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Role of IOTA Criteria to Evaluate the Adnexal Masses Classification Using Ultrasonography

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Abstract

Introduction: In gynecology and ultrasonography, adnexal masses are a major health concern. Ultrasonography and International Ovarian Tumor Analysis (IOTA) criteria are crucial for diagnosing and identifying malignant grades, and an accurate distinction by non-invasive techniques is necessary for proper care. ***Methods:*** From January to May 2025, 400 patients who presented with adnexal masses at the Saudi Hospital for Obstetrics and Gynecology in Khartoum, Sudan, participated in a descriptive cross-sectional study. Adnexal lesions were assessed using transvaginal and abdominal ultrasonography, with the IOTA Simple Rules (SR) employed for classification. To evaluate associations with ultrasound results and final diagnoses, information on patient demographics, age, symptoms, and medical history was examined. ***Result:*** The age categories of 26–40 and 41–55 were the most impacted. The majority of patients experienced symptoms, with pain accounting for about 43.3% of cases. According to the IOTA SR criteria, ultrasonography identified 22% of masses as malignant and 68.8% as benign. Ultrasound characteristics, such as uneven shape, ascites, papillary projections, and vascularity, were found to be significantly associated with malignancy. Malignant lesions were also significantly associated with older age and a history of breast cancer. According to statistical analyses, ovarian cancer can be accurately predicted by certain ultrasonographic features using IOTA Simple Rules. In conclusion, ultrasonography is a reliable and efficient method for assessing and categorizing adnexal masses when used following IOTA guidelines. Combining the patient's age, medical history, and ultrasound characteristics improves diagnostic precision, enables prompt and effective treatment, and lowers the risk of surgery.

Keywords: International Ovarian Tumor Analysis (OTA) criteria, Ovarian tumors, Benign, Malignant, Diagnostic ultrasound.

INTRODUCTION

Since epithelial ovarian cancer makes up the majority of ovarian malignancies and develops quickly, early detection of ovarian cancer is essential. Treatment can be more successful if a gynecologic oncologist is consulted right away to diagnose the type of tumor. Determining whether an adnexal mass is benign or malignant before surgery might change the course of treatment, but this is frequently the most difficult stage because the diagnostic techniques that are currently available are not totally reliable. It is impossible to overestimate the need for improvement, even though the most commonly used procedures are radiological imaging and tumor markers [4].

Abdominal or transvaginal ultrasound is the first-line test for ovarian masses before surgery. The most used method for identifying abdominal and pelvic disorders. Malignant and benign adnexal masses can be reliably distinguished using this non-invasive imaging method [2]. To ascertain the probability that ovarian tumors are malignant, several guidelines and reputable studies have been put out that rely on sonographic characterization. One such guideline that is frequently

applied in clinical practice is the Simple Rules (IOTA), which was created by the IOTA group in 2008 [3]. Five ultrasonography features included in the IOTA-SR can distinguish between benign and malignant tumors. The following are examples of benign tumor characteristics (B-features): B1 is unilocular, B2 has solid parts with the largest solid component less than 7 mm in diameter, B3 has sonic shadows, B4 is a smooth multilocular tumor with a maximum diameter of less than 10 cm, and B5 has no blood supply (color score 1). M1 is an irregular solid tumor, M2 is ascites, M3 is the presence of four or more papillary structures, M4 is an irregular multilocular tumor with a maximum diameter of ≥10 cm, and M5 is very strong blood flow (color score 4) [1]. These are malignant tumor traits, or M-features.

PATIENTS AND METHODS

This retrospective study was conducted from January 2023 to May 2025, involving a total of four hundred patients. This was conducted at the ultrasound department. The study utilized an ultrasound system model Samsung sonocare R7, with curved linear arrays and an endovaginal transducer, manufactured in KOREA, 2013. All patients included in the study underwent a comprehensive medical history review.

Trans abdominal (TA) and trans vaginal (TV) ultrasound procedures are commonly used to check the female pelvis. The TA examination is carried out from the anterior abdominal wall utilizing a curvilinear, or sector, transducer with frequencies of up to 5 MHz in order to identify the uterus and adnexa as a summary of the other pelvic tissues. TA scans usually employ the enlarged bladder as a "sonic" window. Not all institutions start with the bladder fully dilated if the protocol calls for conducting a TA trial in addition to a TV study. A TA scan may be useful as a general review of the pelvic structures, even if the bladder is empty or only slightly distended. The patient's bladder is empty when the TV examination is conducted, and higher transducer frequencies of 7.5 MHz or higher are used. Greater detail and characterization of the uterus and adnexa are made possible by the improved near-field focusing and resolution of these higher frequencies. Both transvaginal and transabdominal sonography are complementary methods that are widely used to assess the female pelvis. At least two orthogonal planes—typically sagittal and axial or coronal and transverse—should be used to identify anatomy and disease, utilizing both methods. [5]

Fig 1: Transvaginal ultrasound image for a 33-year-old who presented with pelvic pain and a history of incomplete miscarriage shows a left ovarian complex lesion with cystic and solid components with acoustic shadow, measured 1.15×1.85 cm

Fig 2: Transvaginal ultrasound image for a 48-year-old who presented with no symptoms or history, shows a right ovarian multilocular cystic lesion measuring 3.92×3.20 cm

Fig 3: Transvaginal ultrasound image for a 23-year-old who presented with pelvic pain and no history, shows a right ovarian unilocular cystic lesion measuring 6.73×4.99 cm

Method of data collection

The following variable was included in the data collecting sheet that was used to gather the data: The study's variables were broken down into four sections: the first dealt with demographics, including participant age; the second dealt with signs and symptoms; the third dealt with clinical history; and the fourth dealt with ultrasound findings using IOTA-SR criteria, which include features 5B and 5M.

Data analysis

For both continuous and categorical variables, the independent samples T-test and the chi-squared test were used to compare the demographic data, which were provided as mean (± standard deviation), morphometric features, and Doppler measurements.

The significance level for the statistical analysis, which was carried out using SPSS (version 21; SPSS Inc., Chicago, IL), was set at p-value<0.05.

Ethical consideration

Following clearance from the Institutional Review Board (IRB) and the local ethics committee (IRB) of the College of Graduate Studies and scientific research, Karary University, Khartoum, Sudan, the study was initiated. Every participant in the study signed a consent form, which was used for research and data for scientific publications.

Only the research team had access to or the availability of identifying information. All data sheets were password-protected and distributed exclusively to the research team.

RESULT

In this retrospective study, four hundred pelvic ultrasound examinations were performed using IOTA criteria to classify adnexal lesion types.

Ultrasound findings according to IOTA SR criteria:

Table 4.1: showed frequency distribution of ultrasound findings according to IOTA SR criteria's

Features			Yes		No	
			Frequency	Percentage	Frequency	Percentage
Benign	Unilocular	B1	114	28.5	286	71.5
	Solid component less than 7 mm	B2	169	42.3	231	57.7
	Acoustic shadow	B3	88	22	312	78
	Multilocular >10mm without solid areas	B4	21	5.3	379	94.7
	Absent vascularity	B5	0	0	400	100
Malignant	Solid with irregular contour	M1	84	21.0	316	79.0
	Ascites	M2	31	7.8	369	92.2
	More than 4 papillary projections	M3	12	3	388	97
	Multilocular > 10 with solid areas	M4	5	1.3	395	98.7
	Abundant vascularity	M5	9	2.3	391	97.7

Concerning the lesion features which was described according to IOTA simple rules about 28.5%, 42.3 %, 22% and 5.3% having B1, B2, B3, B4 features which were unilocular, solid component less than 7mm in diameter, acoustic shadow and multilocular without solid component and concerning malignant features 21%, 7.8%, 3%, 1.3% and 2.3% having an M1, M2, M3, M4 and M5 respectively. **Table 4.1.**

Table 4.2: showed frequency distribution of diagnosis according to IOTA SR criteria's

Final diagnosed	Frequency	Percent
Benign	275	68.75
Malignant	88	22.0
Inconclusive	37	9.25
Total	400	100.0

Concerning the classification of lesions according to IOTA SR criteria, most lesions were categorized as benign 68.8%, followed by malignant 22.0% and then inconclusive, which carried at least one feature of benign and one of malignant 9.3%. Table 4.2.

Table 4.3: showed further classification of masses based on B and M criteria's

Features	Frequency	Percent
B1	98	24.5
B2	74	18.5
B2. B3	59	14.8
M1	54	13.5
B4	17	4.3
B2.M2	14	3.5
B3.M1	14	3.5
B1. B2	12	3.0
M3	11	2.8
M1.M2	8	2.0
B3	6	1.5
M2	6	1.5
B3.M5	4	1.0
M4	4	1.0
B2, B3	3	0.8
B1, B2	2	0.5
B2.M1	2	0.5
B1.M1	1	0.3
B1.M2	1	0.3
B2, B4	1	0.3
B2. B3. B5	1	0.3
B2. B4	1	0.3
B3. B4	1	0.3
B4.M2	1	0.3
M1.M2.M5	1	0.3
M1.M3.M5	1	0.3
M1.M5	1	0.3
M2.M5	1	0.3
M4.M5	1	0.3
Total	400	100.0

Classification of lesions according to the number of B and M features was demonstrated in Table 4.3. For benign categories, most of them have B1 or B2 features, and combined B2 and B3 with 24.5, 18.5, and 14.8%. for malignant most of them carry M1 feature 13.5%, while for inconclusive mostly carry B2, M1 or B1, M2 and B4, M2.

Table 4.4: showed cross-tabulation between diagnosis and demographic (age, symptoms, and history)

		Diagnosis			Total	P value	Chi²	Cramer's V
		Benign	Malignant	Inconclusive				
Age group	18-25	72	10	5	87	<0.001**	40.112	0.224
	26-40	126	29	13	168			
	41-55	66	37	10	113			
	>55	11	12	9	32			
Sign and symptoms	Abdominal Pain	1	0	0	1	0.542	16.726	0.145
	Asymptomatic	117	42	14	173			
	Constipation	5	4	1	10			
	Difficult urination	4	2	1	7			
	Irregular period	11	5	0	16			
	Menopause	4	2	2	8			
	Menorrhagia	1	1	1	3			
	Pain	105	27	16	148			
	Vaginal bleeding	17	2	0	19			
	Vaginal Discharge	10	3	2	15			
History	Breast cancer	6	10	4	20	0.003**	29.974	0.193
	Cancer	1	0	0	1			
	Ectopic pregnancy	20	9	1	30			
	Hysterectomy	10	4	5	19			
	Miscarriage	10	7	1	18			
	No-history	188	51	22	261			
	Post operation	40	7	4	51			
Total		275	88	37	400			

Significant correlation was noticed between age and final diagnosis with the malignancy features based on IOTA SR, which were more common in pre- and post-menopausal patients (40 years and more) than the younger age group. Furthermore, among more than 55 years, the malignant and inconclusive lesion features were more common than benign features (21 related to 11 cases respectively), the strength of association was low as Cramer's V = 0.224 and p< 0.001. insignificant correlation between sign and symptoms and diagnosis, p > 0.05; furthermore, significant correlation between history and mass feature, with those with previous feature of breast cancers were likely to develop malignant tumors than benign ones, p value =0.003, weak association as Cramer's V =0.193. Table 4.4.

Table 4.5 shows the tabulation between the IOTA category and age.

		Age group				Total	P	Cramer's v	Chi ²
		15-25	26-40	41-55	>55				
Features	B1	37	44	16	1	98	0.000	0.342	140.27
	B1, B2	0	2	0	0	2			
	B1. B2	2	8	2	0	12			
	B1.M1	0	1	0	0	1			
	B1.M2	0	0	1	0	1			
	B2	15	33	22	4	74			
	B2, B3	2	1	0	0	3			
	B2, B4	0	0	1	0	1			
	B2. B3	10	30	16	3	59			
	B2.B3. B5	0	0	0	1	1			
	B2. B4	0	0	1	0	1			
	B2.M1	2	0	0	0	2			
	B2.M2	2	5	3	4	14			
	B3	2	2	2	0	6			
	B3. B4	0	1	0	0	1			
	B3.M1	1	5	5	3	14			
	B3.M5	0	2	0	2	4			
	B4	4	5	6	2	17			
	B4.M2	0	0	1	0	1			
	M1	9	19	21	5	54			

	M1.M2	0	2	4	2	8			
	M1.M2.M5	0	0	1	0	1			
	M1.M3.M5	0	0	0	1	1			
	M1.M5	0	0	1	0	1			
	M2	1	0	3	2	6			
	M2.M5	0	1	0	0	1			
	M3	0	5	4	2	11			
	M4	0	1	3	0	4			
	M4.M5	0	1	0	0	1			
Total		87	168	113	32	400			

Moderate significant association was noticed between IOTA category of the ovarian tumors and age. p =0.000, Cramer's v 0.342, and Chi2 = 140.27, Table 4.5.

DISCUSSION

Using ultrasonography, this study assessed the function of IOTA-SR criteria in classifying adnexal masses.

The study's results from tables 4.1 and 4.2 indicate that the majority of adnexal masses are benign, suggesting that IOTA-SR may be useful in the classification of adnexal masses. This finding was in line with research by **Paula Carvalho *et al.*** from 2020, which demonstrated that the majority of adnexal masses are benign [6]. Additionally, it concurred with a 2017 study by **Di Legge *et al.*** that discovered that the majority of ovarian lesions were benign, with a smaller percentage having invasive or borderline malignant tumors..[7].

The current investigation discovered that Table 4.3 showed how lesions were categorized based on the number of benign and malignant features. The majority of benign categories contain sonographic features of unilocular cysts, solid components with the maximum diameters less than 7 mm, and a combination of these features, together with acoustic shadows in 24.5%, 18.5%, and 14.8% of cases. 13.5% of them have irregular solid tumors as a feature, whereas inconclusive ones typically have solid components with a maximum diameter of less than 7 mm, irregular solid tumors or unilocular cysts, and ascites, as well as smooth multilocular tumors with a maximum diameter of less than 100 mm and ascites. This finding was consistent with **Di Legge *et al.* (2017),** who reported that all malignancies had solid components (compared to 43% of benign tumors) and that none of the malignant tumors were unilocular cysts (compared to 50% of benign tumors) [7]

Based on IOTA SR, malignancy features were more common in pre- and post-menopausal patients (40 years and older) than in younger age groups. Additionally, among those over 55, malignant and inconclusive lesion features were more common than benign features (21 related to 11 cases, respectively). The strength of the association was low, with Cramer's V = 0.224 and p<0.001. Table 4.4 demonstrates a significant correlation between age and final diagnosis. There was a weak association, as indicated by Cramer's V = 0.189, but there was a significant correlation between history and mass feature and the likelihood of developing malignant tumors compared to benign ones. Additionally, there was an insignificant correlation between signs and symptoms and diagnosis (p > 0.05). This finding is consistent with research by **Carvalho JP *et al.* (2020**), which found that age is a significant independent risk factor for ovarian cancer in the general population, with a sharp increase in incidence following menopause [6] and concurred with a 2017 study by **Garg S *et al.*** that found that cancer was more prevalent in the age bracket of six to eight decades.[8].

Table 4.5 demonstrates a moderately significant correlation between age and the IOTA category of ovarian tumors. These findings are consistent with a study conducted in 2020 by Carvalho JP *et al*., which found that age is a significant independent risk factor for ovarian cancer in the general population, with the incidence rising sharply after menopause.[6]

CONCLUSION

In order to identify lesions, evaluate the diagnostic effectiveness of ultrasound, and correlate imaging results with patient demographics, symptoms, and history, the study effectively assessed adnexal masses utilizing ultrasonography together with IOTA criteria. The findings showed that the majority of lesions (68.8%) were benign, whereas 22% of cases were malignant and 9.3% were inconclusive. By the IOTA criteria, ultrasound characteristics such as multilocular cysts without solid areas, uneven contours, ascites, many papillary projections, large solid areas, and high vascularity were substantially linked to malignancy.

According to age analysis, younger symptomatic women were more likely to present with specific benign traits, whereas older patients tended to have characteristics suggestive of malignancy. Notably, ovarian cancer and prior breast cancer history were found to be significantly correlated, highlighting the significance of a thorough patient history in risk assessment. The evaluated ultrasonography characteristics confirmed the usefulness of IOTA criteria in clinical practice by offering trustworthy markers for distinguishing benign from malignant tumors.

Overall, the results support the use of ultrasonography to improve diagnostic accuracy and guide care strategies for various patient profiles by confirming that it is a useful technique for the assessment and classification of adnexal masses when directed by IOTA criteria.

To increase the accuracy of their diagnosis and treatment choices, clinicians should take into account the patient's age, presenting symptoms, and medical history in addition to the ultrasound results. To maintain high diagnostic standards, sonographers and gynecologists should get regular training and updates on new ultrasonography techniques and IOTA protocols. It is advised that future research employ a bigger sample size and incorporate additional variables, such as the histopathological outcome.

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