# Relevance of International Ovarian Tumor Analysis (IOTA) ultrasound rules and ADNEX risk calculator in the investigation of ovarian masses in a semi-rural Indian population

# Archna A.Tolani, Nevine Anandan<sup>1</sup>, Nikhil M. Bhuskute<sup>2</sup>, Priti Kapoor

Department of Radio-Diagnosis, MGM Institute of Health Sciences, Kamothe, Navi Mumbai, Maharashtra, India, <sup>1</sup>Radiology Registrar, Leeds Teaching Hospitals NHS Trust, LS13EX, <sup>2</sup>Department of Radio-Diagnosis, MGM Institute of Health Sciences and Consultant at Calderdale and Huddersfield NHS Trust, HX3 OJQ, United Kingdom

## ABSTRACT

**Aims:** The study was undertaken to assess the efficacy of the International Ovarian Tumor Analysis (IOTA) ultrasound rules and the IOTA- Assessment of Different NEoplasias in the adneXa (ADNEX) model risk calculator in the investigation of ovarian masses in a semi-rural Indian population.

**Methods and Material:** The study was a retrospective study. The pre-operative ultrasound images of all patients who had surgery for an adnexal mass over a two year period were looked at and classified according to the IOTA-ADNEX model calculator. **Results:** There were 45 patients who had surgery for an adnexal mass of which 78% had benign findings, 15% were malignant, and 6% were borderline on the final histological diagnosis. After retrospectively applying the ADNEX calculator, the study confirmed the low false positive (4%) and false negative (2%) rates, and this was despite not having cancer antigen 125(CA125) in hand at the time of the scan. There was one case where an adnexal lesion was classified benign on ultrasound, but was proven to be malignant on histology and as per the ADNEX model risk calculator.

**Conclusions:** The study results showed vast potential in the management of adnexal masses in countries where costs, healthcare providers, infrastructure, and patient follow-up can be limited. The use of a predictive algorithm like the ADNEX model can help reduce anxiety, provide reassurance, and importantly avoid unwarranted surgery in patients with benign pathologies.

Key words: Adnexal; IOTA- ADNEX; masses; ultrasound.

# Introduction

The International Ovarian Tumor Analysis (IOTA) group has shown that polytomous risk prediction for the diagnosis of ovarian cancer is feasible.<sup>[1]</sup> The IOTA ultrasound rules for ovarian masses are a simple set of ultrasound findings that classify persistent adnexal masses into benign (B-features), malignant (M-features), or inconclusive (features of both benign and malignant), for the latter evaluation by a specialist in ovarian imaging is recommended.<sup>[2]</sup>

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Correctly discriminating between benign or malignant adnexal masses is the essential starting point for optimal management. Most women with an adnexal mass do not

Address for correspondence: Dr. Archna Ashok Tolani, Department of Radio-Diagnosis, MGM Hospital, MGM Institute of Health Sciences, Kamothe, Navi Mumbai, Maharashtra, India. E-mail: archnatolani@gmail.com

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have cancer.<sup>[3]</sup> Identifying women with benign pathology is important in order to avoid unnecessary intervention as well as needless costs.<sup>[4]</sup>

# Aims

To assess the efficacy, false positives or false negatives, of IOTA ultrasound rules in classifying ovarian masses in women from a semi-rural Indian population attending Mahatma Gandhi Mission's Hospital, Kamothe and Mahatma Gandhi Missions Mother and Child care Hospital, Kalamboli located in Navi Mumbai, Maharashtra, India.

# Subjects and Methods

Ethics: Not submitted to the ethical committee as performed as a retrospective study.

## Source of data

Women who were referred to the Department of Radio Diagnosis, Mahatma Gandhi Mission's Hospital, Kamothe or Mahatma Gandhi Mission's Mother and Child Care Hospital, Kalamboli for an adnexal mass and subsequently underwent surgery for the same. The study was conducted over a period of 27 months between May 2016 and August 2018.

## Method of study

A retrospective study was done looking at the pre-operative ultrasound images of all consecutive patients who underwent surgery for an adnexal mass at Mahatma Gandhi Mission's Hospital, Kamothe or Mahatma Gandhi Mission's Mother and Child Care Hospital, Kalamboli. The ultrasound machines used were Philips HD 11 and Phillips HD 15 and were performed by senior radiology residents who had at least 2 years experience in ultrasound scanning.

This study was carried out in a semi-rural population where cancer antigen-125 (CA-125) values were not available at the time of diagnostic imaging. Hence that parameter was not used at the time of calculation.

Patients who had suspected benign pathology on ultrasound scan (USS) generally had three follow up USS scans. They were operated upon only if they remained symptomatic or were peri menopausal with persistent clinical concern.

The reference standard was the histological classification of the excised adnexal mass stratified as benign, malignant, or borderline.

The IOTA ultrasound rules<sup>[5]</sup> are shown in Figure 1.

#### Table 1: Showing the ADNEX model calculator

Table 1 IOTA ADNEX calculator

- 1. Age of the patient at examination (years)
- 2. Oncology center (referral center for gyn-oncol)?
- 3. Maximal diameter of the lesion (mm)
- 4. Maximal diameter of the largest solid part (mm)
- 5. More than 10 locules?
- 6. Number of papillations (papillary projections)
- 7. Acoustic shadows present?
- 8. Ascites (fluid outside pelvis) present?
- 9. Serum CA-125 (U/ml)

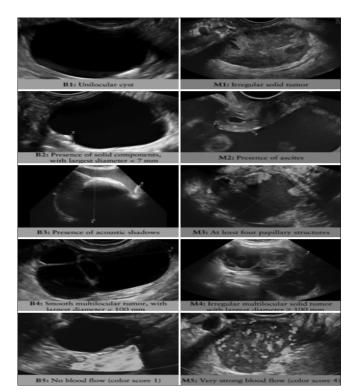


Figure 1: Shows the IOTA ultrasound rules

The ADNEX model has been used in evaluating the risk of ovarian cancer before surgery to help differentiate between benign, borderline, early and advanced stage invasive, and secondary metastatic tumors.<sup>[1]</sup> The risk model discriminates well between benign and malignant tumors and offers fair to excellent discrimination between the four types of ovarian malignancy.<sup>[1]</sup>

The following parameters assign a risk score on the ADNEX calculator [Table 1].

## Data analysis

The data from ultrasound images was used to classify the masses using IOTA-ADNEX model calculator as benign, malignant, or inconclusive. It was then compared with the histological diagnosis. We also reviewed if there was any disparity among the initial ultrasound diagnosis, IOTA-ADNEX model evaluation diagnosis, and histological diagnosis.

# Results

There were 45 patients in the aforementioned period, ages varying between 15 and 97 that underwent surgery for a persistent adnexal mass. The mean and median ages were 38 and 35 years respectively.

Only 7 patients were post-menopausal, the remaining 38 being pre-menopausal. There were 35 (77.8%) benign cases[Figures 2-4], 7 (15.5%) malignant, and 3 (6.7%) borderline cases on post-operative histological diagnosis. No metastatic ovarian lesions was identified in our study population.

Table 2 shows the various histological diagnoses obtained post-operatively.

Of the 7 malignant lesions, only 1 patient was postmenopausal. The remaining 6 were pre and peri-menopausal. The borderline cases were all pre-menopausal.

After retrospectively applying the IOTA-ADNEX risk calculator, there were only 2 cases where the calculation suggested that the mass was malignant, but was disproved on histology to



Figure 2: Transvaginal sonogram showing a well defined mass lesion in the adnexa containing thick non mobile echoes and echogenic areas within which show posterior acoustic shadowing corresponding to calcification. The mass was classified as benign according to IOTA ADNEX model and histopathology confirmed diagnosis of mature cystic teratoma

Table	2:	Listing	histological	diagnosis	in	each	category

be benign lesions (false positives). The initial USS findings suggested a neoplastic mass in 1 patient and a germ cell tumor in the other. Both cases had ischemic necrosis on histology.

There was 1 case where the IOTA ultrasound rules suggested benignity, but the mass proved malignant on histology (false negative). This was a case of low grade serous borderline tumor of the ovary in a 20-year-old patient who had benign appearances on the initial ultrasound and had surgery due to being symptomatic.

When the IOTA ADNEX rules were not followed, and clinical diagnosis was mainly based on USS findings, there was one case where the USS findings suggested benign features, but proved to be a mucin secreting adenocarcinoma, and was accounted to be malignant as per the ADNEX calculation even without the CA125 results [Figure 5].

# Discussion

The study shows that the IOTA rules and ADNEX model have a very high sensitivity and specificity and can be reliably applied in a population setting where costs are important and also avoids unwarranted surgery.

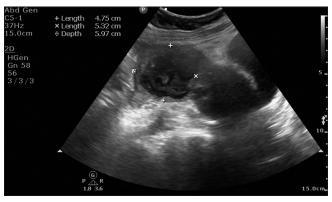


Figure 3: Transabdominal gray scale image of a right adnexal mass lesion, which was well defined with echogenic strands within and on color Doppler imaging (not shown), showed only peripheral vascularity. It was classified as benign according to IOTA ADNEX calculator and proved to be oophoritis on histopathology

Histological diagnosis						
Benign - 35	Malignant -7	Borderline- 3				
Serous cystadenoma-7	Mucinous carcinoma-3	Borderline serous tumor-2				
Simple cysts - 6	Serous cystadeno-carcinoma- 3	Borderline mucinous tumor -1				
Hemorrhagic cysts- 5	Poorly differentiated adenocarcinoma -1					
Dermoid - 3						
Endometrioma -3						
Corpus luteal cyst -2						
Others including hemorhagic ischemic necrosis, fimbrial cyst, mucinous cystadenoma, fibroma, retained products of conception, oophoritis etc - 9						

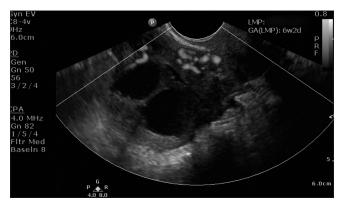


Figure 4: Transvaginal sonogram which showed a adnexal mass lesion with features of endometrioma. According to IOTA ADNEX calculator it was benign and proved to be benign on histopathology as well

There were one false negative (2%) and two false positives (4%) using the above and this was despite not having CA125 at hand for aiding diagnosis. This could be possibly reduced even further if the serum marker is available at the time of the scan; however adding CA-125 to clinical and ultrasound information does not improve discrimination of mathematical models between benign and malignant adnexal masses.<sup>[6]</sup> The use of ADNEX has the potential to improve triaging and management decisions and thereby reduces morbidity and mortality associated with adnexal pathology.<sup>[1]</sup>

It is already confirmed that in well-trained and experienced hands, subjective impression about an ovarian mass is very accurate although not all ultrasound practitioners can perform at this level. This is where a predictive algorithm like IOTA-ADNEX scoring can help less experienced sonographers.<sup>[7,8]</sup> In a health model where a large proportion of patients do not have access to expensive investigations, adherence to the ADNEX model was found safe to apply. The shortage of healthcare providers is most acute in rural areas; this is further compelled by the lack of infrastructure and resources. This simple approach would help reduce the anxiety, economic burden, and unnecessary surgical intervention for patients.

## **Clinical significance**

The study findings were presented locally and new USS machines with incorporated IOTA ADNEX risk calculators were agreed to be brought into the Radiology department. This will help easy risk assessment at the time of the scan and provide patient reassurance as well as importantly help avoid unnecessary surgeries.

In rural India, where patients often have limited funds and long-term patient follow up is extremely difficult, ultrasound is clearly the imaging test of choice in a variety of circumstances.<sup>[5]</sup>



Figure 5: Large mass lesion arising from the adnexa in a 47-year-old premenopausal woman, which was suspected to be a benign tumor of the ovary, however according to IOTA ADNEX model it was of malignant etiology. Post operatively, mucin secreting adenocarcinoma was confirmed on histopathology

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## **Conflicts of interest**

There are no conflicts of interest.

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