according to the median tumor size, presuming a type alpha error of 10% and a type beta error of 80%. With these parameters, it was estimated that 26 women were required for each group (below or above median tumor size). We used a recursive partitioning algorithm based on a linear regression model to confirm the contribution of age, CA-125 level, number

of prior abdominal surgeries, IRM, largest tumor diameter to failure. A conditional inference tree was generated, resulting in the determination of optimal cutoff points predicting laparoscopy failure. Next, we fit a logistic regression model to produce adjusted odds ratios (ORs) for each factor, considering as thresholds the optimal points provided by the Ward model. The resulting ORs are presented in **Table 1**. Finally, using the  $\chi^2$  and Fisher exact tests where appropriate, we tested whether different setups of IRM, ACOG, and largest tumor diameter were associated with laparoscopy failure (**Table 2**) and compared them with our baseline method of selection, which is the expertise of our gynecology-oncologists.

## RESULTS

Of 174 women operated on for an adnexal mass, surgeons selected 58 of those for laparoscopy. The baseline clinical characteristics of the women are shown in **Table 1**. Forty (69%) laparoscopies were considered successful and 18 (31%) were considered failures. The reasons for the 18 failures were 9 laparoscopies with malignant tumors, 5 converted to laparotomy because of intraoperative complications, and 4 converted to laparotomy because of a large tumor. Only tumor diameter  $>7$  cm was associated with laparoscopy failure (OR, 10.3, 95% CI, 2.47–42.95,  $P < .01$ ).

The results obtained applying the Absence of factors of the ACOG guideline (ACOG negative) in association with the different tumor diameters over the same population, in order to restrict the indication of laparoscopy, were the following: ACOG negative and tumor diameter less than 14cm would have restricted the indication of laparoscopy to 53 instead of 58 women and the laparoscopy was successful in 39 (74%) of the cases. This result was the same when restricting to tumor of less than 12cm. When the same was applied to tumors of less than 10cm the indication of laparoscopy would be restricted to 49 women and laparoscopy would be successful in 38 (78%) cases. Using the IRM as restrictive criterion we found that the cutoff at 300 points [(40/55 (73%) of successful laparoscopies] was superior to 100 [35/49 (71%)], 200 [(37/52 (71%)] and 400 [40/56 (71%)] as predictor of laparoscopy success. Associating the  $IRM < 300$  cutoff with tumor diameters of 14cm, 12cm and 10cm the rates of laparoscopy success were respectively: 38/51 (75%), 38/51 (75%) and 38/49 (78%) cases (table 2).

Table 2 compares the results of the surgeons' experience with the other selection criteria and demonstrates that the

**Table 1.**  
Clinical Characteristics of Women in the Study

Characteristic	Successful Laparoscopy (n = 40)	Unsuccessful Laparoscopy (n = 18)	Total (N = 58)	Adjusted OR (95% CI)	P Value (LR Test)
Age (y)					
Mean (SD)	46 (15)	50 (13)	47 (15)	0.9 (0.21, 3.9)	.887
BMI (kg/m <sup>2</sup> )					
Mean (SD)	27 (5)	27 (4)	27 (5)	1.2 (0.32, 4.52)	.792
Prior abdominal surgeries, n (%)					
0-1	31	11	42		
2+	9	7	16	0.92 (0.2, 4.26)	.917
CA-125 (U/mL)					
Mean (SD)	15 (14)	61 (106)	29 (63)	1.89 (0.45, 8.04)	.379
IRM					
Mean (SD)	39 (71)	370 (1181)	141 (666)	1.28 (0.32, 5.15)	.726
Largest tumor diameter (cm)					
Mean (SD)	5 (2)	7 (4)	6 (3)	0.1 (0.02, 0.4)	<.001

BMI = body mass index.

**Table 2.**

Comparison of Performance of Different Indexes Against Surgeons' Subjective Criteria for Selection of Women with Adnexal Mass for Successful Laparoscopy

Selection Criteria	Successful, n (%)	Unsuccessful, n (%)	Total N	P Value
Subjective <sup>a</sup>	40 (69)	18 (31)	58	
IRM <100	35 (71)	14 (29)	49	.78
IRM <200	37 (71)	15 (29)	52	.80
IRM <300	40 (73)	15 (27)	55	.66
IRM <300 D <sup>*</sup> < 10 cm	38 (78)	11 (22)	49	.31
IRM <300 D <sup>*</sup> < 12 cm	38 (75)	13 (25)	51	.52
IRM <300 D <sup>*</sup> < 14 cm	38 (75)	13 (25)	51	.52
IRM <400	40 (71)	16 (29)	56	.77
ACOG neg	39 (74)	14 (26)	53	.59
ACOG neg D <sup>*</sup> < 10 cm	38 (78)	11 (22)	49	.31
ACOG neg D <sup>*</sup> < 12 cm	39 (74)	14 (26)	53	.59
ACOG neg D <sup>*</sup> < 14 cm	39 (74)	14 (26)	53	.59

D<sup>\*</sup> = tumor diameter.

<sup>a</sup>Subjective surgeons' criteria; used as a baseline for evaluation of performance of the other indexes.

use of both ACOG guidelines and IRM associated with the tumor diameter is no better than the expertise of a gynecologist-oncologist for the evaluation of which cases should be operated by laparoscopy.

## DISCUSSION

This study evaluated a simple yet reproducible way to select women with an adnexal mass to be successfully

operated by laparoscopy by general gynecologic surgeons. We selected the IRM and the ACOG guideline for referral of patients to gynecologic oncology service because both have proven their usability to separate high risk from low risk for malignancy of adnexal masses and associated them with tumor volume because this appears to be the most recurrent tumor characteristic described as cause of laparoscopy failure and was associated with laparoscopy failure in our study. The results showed that both associations do not surpass the experience of a gynecology-oncologist for this intention.

For many years, surgeons have accumulated experience on minimally invasive surgery for the treatment of adnexal masses,<sup>1,5</sup> but even nowadays there are unanswered questions about the safety of this surgical approach for the treatment of malignant adnexal masses.<sup>4</sup> In addition, the complexity of surgical treatment of tubal and ovarian cancer is beyond the skills of some general gynecologic surgeons. The number of gynecology-oncologists, however, is limited around the globe, resulting in the near impossibility that all adnexal tumors be operated on by a specialist.<sup>19–25</sup> Appropriate selection and adequate intra-operative management are key points in the laparoscopic approach to adnexal masses.

For those reasons, the development of methods of selection of women of low risk for malignant adnexal mass to be operated on by laparoscopy by general gynecologic surgeons is desirable. In fact, in the United Kingdom, the IRM developed by Jacobs et al was studied and is currently in use with the cutoff point at 200 as a method of triage for referral of high-risk women for consult of a gynecology-oncologist.<sup>16</sup> Similarly, in the United States, the ACOG developed a guideline for basically the same principle.<sup>14</sup> However, the IRM and/or the ACOG guidelines alone did not seem to cope with the peculiarities of the minimally invasive surgery.<sup>2</sup>

In this study we tested whether the ACOG guideline for referral of adnexal masses to a gynecologic oncologist or the IRM associated with the tumor diameter could be better than the surgeons' experience alone to select women for successful laparoscopy.

Both the ACOG guideline and IRM, when associated with tumor volume, did not present better performance than our baseline assessment. We suppose this is a result of our surgeons' experience with selection of women with a high risk for malignancy because surgeons in this study are gynecology-oncologists. We think, however, that both methods are reproducible and easy to apply to all women with an adnexal mass, so when they are applied

by general gynecologists, they could be useful in improving the selection of women for successful laparoscopy. At the same time, the opinion of an expert gynecology-oncologist seems to still be the best option when the doubt of malignancy of an adnexal mass persists. Both selection criteria had similar results, but the ACOG guideline associated with tumor diameter seemed simpler to use because it is independent of calculations. However, new studies are necessary in different populations to assess the real usefulness of the association of the ACOG guideline and the IRM associated with tumor diameter for the selection of women with adnexal mass for laparoscopic surgery.

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