

ORIGINAL ARTICLE

*Evaluation of International Ovarian Tumor Analysis Group (Iota) Simple Ultrasound Rules to Distinguish Between Benign and Malignant Ovarian Tumors in Tertiary Care Centre*Priyadarshini Adsul¹, Shilpa Chaudhari¹, Kishorkumar Hol¹ and Shraddha Shastri¹¹Department of Obstetrics and Gynaecology¹ Smt. Kashibai Navale Medical College and General Hospital, Pune-411041, Maharashtra, India**Abstract:**

Introduction: Ovary is a totipotent organ by totipotent meaning egg which is released from ovary has potential to fuse with sperm and can construct a complete, viable organism. Cells produced by first divisions of fertilised egg are also totipotent. with a propensity for developing cysts or masses. An adnexal mass (mass of ovary, fallopian tube, or surrounding connective tissues) is a common gynaecological problem. Adnexal masses present a diagnostic dilemma; the differential diagnosis is extensive, and most masses are benign. Ultrasound is typically the first-line imaging tool, and several ultrasound- based scoring system exists for assessing the risk of an ovarian tumor to be malignant. The IOTA group published ultrasound simple rules to distinguish adnexal mass into benign malignant or intermediate. To assess diagnostic performance of International Ovarian Tumor Analysis (IOTA) simple ultrasound rules to distinguish ovarian masses and benign or malignant, and to correlate ultrasound findings with histopathology report.

Material and Methods: This is a prospective based study was conducted in Obstetrics and gynaecology department of tertiary care hospital. Total 75 patients were evaluated, who fulfilled all inclusion criteria. On these patients transvaginal ultrasonography was performed. IOTA simple rules check list filled and at the end mass was classified as benign if one or more B features were present in the absence of M features. Mass was classified as malignant if one or more M features were present in the absence of B features. If both B and M rules were applied or none were present, the mass was classified inconclusive. And after surgery histopathological co-relation was done.

Results: Out of 75 patients evaluated with ultrasonographically with IOTA simple rules 52 were benign, 14 were malignant, and 9 were found inconclusive. Out of total 75 patients studied on IOTA findings 52 patients had benign mass of only 51 were

confirmed histopathologically. And 1 mass was found to be malignant on histopathologically which prior on USG IOTA showed B features. Out of 14 malignant patients diagnosed from IOTA, 8 patients had benign mass which was found on histopathology report and 6 were confirmed malignant histopathologically. Sensitivity for detection of malignancy in cases where IOTA simple ultrasound rules were applicable was 85.71%, and specificity is 86.44%.

Conclusion: Our study shows that the IOTA simple ultrasound rules are able to differentiate more accurately between benign, borderline and malignant ovarian tumors. Therefore, it improves the decisions of patient triage and management.

Keywords: Ovarian tumors, International ovarian tumor analysis (IOTA), ultrasonography (usg), sensitivity, specificity, ca-125, histopathology report.

Introduction:

Ovary is a totipotent organ by totipotent meaning egg which is released from ovary has potential to fuse with sperm and can construct a complete, viable organism. Cells produced by first divisions of fertilised egg are also totipotent. with a propensity for developing cysts or masses. Ovarian cysts or masses may represent physiologic cysts, benign neoplasms, or malignant neoplasms.^[1] An adnexal mass (mass of ovary, fallopian tube, or surrounding connective tissues) is a common gynaecological problem. Adnexal masses present a diagnostic dilemma; the differential diagnosis is extensive, and most masses are benign.^[2] Overall 70 % of ovarian masses are benign and about 30% are malignant. The main objective of imaging patients with symptoms suggestive of ovarian lesions is to distinguish benign findings from malignant findings. Masses can be characterised with a variety of non invasive imaging techniques, including transabdominal and transvaginal ultrasound, CT, MRI. Each of these modalities have its advantages and limitations. Appearance of benign and

malignant lesions on imaging can sometimes have overlapping characteristics, creating a diagnostic dilemma. This should be borne in mind, whichever modality is chosen. Ultrasound is typically the first-line imaging tool. It is readily available, free from ionising radiation, and able to provide important information on adnexal masses in certain cases.^[3] It can help determine whether a mass is ovarian or extra-ovarian, solid or cystic, simple or complex, and vascular or avascular. It can also be used to monitor lesions that are thought to be benign. Ultrasound has a high sensitivity for the detection of malignant ovarian masses. Several ultrasound- based scoring system exists for assessing the risk of an ovarian tumor to be malignant. The IOTA group published ultrasound simple rules to distinguish adnexal mass into benign malignant or intermediate. This has the best predictive test for Pre operative classification of adnexal tumors. This helps the specialist to make management decisions. It is simple and easy to use, and have been validated by multiple reports.^[4] The steering committee of International Ovarian Tumor Analysis (IOTA) group help special meetings to discuss the problems of standardisation and to formulate terms and procedures to derive morphologic end-points by B-mode imaging and end-points of vascularity and blood flow by color Doppler imaging.^[5] Objective of this study is to assess diagnostic performance of International Ovarian Tumor Analysis (IOTA) simple ultrasound rules to distinguish ovarian masses into benign or malignant and to correlate ultrasound findings with histopathology report.

Material and Methods:

This is a prospective based study was conducted in Obstetrics and gynaecology department of tertiary care hospital during period of 2 years Oct 2020 to Oct 2022. Once the patients were enrolled for the study, a thorough history and physical examination was done as per pro forma. An informed consent was taken in written from patients or patient's attendant. A detailed history, clinical findings and investigations of admitted patients were noted in ward as per pro-forma. On selected cases transvaginal ultrasonography was performed in standardised manner. Transabdominal sonography was performed incase of large mass could not be fully assessed transvaginally. During examination assessment of sonographic morphology of masses together with color Doppler study was performed to characterise masses. Then evaluated the mass for presence or absence of each benign or malignant ultrasound feature. Then IOTA simple rules check list will be filled by reading original paper published by

IOTA group. At the end of examination, Mass was classified as benign if one or more B features were present in the absence of M features. Mass was classified as malignant if one or more M features were present in the absence of B features. If both B and M rules were applied or none were present, the mass was classified inconclusive.

Results:

Table1: Simple IOTA rules for predicting benign or malignant ovarian tumors

B Rules	M Rules
B1- unilocular cyst.	M1- irregular solid tumor
B2- presence of solid component where largest solid component is < 7 mm in diameter.	M2- presence of ascites.
B3- presence of acoustic shadows.	M3- at least 4 papillary structures.
B4- smooth multilocular tumor with largest diameter <10 cm.	M4- irregular multilocular solid tumor with largest diameter \geq 10 cm.
B5- no blood flow.	M5- very strong blood flow.

Surgery was performed in case of mass was found persistent. In case of symptomatic masses suspected malignancy or at the patients request surgery was performed more quickly either by laparoscopy or laparotomy. All patients included in the study underwent surgery (within 120days of usg examination). Histopathologic diagnosis of all patients was done postoperatively and used as gold standard. Collected data was statistically analysed using chi square test and kappa statistical method.

Table 2: Distribution of patients according to age

Age(in years)	No. of patients	Percentage
15-25	17	22.66
26-35	26	34.66
36-45	14	18.67
46-55	11	14.67
56-65	4	5.34
66-75	3	4
Total	75	100

Table 2 and depicts Majority of the subjects were in age group of 26-35. About 34.66%. And only 5.34% were in age group of 56-65. Youngest patient in present study was 16 year old. Eldest was 74 year old female. Mean age is 36.3years. Table 3 depicts as IOTA rules classified 75 patients, 52 benign, 14 malignant. And for 9 cases rules could not be applied or where both B and M

rules were applicable were labelled as inconclusive cases.

Table 3: classification of cases as per IOTA simple ultrasound rules.

No. As per IOTA rules	Number
Benign	52
Malignant	14
Inconclusive	9
Total	75

Table 4: comparison of results of IOTA simple ultrasound rules with Histopathological findings

No. of mass as per IOTA	Number	Histopathological result	
		Benign	Malignant
Benign	52	51	1
Malignant	14	8	6
Inconclusive	9	9	0
Total	75	68	7

Table 4 depicts out of total 75 patients studied on IOTA findings 52 patients had benign mass of only 51 were confirmed Histopathologically. And 1 mass was found to be malignant on histopathologically which prior on USG IOTA showed B features. Out of 14 malignant patients diagnosed from IOTA, 8 patients had benign mass which was found on histopathology report and 6 were confirmed malignant histopathologically. Out of 9 inconclusive cases all were found to be benign histopathologically. Table 5 depicts 65% patients had CA-125 level <50 IU. 7% patients had CA-125 level between 51-100 IU. About 3% had CA-125 level between 101-200 IU. And 4% had > 200 IU CA-125 levels. About 21% patients CA-125 levels were not done.

Table 5: distribution of study subjects based on CA-125 level values

CA-125	Frequency	Percentage
<50	49	65.34
51-100	5	6.66
101-200	2	2.66
>200	3	4.00
Not done	16	21.34

These 9 patients had both benign and malignant features on usg findings. So these were classified as inconclusive on IOTA simple ultrasound rules. CA125 levels in 7 patients were below < 35 IU . And in 2 patients CA125 levels were >50IU. These patients further went for surgery and on Histopathological correlation all were found to be benign .

Table 6: comparison between sonographic and histopathological findings of inconclusive cases.

Sr. No	Sonographic findings (IOTA rules)	CA-125	Histopathology Report
1	B5+M2+M4	10.3	Serouscystadenoma
2	B3+M1+M4	34.6	Thecoma fibroma
3	B5+M4	57.6	Mucinouscystadenoma
4	B4+M5	20	Tubo-ovarian mass
5	B4+M4	56.1	Mucinouscystadenoma
6	B1+M4	18.7	Serouscystadenoma
7	B1+B2+M5	26	Serouscystadenoma
8	B5+M4	31.5	Mucinouscystadenoma
9	B5+M4	20.6	Serouscystadenoma

Table 7 : correlation of IOTA simple ultrasound rules with histopathological findings kappa coefficient .

IOTA simple ultrasound rules findings	Histopathology Report	
	Benign	Malignant
Benign	51	Benign
Malignant	8	Malignant

Table 8: Efficacy of IOTA simple rules

Factors	Percentage
Sensitivity	85.71
Specificity	86.44
Positive predictive value	42.85
Negative predictive value	98.07
Accuracy	86.36

Sensitivity for detection of malignancy in cases where IOTA simple ultrasound rules were applicable was 85.71%, and specificity is 86.44% Negative predictive value was 98.07% means patients who were tested benign also had histopathology of benign variety. Positive predictive value is 42.85% means out of all patients who were diagnosed malignant on IOTA were confirmed malignant on histopathologically. Accuracy of this IOTA test for this particular study is 86.36%. A hospital based prospective study was conducted with 75 patients to For evaluation of IOTA simple ultrasound rules to distinguish benign and malignant ovarian tumors. The following observations were noted: Out of 75 patients evaluated with ultrasonographically with IOTA simple rules 52 were benign , 14 were malignant, and 9 were found inconclusive. Majority of benign masses were based on IOTA simple ultrasound rules were found in age group of 26-35. Accounting of 40.38%.and only 1.92% cases found in age group of 66-75 . Similarly majority of malignant cases were found in age group of 56-65 accounting of 21.42% and non were found in age

group of 15-25. Out of total 75 patients studied on IOTA findings 52 patients had a benign mass of only 51 were confirmed Histopathologically. And 1 mass was found to be malignant on histopathologically which prior on USG IOTA showed B features. Out of 14 malignant patients diagnosed from IOTA, 8 patients had benign mass which was found on histopathology report and 6 were confirmed malignant histopathologically. Out of 9 inconclusive cases all were found to be benign histopathologically. 65% patients had CA-125 level <50 IU. 7% patients had CA-125 level between 51-100 IU. 3% had CA-125 level between 101-200 IU. And 4% had > 200 IU CA-125 levels. About 21% patients CA-125 levels were not done. In previous published studies IOTA ultrasound rules were not directly applied during sonographic examination. The sonographic data was later collected from the patient and was evaluated as per IOTA simple ultrasound rules. Till date only few studies which applied this test directly to patient have been performed. Our study overcomes the limitation by directly applying IOTA simple ultrasound rules on the patients. A total 80 patients with suspected ovarian pathology were evaluated using transvaginal ultrasonography and transabdominal when transvaginal approach was not feasible. Findings were correlated with histopathological findings. Out of 80 patients evaluated for the study 75 patients were included in the final analysis who underwent surgery. The rate of inconclusive was 12 %. The sensitivity and specificity of present study most closely related to study by Alcazar and Nunes N et. al, who reported a sensitivity and specificity of 88% and 89% respectively. The specificity of our study was lower as compared to these seven studies. This variation may be due to limited number of patients studied in the present study as compared to other studies [6,7]. The advent of imagistic exploration has accelerated the possibility of an accurate ultrasound diagnosis. The main reason for attempting to establish a differential diagnosis between benign and malignant tumors is to correctly refer the patients with a malignant mass to an oncological center, where therapeutic results are clearly superior if treated by a gynecologic oncology team. [8,9,10] Many patients with ovarian cancer are not diagnosed at an early stage due to a lack of symptoms, this aspect being responsible for its high mortality rate. More than 90% of the ovarian cancers could be managed successfully if a more specific diagnosis were possible in the early stage of cancer development. Not one of the serum biomarkers used to detect ovarian cancer showed enough high sensitivity and specificity to be detected in the early stage. In many situations that concern patients

with a persistent ovarian mass, especially in postmenopausal women, surgical treatment is recommended. Furthermore, the final diagnosis is based on the histological analysis, after the examination of the surgically removed tissue. The classification of ovarian tumors included in the study was based on the correlation of pathologic criteria of ovarian tumors 2020 according to the World Health Organization (WHO), considering the histopathological aspects that included a wide spectrum of malignancy aspects, such as the tumor growth, the arrangement of glands, the morphology of the lining epithelium, the pattern of invasion and the stromal characteristics. [11,12] Previously, the ultrasound examination alone, or the combinations between ultrasound correlated with serum biomarkers, seemed to be the best modalities to detect ovarian cancer and to distinguish between malignant or benign ovarian masses. In addition, the ultrasound can influence the decisional strategy of surgical treatment. It has become clear that transvaginal sonography has a sensitivity of <90% for early ovarian cancer and a specificity of 94-99%. [13,14] In assessing the malignancy risk of an ovarian mass, there are a lot of scoring systems based on ultrasound. The IOTA group proposes two original models to predict the risk of malignancy in an ovarian mass: the ultrasound Simple Rules. [15] In order to identify the accuracy of imagistic evaluation, we compared the results obtained according to the IOTA criteria analysis of the ovarian mass versus morphological aspects of the lesion. We classified the tumors according to the IOTA simple rules as being benign, borderline and malign. Afterwards, we compared the results to the pathological examination. For comparison of the IOTA simple rules chance of a benign tumor, we used a non-parametric test because we did not have the statistical power to verify the normality of the data. [16] Our results showed that the averages are close but so are the medians. The results of our study of ovarian mass showed that the IOTA simple rules provides more accurate results than the ultrasound examination alone in differentiating between benign and malignant adnexal masses. [17] It also strongly correlates with the histopathological findings having minimum rate of error. This method is considered to be a highly useful tool in developing countries that need to be extremely effective in triaging patients to offer cost-efficient management. These changes were independent of menopausal status. The ACOG (American College of Obstetricians and Gynaecologists) also suggests that the IOTA simple ultrasound rules predicts the risk of a specific type of adnexal mass with high accuracy and can therefore offer better management for patients with ovarian tumors. [18] The IOTA simple rules is available in two versions: with or without the inclusion of the CA-

125 value. Van Calster B. et al., 2014, concluded that CA-125 is a nonspecific marker in the differentiation between benign or malignant adnexal masses ^[19] Erdogan Nohuz, 2018, used the IOTA simple rules algorithm in 107 patients over 43 years old. The algorithm proved to be very useful in distinguishing between benign and malignant tumors. An ultrasound examination can be used by inexperienced sonographers and may help them to correctly evaluate the findings and classify them as presumed benign or malignant, representing a useful tool for sorting these patients for further, more specific explorations.^[20] As we showed in our study, Szubert et al., 2016, demonstrated that the results obtained using this IOTA simple rules were highly accurate and can be used for the differential diagnosis of ovarian masses.^[21,22] However, our study had some limitations. First, the small number of patients included in our study and, second, the lack of evidence of the number of patients that were evaluated in the private sector that might have been directly referred to an oncological center without being evaluated in our hospital beforehand. In this context, the imagistic mechanism by which some parameters cause radically different results (malignant lesion identified on surgical samples versus the IOTA ultrasound rules criteria) has not been shown in all cases, as in our case.^[23] However, one of the strong points to support our findings is the fact that there are few prospective

studies in the literature that evaluate the accuracy of the IOTA ultrasound simple rules for evaluation of ovarian masses. This is the main reason we want to embark on a larger prospective study with the help of our gynecologic oncology colleagues to better evaluate the accuracy of this important scoring system and help implement this protocol of evaluation in our country.^[24]

Conclusion:

Our study shows that the IOTA simple ultrasound rules is able to differentiate more accurately between benign, borderline and malignant ovarian tumors. Therefore, it improves the decisions of patient triage and management, thus reducing the morbidity and mortality associated with adnexal pathology. These methods can be used even in the absence of an experienced clinician, with successful management and better patient outcomes. This concludes that individual risk estimates can be derived from the 10 ultrasound features in the simple ultrasound rules with performance similar to best previously published algorithms. A simple classification based on these risk estimates may form the basis of a clinical management system. This will hopefully facilitate choosing optimal treatment for all patients presenting with adnexal masses.

Sources of supports: Nil

Conflicts of Interest: Nil

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