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# Adnex Method in Predicting Malignancy or Benignity in Adnexal Tumors in the Gynecology Service of the Federal Hospital of Ipanema

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## ABSTRACT

***Introduction:*** *Adnexal tumors are an important cause of gynecological care for patients in all age groups. Early diagnosis and treatment are important factors for prognosis, despite this, there is still no guideline for screening ovarian cancer. Pelvic ultrasonography (transvaginal or transabdominal) is a low-cost method of choice for assessing adnexal tumors, with a diagnostic accuracy of 89-92%.*

***Objectives:*** *This study aims to analyze the ability of ultrasound exams at the Hospital Federal de Ipanema (HFI) to predict malignancy and benignity in the study of adnexal lesions using the IOTA ADNEX method and correlate its findings with histopathological results.*

***Methods:*** *This is an observational and retrospective study correlating the ultrasound findings and the IOTA ADNEX calculation with the histopathological results of all patients undergoing surgery for adnexal tumor at the HFI from March 2019 to October 2020.*

***Results:*** *A total of 104 patients undergoing surgery for adnexal tumor from March 2019 to October 2020. From these, 48 patients (46%) had an ultrasound performed at the service with IOTA ADNEX calculation and histopathological result available. Benign cases totaled 39 patients (81.2%) and malignant (18.8%). For the cut-off point of 10%, we had a sensitivity of 100%, specificity of 84%, positive predictive value-PPV of 60%, negative predictive value-NPV of 100% and accuracy of 87%. For the cut-off points of 20% and 30%, we found, respectively, sensitivity 100% and 88%, specificity of 95% and 95%, PPV 99% and 80%, NPV 100% and 97% and accuracy of 95 % and 93%.*

***Conclusion:*** *The ADNEX model performed well in differentiating between malignant and benign lesions, especially with a 20% cut-off point. However, the cut-off point should be used in conjunction with the individualized clinical assessment of each patient. Further studies are needed to better define the cutoff point and performance of IOTA ADNEX at HFI.*

**Keywords**
Gynecology, Iota Adnex method, Malignancy, Benignity, Adnexal Tumors.

## Introduction

Adnexal tumors correspond to an important cause of gynecological care for patients in all age groups [1]. Ovarian cancer corresponds to the second most common gynecological cancer in Brazil and was responsible for 3921 deaths in women in 2020 [2,3]. Most women with adnexal tumors will not be diagnosed with cancer therefore; identifying patients with benign tumors allows us to avoid unnecessary interventions, reducing morbidity and treatment costs. necessary treatment, promoting better prognosis and quality of life [4,5].

Considering its relevance, early diagnosis and treatment have a great impact on the prognosis and consequently on the population [6]. Despite this, there is still no method for screening ovarian cancer and, therefore, no protocol for its diagnosis in early stages [7]. The *United Kingdom Collaborative Trial of ovarian Cancer Screening (UKCTOCS),* has been carried out since 2001, aiming at the development of a screening protocol for ovarian cancer, but no data have yet been found to justify a national screening guideline [8,9]. However, there were hopes that the group's new study: *Long term impact of screening on ovarian cancer mortality in the UKCTOCS* , offered new data, but the large-scale randomized trial of annual ovarian cancer screening, led by researchers at the University College London , demonstrated that deaths from the disease were not reduced, despite one of the tested screening methods detecting cancers earlier [9].

The diagnosis, then, is usually an incidental finding or when the patient already has symptoms, which in many cases occurs in more advanced stages of the disease. Pelvic ultrasound (transvaginal or transabdominal ) is a low-cost method of choice for evaluating adnexal tumors, with a diagnostic accuracy of 89-92% [10-12]. Despite its high sensitivity for identifying adnexal tumors, it has low specificity for detecting malignancy [13]. Several morphological aspects must be evaluated during the imaging exam to estimate the risk of malignancy of the lesion, some examples would be size of the lesion, presence of a solid component, appearance of the internal wall, content, presence of septations and their characteristics, vascularization, among others. The lack of standardized terms for describing these aspects and categorization of adnexal injuries generates diversified reports, confusing the clinician's interpretation [14].

With that in mind, an initiative was created to solve data standardization problems and formulate terms and methods for describing B-mode and Doppler images in ultrasound. The participants of this committee comprise the *International group Ovarian Tumor Analysis* (*IOTA*). Since 2005, the *IOTA* group has developed different models to assess the risk of malignancy from ovarian tumors. One of the most applicable and simple models, in which the sonographer does not need technology for calculations, is the "Simple Rules" (*Simple Rules),* created in 2008. This model is capable of classifying 75% of adnexal tumors and consists of classifying them as malignant when at least one of five findings of malignancy (*M- features)* - table *1*) is present and in benign when at least one out of five benign findings (*B- features - table 1*) is present. Tumors with characteristics of both groups or none of them are defined as inconclusive and another method must be used [15-17].

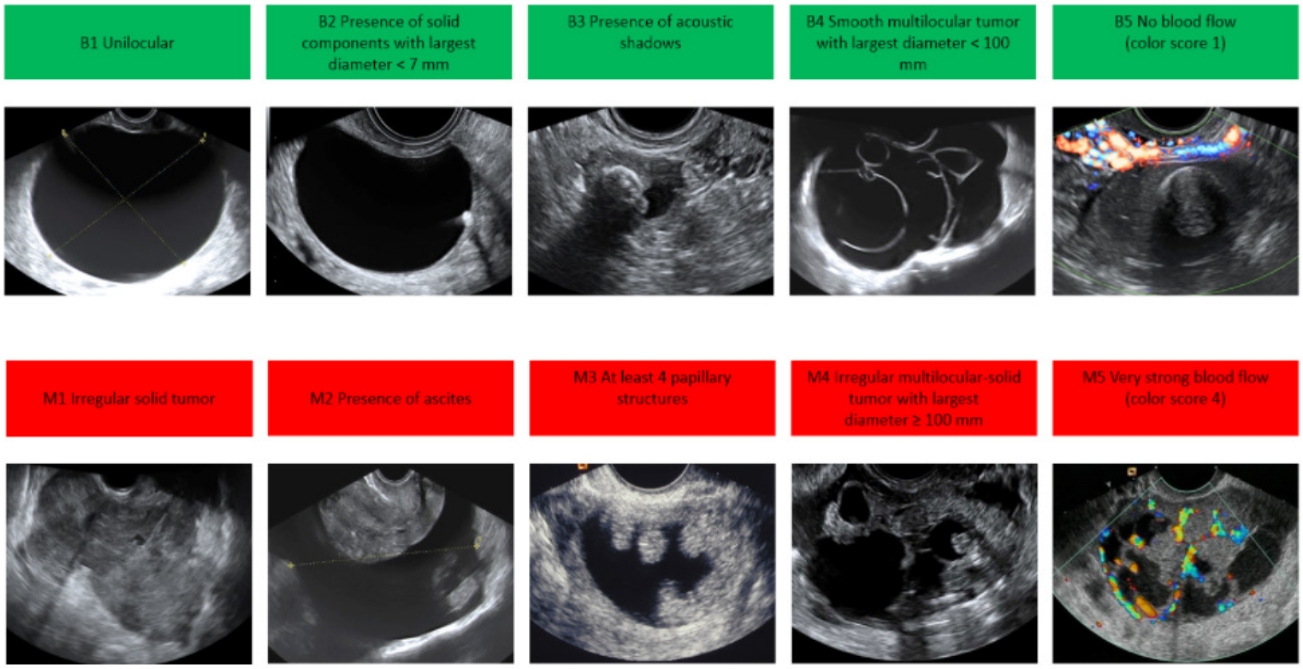


**Figure 1:** Illustration of findings "simple rules".

Source: International Ovarian Tumor Analysis (IOTA)

**Table 1:** Simple Criteria Rules.

| *M - FEATURES* | *B - FEATURES* |
|---|---|
| Presence ≥ 4 papillary projections<br>irregular solid tumor<br>Presence of ascites<br>Multilocular tumor with solid component ≥ 100mm<br>High flux on Doppler | Largest solid component < 7mm<br>unilocular cyst<br>acoustic shadow<br>Regular multilocular tumor with diameter < 100mm<br>No flow on Doppler |

Source: International Ovarian Tumor Analysis (IOTA)

The committee also defined six "typical findings" (*easy descriptors*), four benign and two malignant (Table 2), that allow instant diagnosis of certain tumors, facilitating the therapeutic approach.

**Table 2:** Easy Criteria Descriptors.

| | |
|---|---|
| *KINDNESS* | Unilocular cyst with ground-glass content (ENDOMETRIOMA)<br>Unilocular cyst with mixed contents and acoustic shadow (TERATOMA)<br>Unilocular cyst with regular walls and < 10cm (SIMPLE CYST/ CYSTADENOMA)<br>remaining cyst with regular walls |
| *MALIGNANCY* | Tumor with ascites and moderate flow on postmenopausal doppler<br>> 50 years and CA 125 > 100 U/ml |

Source: International Ovarian Tumor Analysis (IOTA)

In 2014, a more complex model was developed, the *Assessment of Different Neoplasms from the Adnexa (ADNEX)*. This model is based on three clinical criteria and six ultrasonographic criteria: age, serum level of CA-125, type of center (oncology center or other hospital center), and maximum lesion diameter, proportion of solid tissues, presence of > 10 locules per cyst, number of papillary projections, presence of acoustic shadow and presence of ascites (Table 3). Based on a mathematical calculation, the result offers the percentage of risk of malignancy and allows suggesting the staging of the disease [4,18].

**Table 3:** ADNEX Criteria.

| *CLINICS* | *ULTRASOUND* |
|---|---|
| Age<br>CA 125<br>type of center | Maximum diameter (mm)<br>Proportion of solid fabrics<br>Presence of > 10 locules per cyst (yes/no)<br>Number of papillary projections (0,1,2,3, >3)<br>Presence of acoustic shadow<br>Presence of ascites (yes/no) |

Source: International Ovarian Tumor Analysis (IOTA)

Considering the need for standardization of reports for a better approach and classification of patients, the gynecology service of the Federal Hospital of Ipanema (HFI), since 2019, has adopted as a protocol the performance of ultrasonography in the service of all patients treated with adnexal tumors and reports based on in *the* IOTA *ADNEX* model. As it was a new model and new protocol added to the service, it motivated this study.

*ADNEX* model in differentiating malignancy and benignity of adnexal tumors in patients undergoing surgery for adnexal tumors at the Federal Hospital of Ipanema, using the histopathological result as the gold standard.

## Methods

This was a monocentric, observational and retrospective study, carried out in a tertiary health unit, specializing in oncology and gynecology. All patients who underwent surgery for adnexal tumor from March 2019 to October 2020 were selected through the surgical map database of the gynecology service. All patients who underwent surgery for adnexal tumor at the Federal Hospital of Ipanema and who had an ultrasound performed at the Gynecology service with risk calculation using the IOTA ADNEX model were included. We excluded patients who did not have an ultrasound performed by the HFI gynecology service or who did not have the IOTA ADNEX calculation, as well as patients whose histopathological report was unavailable on the date of data collection.

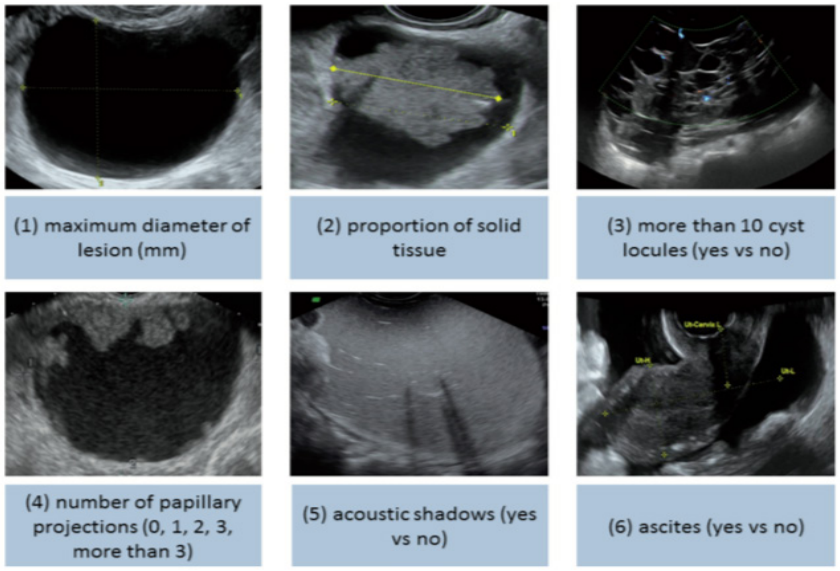


**Figure 2:** Illustration of the ADNEX criteria.

Source: International Ovarian Tumor Analysis (IOTA)

The ultrasounds were performed in a TOSHIBA XARIO ISTYLE device with an endocavity transducer 4.0 to 9.0 MHz with gray scales and color Doppler. The 3.0 to 7.0 MHz convex transducer, used when the abdominal route was necessary for complementation.

The exams were performed by two different professionals, both with the same training and qualified to perform ultrasound exams in gynecology. The ADNEX calculation in the present study did not include the serum level of CA 125. However, we believe that, as verified by Chen et al., [19] and described by Van Calster, et al. [20], the omission of CA 125 in the ADNEX calculation has a limited impact on the differentiation between benign and malignant pathology 7, which is the main objective of this study.

We used 3 cutoff points to calculate sensitivity, specificity, positive and negative predictive values and accuracy, namely 10%, 20% and 30%. The histopathological result was defined as the gold standard test. The histopathological reports were evaluated by different pathologists who make up the HFI's professional body.

A total of 104 patients who underwent surgery for adnexal tumors were found based on data collected from the archives of the HFI gynecology service. Of these, only 52 (50%) patients had an ultrasound report from the service with IOTA ADNEX calculation. Four patients (7.6%) were excluded due to unavailable histopathological results, resulting in a final sample of 48 patients who met the inclusion criteria for the study.

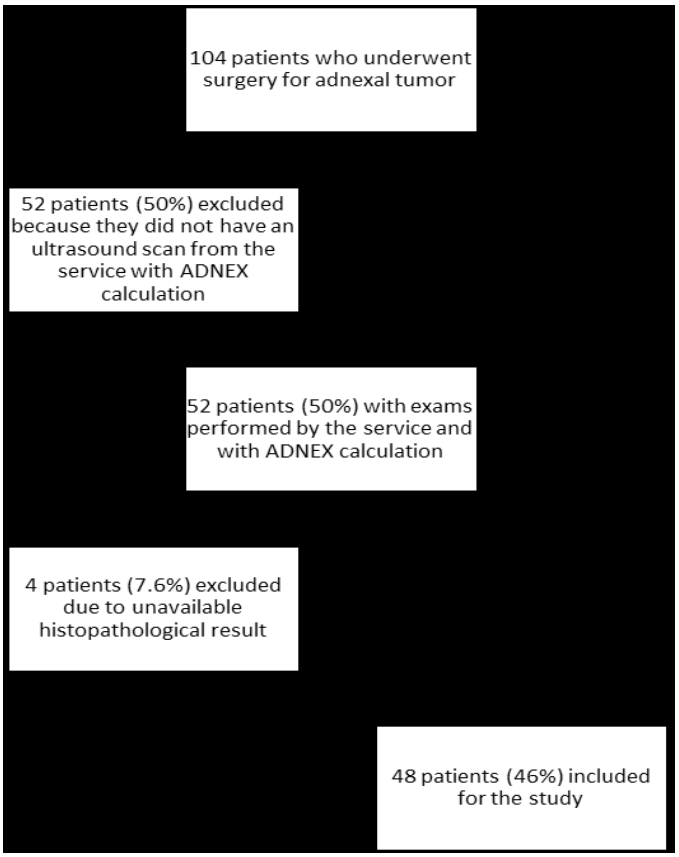


**Figure 3:** Patient selection organization chart.

## Results

From March 2019 to October 2020, a total of 104 patients underwent surgery at the HFI due to adnexal tumor. Of these, only 48 patients met the inclusion criteria for the study. Among the participants, 24 (50%) were aged 18-50 years and 24 (50%) were aged > 50 years. The histopathological result was malignant in 09 cases (18.8%) and benign in 39 cases (81.2%). Of the malignant tumors, 3 cases (33%) were classified as borderline tumors, 2 cases as serous carcinomas (22%), 1 case as a sex cord tumor (11%), 1 case as Yolk tumor sac (11%) and 1 case (11%) as extra-ovarian malignancy. Among the benign pathologies, the vast majority (33.3%) were classified as serous cystadenomas. These findings are illustrated in table 4.

**Table 4:** Histopathological results found.

| ***Histopathological*** | ***No*** | ***%*** |
|---|---|---|
| **benign** | **39** | **81.2** |
| serous cystadenoma | 13 | 33.3 |
| mucinous cystadenoma | 5 | 12.8 |
| simple cyst | 3 | 7.69 |
| serous cystadenofibroma | 3 | 7.69 |
| endometrioma | two | 5.12 |
| hydrosalpinx | two | 5.12 |
| ovarian abscess | 1 | 2.5 |
| broad ligament cyst | 1 | 2.5 |
| Brenner tumor | two | 5.12 |
| functional cyst | two | 5.12 |
| mature cystic teratoma | 1 | 2.5 |
| Fibrous and serous cystadenoma | 1 | 2.5 |
| Epithelial inclusion cysts | 1 | 2.5 |
| Ossified Fibroma | 1 | 2.5 |
| cystic follicles | 1 | 2.5 |
| **Borderline** | **3** | **6.25** |
| serous borderline tumor | 1 | 33.3 |
| Borderline seromucinous tumor | 1 | 33.3 |
| mucinous borderline tumor | 1 | 33.3 |
| **malignant** | **6** | **12.5** |
| low grade serous carcinoma | two | 33.3 |
| colon adenocarcinoma | 1 | 16.6 |
| sex cord tumor | 1 | 16.6 |
| immature teratoma | 1 | 16.6 |
| Yolk sac tumor | 1 | 16.6 |

The age of patients with a diagnosis of benign pathology ranged from 18 to 76 years and of malignant pathology from 20 to 67 years. The mean age found for both categories was 49 years, with a standard deviation of 16 years for benignity and 18 for malignancy. We verified a predominance of the presence of solid component among malignant pathologies and of larger diameters of solid part in this category. The presence of ascites was a finding exclusive to malignant pathologies and acoustic shadow exclusive to benign pathologies.

Based on these findings, the calculation of sensitivity, specificity, negative predictive value and positive predictive value and accuracy were calculated considering the cutoff points of 10%, 20% and 30%. For the 10% cutoff point of *IOTA ADNEX* we had a sensitivity of 100% and a specificity of 84%. The probability

of malignant disease when *ADNEX* ≥ 10% (positive predictive value-PPV) was 60% and the probability of benignity when < 10% (negative predictive value-NPV) was 100%. The accuracy for the 10% cutoff point was 87%. For the cutoff points of 20% and 30%, we found, respectively, sensitivity 100% and 88% and specificity of 95% and 95%, PPV 99% and 80%, NPV 100% and 97%, as well as accuracies of 95 % and 93%. The values obtained are shown in tables 5, 6 and 7 and will be discussed below.

Table 5: ADNEX 10%.

| ***Histopathological*** **ADNEX** | ***Malignant*** | ***Benign*** |
|---|---|---|
| ≥ 10% | 9 | 6 |
| <10% | 0 | 33 |

| *Only 100%* | *And 84%* |
|---|---|
| VPP 60% | VPN 100% |
| Accuracy: 87% | |

Table 6: ADNEX 20%.

| ***Histopathological*** **ADNEX** | ***Malignant*** | ***Benign*** |
|---|---|---|
| ≥ 20% | 9 | two |
| <20% | 0 | 37 |

| *Only 100%* | *And 94%* |
|---|---|
| VPP 99% | VPN 100% |
| Accuracy: 95% | |

Table 7: ADNEX 30%

| ***Histopathological*** **ADNEX** | ***Malignant*** | ***Benign*** |
|---|---|---|
| ≥ 30% | 8 | two |
| <30% | 1 | 37 |

| *S 88%* | *And 94%* |
|---|---|
| VPP 80% | VPN 97% |
| Accuracy: 93% | |

Due to the small number of cases of malignancy and their diversity of histopathological results, it was not possible to evaluate the cutoff points for discrimination in the subtypes of malignant pathology that the original study of the IOTA group proposes [19].

## Discussion

Some studies found that the subjective evaluation of the ultrasound image of adnexal tumors, even if performed by an experienced professional, leads to misclassification, especially of borderline tumors in approximately 50% of cases [21-23]. A similar finding was found by Viora, et al. [24], reinforcing the importance of a more efficient model in predicting malignancy.

In view of this importance, several risk calculation models have been developed in recent years. The *Assessment of Different Neoplasms from the Adnexa (ADNEX) is the most recent model created by the IOTA* group and also the most elaborate [25]. After its publication in 2014, many works were carried out in several centers to validate the performance of the model.

A prospective observational study published in 2014 in the British Medicine Journal (BMJ) by the *IOTA* group, with data collected from 24 centers in 10 countries, with a total of 5,909 patients, concluded that the *ADNEX model* is capable of adequately discriminating malignant and benign lesions, as well as it also makes good discrimination between the 4 types of ovarian malignancies [20]. Despite this, we must take into account that the definition of a rigid cutoff point can lead to suboptimal results and often even act unethically as described by Van Calster, et al. [20], generating an evaluation and treatments managed by technology and not centered on the individualized patient.

*IOTA* group published 2015 in the Journal of the European Society for Gynecological Endoscopy (ESGE) an article suggesting ways to apply *ADNEX* to clinical practice by performing a 2-step model. The first step with *ADNEX calculation*, classifying the tumors as benign or malignant according to the cutoff point defined by the health unit. This first step could be carried out without measuring CA 125 without major damage. In this first stage, patients classified as benign could, after individualizing each case, be clinically followed up. Those that were classified as malignant would enter the second stage and would be referred to the oncogynecologist for classification into 4 subtypes of malignancy (borderline, stage 1, stage 2-4 and metastatic carcinoma) to define the best surgical approach [20].

In our study, we limited ourselves to analyzing the data and performance of the *IOTA ADNEX model* in the discrimination of benign and malignant pathologies. Furthermore, the CA 125 dosage was not used for the calculation, as previously described. In this way, considering the two-step model suggested by *IOTA*, we evaluated the *ADNEX model* in the first step.

When evaluating the criteria for calculating the *ADNEX,* we did not find any strong relationship between any criterion and the diagnosis of malignancy or benignity. The presence of ascites was a finding exclusive to malignant pathologies and acoustic shadow exclusive to benign pathologies. However, the number of cases was too small to suggest a causal relationship. Although the presence of acoustic shadow has already been defined as a benign criterion [26,27].

Correlating our findings with those described by the *IOTA group,* we found some differences. The original study found a sensitivity of 96.5% and specificity of 71.3% with a cutoff of 10% [20]. Our study found sensitivity of 100% and specificity of 84% for the same cutoff point. Araujo, et al. [28] , used a cutoff of 15% and found results similar to the *IOTA study* for sensitivity (91.2%) and specificity (71.4%). The difference found is probably related to the small sample size of our study and we believe that future studies with a larger number of patients should find values similar to those described in the literature.

Analyzing the values found, we can conclude that the cutoff point with the greatest balance between sensitivity and specificity found would be 20%. A similar result was described by a retrospective

study carried out in the Netherlands, with a sample of 326 patients, which found the optimal cutoff point of 26.1% [29]. Despite the values found, we suggest that more studies be carried out, with a larger sample of patients to define an optimal cutoff point for the gynecology service at the HFI.

According to the data shown in this study, we can see that the *IOTA ADNEX* is a good tool in the preoperative discrimination of benign and malignant adnexal tumors in the gynecology service of the Federal Hospital of Ipanema.

Attention should be given to the fact that the study analyzed only the patients who underwent surgery, therefore, not evaluating the data of patients undergoing clinical follow-up and their outcomes. It is important to emphasize that, of the 104 cases selected in the HFI surgeries database, only 50% of the cases had an ultrasound performed by the service with *IOTA ADNEX calculation*. This finding shows us that, despite having implemented the calculation for all exams performed at the HFI gynecology service, many patients undergoing surgery do not have an imaging exam performed by the service, but from other units that do not perform the calculation.

## Final Considerations

We were able to verify that the data found in our study are close to those found in the literature, which confirms that the values found are reliable, despite the small sample available.

*ADNEX* model had a good performance in discriminating malignant lesions, mainly with a cutoff of 20%, offering a positive predictive value of 99% and accuracy of 95%.

In this way, we believe that the use of the calculation for preoperative evaluation is valid and can help in defining the best strategy for each patient, always taking into account that the defined cutoff point is interpreted individually for each patient considering other aspects , such as past pathological history, comorbidities, surgical risk, reproductive desire, symptoms, among others. We therefore suggest that an ultrasound be performed by the gynecology service at the HFI, with the calculation of the *IOTA ADNEX*, for all patients treated with adnexal tumors, even if they have had recent exams performed in another unit. The definition of a specific cutoff point for the HFI service requires further studies and a larger sample, so it is more prudent to use the cutoff point suggested by the original study of the IOTA group of 10% until new evaluations are *made.* Performed. We also reinforce that the spreadsheet created for this study, whenever a patient undergoes surgery for adnexal tumor, will facilitate future studies and, if it is interesting to the service and residents, it should be incorporated as a service protocol.

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