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Original Research Article

Comparison of diagnostic performance of simple international ovarian tumor analysis rules versus subjective pattern recognition for triage of adnexal masses

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ABSTRACT

Background: Accurate and early diagnosis of adnexal masses is essential for optimal clinical decision-making. The aim of the study was to compare the diagnostic performance of simple international ovarian tumor analysis (IOTA) rules vs subjective pattern recognition, to discriminate between benign and malignant adnexal mass, and to establish the diagnostic utility of IOTA rules as a standardized examination tool in early diagnosis of ovarian malignancy.
Methods: A prospective cohort study was conducted at a tertiary care hospital between November 2017 and March 2019 on 100 women with adnexal masses. All adnexal masses detected on ultrasound were classified according to IOTA rules by the trainee, followed by subjective pattern recognition by experts. These observations were further correlated with histopathology/intraoperative findings/ follow-up examination. Diagnostic efficacy was assessed by comparing sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and accuracy.
Results: Among the 100 patients, 81 had benign, and 19 had malignant masses on final diagnosis. The sensitivity, specificity, PPV, NPV, and accuracy for the detection of malignancy using IOTA rules by trainee were 100%, 95.59%, 81.82%, 100%, and 95.65%, and by subjective evaluation by experts were 100%, 97.5%%, 90.5%, 100%, and 98% respectively. No statistically significant difference was found between the diagnostic accuracy of the two methods.
Conclusions: Simple IOTA rules are as accurate as subjective evaluation by experts in the characterization of adnexal masses. Their inherent simplicity and reproducibility make them ideal for use by less experienced sonographers.

Keywords: Adnexal masses, Histopathological correlation, Simple IOTA rules, Subjective evaluation

INTRODUCTION

Ovarian cancer is the second most common gynecological malignancy worldwide, leading to high morbidity and poor survival rate.[1] Even with the advancement in the diagnostic armamentarium, the benign or malignant nature of a clinically diagnosed adnexal mass may not be established before surgical exploration and histopathology. Accurate and early diagnosis is essential for optimal clinical decision-making. Therefore, an effective standardized method is required which could differentiate between benign and malignant adnexal masses so that appropriate subspecialty referral, optimal pre-operative planning, and prognostication of the patients can be done.[2]

Ultrasonography (USG) is the primary imaging modality for the evaluation and characterization of adnexal masses. Ultrasound is widely available, safer, and simple to perform. High-resolution imaging by transvaginal

ultrasound provides high diagnostic accuracy for adnexal pathology.[3]

There have been studies using different sonographic approaches for the characterization of adnexal masses, including the pattern recognition approach, simple scoring systems, and complex mathematical models such as neural networks. Among all these, pattern recognition shows higher diagnostic accuracy; however, it requires expertise that may only be available at most primary healthcare facilities.[4,5]

In 2008, the International Ovarian Tumor Analysis (IOTA) group proposed simple ultrasound-based rules for the characterization of adnexal masses into benign and malignant. IOTA rules include 5 benign features (B-rules) and 5 malignant features (M-rules). Benign sonographic features include unilocular cyst (B1), solid component smaller than 7mm in largest diameter (B2), acoustic shadowing (B3), smooth multilocular tumor smaller than 100mm (B4), and no detectable blood flow on color Doppler (B5). Malignant sonographic features include irregular solid tumor (M1), ascites (M2), at least 4 papillary projections (M3), irregular multilocular solid tumor measuring 100mm or larger (M4), and very strong color flow (M5). Presence of one or more M features in the absence of a B feature, the mass is classified as malignant, and in the presence of one or more B features in the absence of an M feature, the mass is classified as benign. If both B and M features are present or if none of the features are present, the simple rules are inconclusive.[6] The aim of the present study was to compare the diagnostic performance of simple IOTA rules and subjective pattern recognition to discriminate between benign and malignant masses and to establish the diagnostic utility of simple IOTA rules as a standardized examination tool in the early diagnosis of ovarian malignancy.

METHODS

The present study was a prospective cohort study conducted from November 2017 to March 2019 in the Department of Radiodiagnosis in collaboration with the Department of Obstetrics and Gynaecology and the Department of Pathology, Lady Hardinge Medical College and Smt. Sucheta Kriplani Hospital, New Delhi, India. The study was approved by the institution's ethics committee. Clinically suspected cases of adnexal mass lesions and those found incidentally on USG were included in the study. Patients with adnexal masses who were already on treatment or follow-up and patients with ectopic pregnancy were excluded from the study. After applying the inclusion and exclusion criteria, a total of 108 patients were taken; however, 8 patients were excluded as they were lost to follow-up. Thus, a total of 100 patients were included in the study. After eliciting a detailed history, clinical examination, routine laboratory investigations, and specific serum tumor markers (CA-125-cancer antigen 125, AFP-alpha-fetoprotein, etc.), patients were subjected to ultrasound examination (Figure 1).

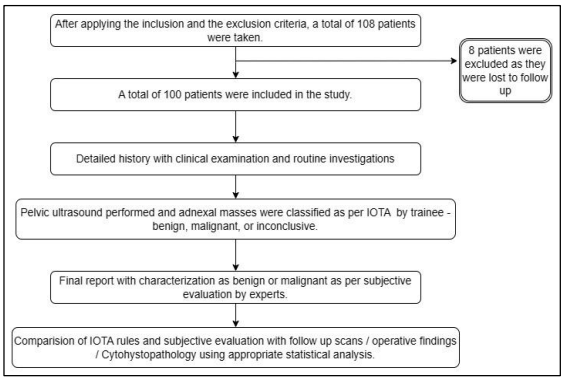

Figure 1: Study flow diagram.

Ultrasound imaging

Transabdominal sonography (TAS) followed by transvaginal sonography (TVS) was performed on all the patients except for females who were sexually inactive, on whom only TAS was performed. Sonographic assessment of the given adnexal masses was done on PHILIPS iU-22 (intelligent U/S and high-end color doppler) ultrasound machine using high-frequency endocavitatory (5-9MHz) and curvilinear (2-5MHz) probe supplemented with color doppler. The IOTA simple rules checklist was prepared by the trainee on the basis of the original paper published by the IOTA group.[6] Ultrasound examination was performed by the trainee (PS) in the presence of an expert examiner (RA/ST) who, however, did not participate in the ultrasound analysis until the trainee had completed the scan and filled the checklist. At the end of the examination, the adnexal masses were characterized as benign, malignant, or inconclusive on the basis of simple IOTA rules by the trainee.

A papillary projection was defined as a solid projection into a cyst cavity from the cyst wall >3mm in height. A color score of 1 was given to indicate no flow; a score of 2 indicated minimal flow; a score of 3 indicated moderate flow, whereas a color score of 4 indicated abundant flow.[7]

Once the trainee had completed the examination, the expert re-evaluated the adnexal masses, and the final report with characterization as benign or malignant was given as per subjective pattern recognition by the expert. Following are the reference standard used in this study. 1) Intraoperative findings/ histopathology (HPE)- for adnexal masses which were operated on and 2) Follow up on regular USG examination every 3 months till the resolution of adnexal masses or till the end of the study period for masses that were kept on conservative management.

Statistical analysis

The data generated from our research study was analysed using the appropriate statistical SPSS software (version 25), and a chi-square test was performed. Qualitative data

was expressed as proportions and percentages, while the quantitative data was expressed as mean, range and standard deviation. P-value of <0.05 was considered statistically significant. Diagnostic efficacy of the two methods were compared in terms of sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) and accuracy.

RESULTS

Among the 100 patients, 73 patients had unilateral adnexal masses, and 27 patients had bilateral adnexal masses. Out of these 27 patients, 25 had the same pathology on both sides, in whom the larger mass was considered for the study. 2 patients had different pathology on each side (para ovarian cyst and mature cystic teratoma in one case and simple and hemorrhagic cyst in the other case) in whom the adnexal mass with more worrisome features, i.e., mature cystic teratoma and hemorrhagic cyst respectively were included in the study.

Out of the 100 masses included in the study, 81 were benign, and 19 were malignant on final diagnosis (Table 1).

Table 1: Final diagnosis of adnexal masses.

Final diagnosis	Frequency
Benign	
Simple cyst	1
Hemorrhagic cyst	4
Endometrioma	13
Inflammatory to masses	12
Hydrosalpinx	8
Broad ligament fibroid	1
Ovarian torsion	4
Para ovarian cyst	1
Peritoneal inclusion cyst	4
Benign ovarian neoplasm	
Mature cystic teratoma	17
Serous cystadenoma	8
Mucinous cystadenoma	6
Cystadenofibroma	1
Thecoma	1
Total benign masses	81
Malignant	
Serous cystadenocarcinoma	5
Mucinous cystadenocarcinoma	3
Granulosa cell tumor	3
Sertoli-leydig tumor	2
Immature teratoma	1
Yolk sac tumor	1
Metastatic ovarian neoplasm	4
Total malignant masses	19
Total	**100**

Among the 81 benign cases, 49 cases were operated on, out of which HPE was available in 45 patients, while in 4 operated patients of ovarian torsion, surgical detorsion with ovarian conservation was performed. Out of the 19 malignant cases, HPE was available in 17 cases, while in 2 cases, atypical malignant cells were found on ascitic fluid cytology. Among the malignant cases, 12 were operated while 7 were managed by chemotherapy.

The age of the patients ranged from 10yrs to 70yrs, with a mean age of 31±11.5 years. The age group of 10-25 years (N=35/81, 43.20%) had the maximum number of benign masses, and the age group of 41-55 years (N=8/19, 42.10%) had the maximum number of malignant masses.

A higher incidence of malignant masses was observed in postmenopausal women (57.89%) compared to premenopausal women (42.11%).

Most of the patients presented with abdominal pain (71%) followed by abdominal lump (35%). Postmenopausal bleeding was the presenting complaint in three cases with malignant adnexal mass (2 granulosa cell tumors and 1 sertoli-leydig cell tumor). A 17-year-old unmarried female diagnosed with sertoli leydig cell tumor presented with virilism and secondary amenorrhoea (Table 2).

Table 2: Patient demographics.

Age (years)	**31.2±11.5 years (mean±SD)**	
Menopausal status	**Benign lesions (%)**	**Malignant lesions (%)**
Premenopausal	68 (83.95%)	8 (42.11%)
Post-menopausal	13 (16.05%)	11 (57.89%)
Presenting complaints	**No. of patients (n=100)**	**Percentage (%)**
Abdominal pain	71	71
Abdominal lump	35	35
Abnormal uterine bleeding	13	13
Abdominal distension	11	11
Infertility	10	10
Weight loss	7	7
Fever	5	5
Postmenopausal bleeding	3	3
Secondary amenorrhoea	1	1
Virilism	1	1

*More than 1 symptoms were present in many patients; smaller masses may not be noticed by some patients

Krukenberg tumors were seen in 4 patients (4%) of metastatic ovarian neoplasm (2 patients of Carcinoma Gall bladder and 1each of Ca stomach and Ca colon). All 4 patients with peritoneal inclusion cysts had a prior history of surgery.

Ascitic tap was done in 14 patients (benign-4, malignant-10). In 7/10 malignant cases, ascitic fluid cytology was

positive for atypical malignant cells (4 cases of krukenberg tumor, 2 cases of serous cystadenocarcinoma, and 1 case of yolk sac tumor). Out of the 12 patients with inflammatory tubo-ovarian masses (TO masses), 9 (75%) had positive tuberculosis workup, of which 3 were known cases of pulmonary tuberculosis.

CA 125 was elevated in 12 patients (8 malignant cases, 42%). Inhibin and AFP levels were raised in one patient each of luteinizing thecoma and yolk sac tumor, respectively. A patient with sertoli-leydig tumor showed increased serum testosterone levels.

IOTA simple rules

Of 100 cases, IOTA (by trainee PS) classified 70 as benign, and 22 as malignant. 8 cases were classified as inconclusive as they shared both B and M features. Figure 2 demonstrates cases depicting IOTA B-rules and M-rules.

Among the B rules, B1 (unilocular cyst) was the most commonly occurring feature in all benign adnexal masses (80.2%), followed by B5 (no color flow, 77.7%). B1 (unilocular cyst), B2 (solid component <7mm), B3 (acoustic shadow), and B4 (smooth multilocular cyst <10cm) rules predicted the result correctly in 100% of cases. B5 feature was observed in one case of malignant adnexal mass (granulosa cell tumor). Figure 3 demonstrates a HPE proven case of mature cystic teratoma which was classified as benign according to IOTA rules (B1 + B5).

Among the M rules, M1 (irregular solid tumor) was the most commonly occurring feature in all malignant cases (84.2%), followed by M2 (presence of ascites, 73.7%). M4 (irregular multilocular solid tumor with the largest diameter ≥10cm) predicted the result most correctly (87.5%), followed by M1 (81.2%) (Table 3). Figure 4 demonstrates a HPE proven case of high-grade mucinous cystadenocarcinoma which was classified as malignant according to IOTA rules (M4+M5).

Table 3: Predictive power of B and M rules.

Rules	Predicted diagnosis	Result as per final diagnosis	Percentage (%)
B1	65	65	100
B2	2	2	100
B3	15	15	100
B4	13	13	100
B5	63	62	98.4
M1	16	13	81.2
M2	14	10	71.4
M3	5	4	80
M4	8	7	87.5
M5	11	5	45.4

All 70 cases diagnosed with benign adnexal mass as per IOTA rules were confirmed as benign on follow-up/HPE.

Out of 22 cases in which the adnexal mass was classified as malignant as per IOTA, 18 were malignant, and 4 were benign as per the final diagnosis. No malignant cases were misclassified as benign as per IOTA rules (Table 4).

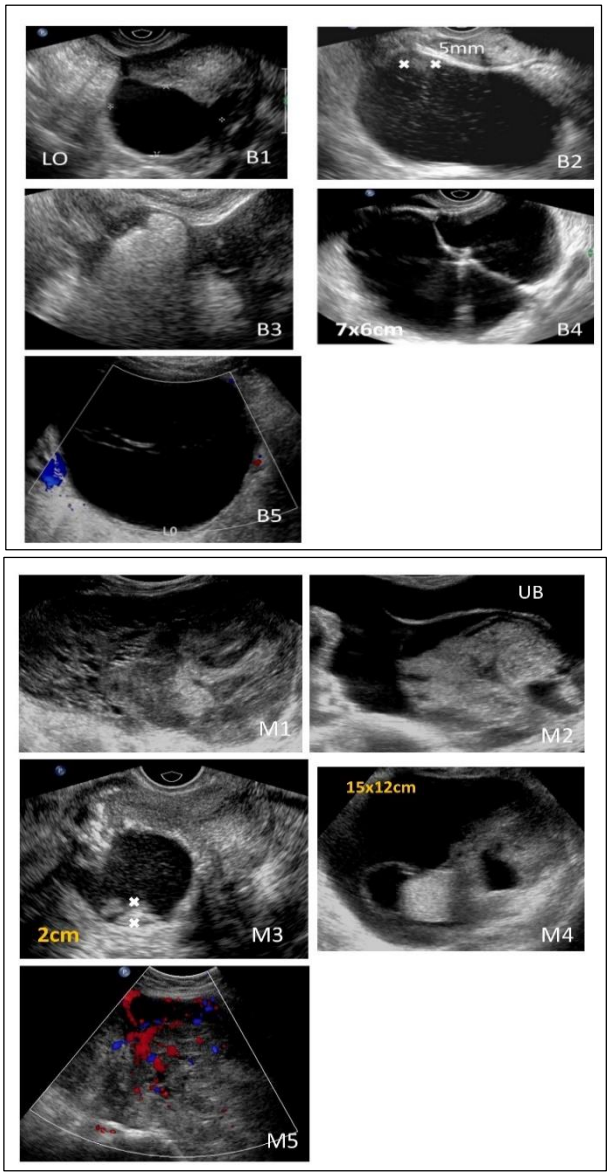

Figure 2: Cases depicting iota rules. B-Rules: B1: case of a unilocular simple cyst
B2: case of a serous cystadenoma with a solid component of largest diameter <7mm; B3: case of a dermoid cyst with posterior acoustic shadow; B4: case of a smooth multilocular mucinous cystadenoma with the largest diameter <100mm; B5: case of a Serous cystadenoma with absent color flow. M-Rules: M1: case of an irregular solid tumor diagnosed as granulosa cell tumor on HPE; M2: case of mucinous cystadenocarcinoma with ascites; M3: case of Kruckenberg with 4 papillary projections (height>3mm); M4: case of irregular multilocular solid tumor >10cm diagnosed as mucinous cystadenocarcinoma; M5: case of immature teratoma with very strong blood flow.

Table 4: Classification of adnexal masses according to IOTA rules and subjective evaluation compared with final diagnosis.

	Final Diagnosis		Total	P - value
	Malignant	Benign		
Simple IOTA rules				
Malignant	18	4	22	<0.001
Benign	0	70	70	
Inconclusive	1	7	8	
Total	19	81	100	
Subjective evaluation				
Malignant	19	2	21	<0.001
Benign	0	79	79	
Total	19	81	100	

The sensitivity for the detection of malignancy with the help of IOTA simple rules in adnexal masses in which IOTA rules were applicable, was 100%, and the specificity was 95.59%. PPV, NPV, and Accuracy were 81.82%, 100%, and 95.65% respectively.

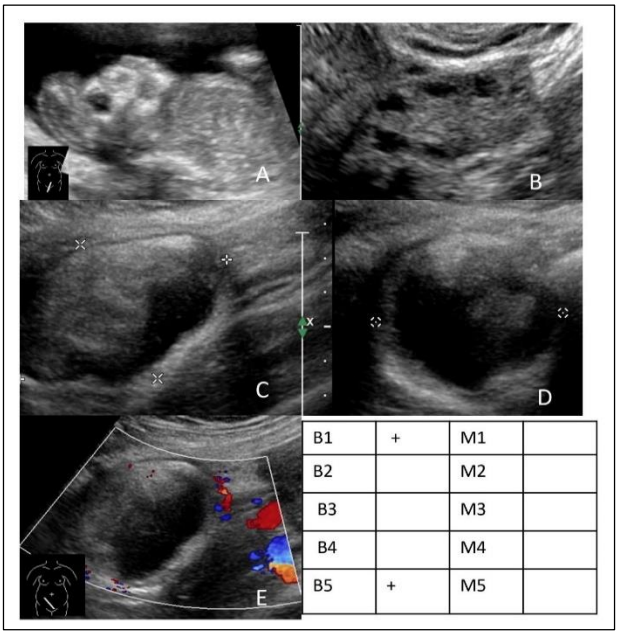

Figure 3: Mature cystic teratoma. A 21 years pregnant female (15wk+1d) with abdominal pain. TAS (A, B): reveals anencephaly in the fetus and normal left ovary; TAS(C-E): Right ovary shows a well-defined unilocular cystic lesion with an echogenic nodule protruding into the cyst suggestive of mature cystic teratoma. Color score=1. HPE: mature cystic teratoma; IOTA=B(B1+B5), Subjective Evaluation=B, Final Diagnosis=B.

Subjective pattern recognition

According to subjective evaluation by experts (RA&ST), 79 cases were classified as benign and 21 as malignant. All 79 cases classified as benign as per subjective evaluation (S.E) were confirmed as benign on follow-up/HPE. Out of 21 cases classified as malignant as per subjective evaluation, 19 were malignant, and 2 were benign (one case each of seromucinous cystadenoma with torsion and endometriosis) as per HPE (Table 4).

The sensitivity for the detection of malignancy with the subjective evaluation by experts was 100%, and the specificity was 97.5%. PPV, NPV, and accuracy were 90.5%, 100%, and 98% respectively.

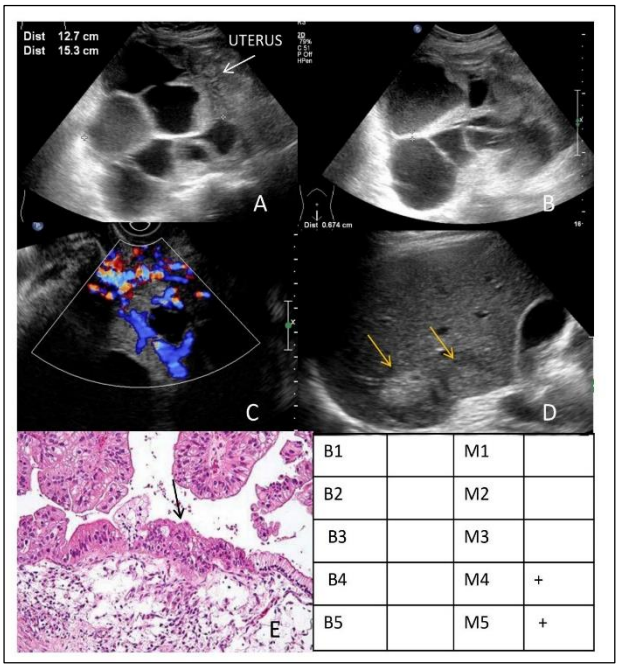

Figure 4: Mucinous cystadenocarcinoma. A 42yr female with abdominal pain, distension, and raised CA125. TAS (A-C): shows a large right adnexal multiloculated solid-cystic mass (size>10cm) with thick septa and few of the locules showing thick internal echoes suggestive of mucinous contents. Color score=4. TAS (D): shows echogenic liver metastasis (yellow arrows). H&E 300x(E): shows mucinous cell lining with cellular atypia, thus confirming the diagnosis of high-grade Mucinous cystadenocarcinoma. IOTA=M(M4+M5), Subjective Evaluation=M, Final Diagnosis=M.

Total 8 cases were classified as inconclusive according to simple IOTA rules, which included one case each of granulosa cell tumor, mature cystic teratoma, endometrioma, and 5 cases of inflammatory tubo-ovarian masses. Figure 5 demonstrates a patient with inflammatory tubo-ovarian mass which was classified as inconclusive according to IOTA rules (B4+M2+M5). Out of the 8 inconclusive cases, 2 masses were classified as malignant and the rest 6 as benign as per subjective evaluation by experts. One case of endometrioma was incorrectly diagnosed as malignant by subjective evaluation because of the presence of >4 papillary projections with height >3mm (M3).

Total 4 benign cases were incorrectly classified as malignant by IOTA rules, which included one case each of thecoma, seromucinous cystadenoma with torsion, mucinous cystadenoma and broad ligament fibroid. On subjective evaluation, 3 of them were classified as benign, which was in concordance with the HPE report, while a case of HPE-proven seromucinous cystadenoma with torsion was incorrectly diagnosed as malignant by subjective evaluation.

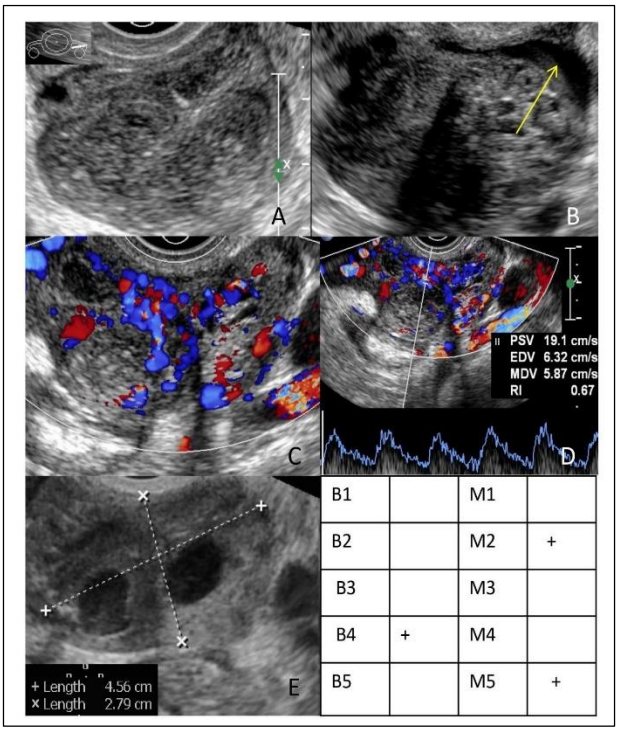

Figure 5: Tubo-ovarian mass (tubercular). A 38yr female with abdominal pain and fever. TVS(A-D): shows a smooth multilocular solid-cystic mass in the left adnexa (6x4cm) with ascites (yellow arrow). Left ovary was not visualized separately. Color score=4. TVS(E): Follow-up USG after 3months shows reduction in size of the mass(4.5x2.7cm). IOTA=Inconclusive(B4+M2+M5), Subjective Evaluation=B, Final Diagnosis=B.

Comparison between IOTA and subjective pattern recognition

In ROC analysis, the AUC for the diagnosis of malignancy was 0.973 for IOTA rules and 0.988 for subjective evaluation, thereby suggesting that the performance of IOTA rules in predicting malignancy is comparable to subjective evaluation.

DISCUSSION

Precise characterization of adnexal masses is essential for timely management and improvement of outcomes of patients with ovarian cancer. As ultrasound is the most reliable primary imaging modality, several scoring systems and logistic regression models have been developed in an attempt to make ultrasound assessment of adnexal masses more objective.[8]

In 2008, the IOTA group proposed the ultrasound-based simple IOTA rules. The rules are easy to apply even by a trainee for classifying benign and malignant adnexal masses. When tested prospectively by the IOTA group on 507 masses, the rules could easily classify 76% of the masses with a malignancy rate of 28.4%, for which sensitivity and specificity for detection of malignancy were 95% and 91%, respectively.[6]

Since the inception of simple IOTA rules; several studies have been conducted and their results have been compared with the present study as depicted in (Table 5)[6,8-14].

In 2010, the IOTA group reported a temporal prospective multicentre study including 1938 masses, with a malignancy rate of 19.2%. The simple rules yielded conclusive results in 77% of cases, with a reported sensitivity and specificity of 92% and 96%, respectively.[9] Another prospective study was performed by Alcazar et al.[8] on 340 females to evaluate the diagnostic performance of the simple rules among nonexpert examiners to discriminate between benign and malignant adnexal masses. They reported that IOTA rules were applicable in 270 (79.4%) cases with sensitivity and specificity of 87.9% and 97.5%.

Table 5: Comparison with previous studies.

Author and year of study	No. of patients	Patients on whom rules are applicable	Malignancy rate (%)	Sensitivity %	Specificity %
Timmerman et al (2008)[6]	507	386	28.4	95	91
Timmerman et al (2010)[9]	1938	1501	19.2	92	96
Fathallah K et al (2011)[10]	122	109	11.5	73	97
Hartman et al (2012)[11]	103	91	28.2	90	87
Alcazar et al (2013)[8]	340	270	16.2	87.9	97.5
Nunes et al (2014)[12]	303	237	38.3	96.2	88.6
Koneczny et al (2017)[13]	271	236	28.7	90.6	95.3
Garg et al (2017)[14]	50	45	28	91.66	84.84
Present study	100	92	19	100	94.59

Similar results were obtained in the study conducted by Meys et al.[15] The authors stressed upon proper training of the residents with simple rules and IOTA terminology before their application in clinical practice by the trainee.

The present prospective study demonstrated that the simple IOTA rules and subjective pattern recognition had comparable sensitivity (100% vs 100%), specificity (94.6 vs 97.5%), accuracy (95.65 vs 98%), and AUC in ROC analysis (0.973 vs 0.988) for detecting ovarian malignancy confirming IOTA rules which are simple to perform can be as good as subjective evaluation by experts.

The specificity of the present study was found to be comparable to the previously conducted studies. The sensitivity of the present study was higher than any of the previously conducted studies, as no malignant cases were misclassified as benign as per IOTA rules. The reason for 100% sensitivity can be explained by the fact that we did not have any borderline malignant adnexal mass in our study.

Total 8 cases were classified as inconclusive according to simple IOTA rules, of which 2 masses were classified as malignant and the rest 6 as benign (5 cases of inflammatory TO masses and 1 case of mature cystic teratoma) as per subjective evaluation by experts. In our study, the inflammatory TO masses were the most common inconclusive cases (5/8) as they shared both B and M rules. For other inconclusive cases, apart from the B features, 2 cases had high blood flow (M5), and 3 cases with tubercular etiology had ascites (M2). Subjective evaluation was able to classify these masses correctly as benign based on clinical and ultrasound findings. One case of endometrioma in a 50year old postmenopausal female was misclassified as malignant by subjective evaluation due to the atypical appearance with papillary projections.

Among the 4 benign cases which were incorrectly classified as malignant by IOTA; on subjective evaluation, 3 were classified as benign which was in concordance with the HPE report. A case of HPE-proven seromucinous cystadenoma with torsion was incorrectly diagnosed as malignant by both IOTA and subjective evaluation due to its appearance as a large irregular solid mass with areas of hemorrhage and necrosis along with ascites and peripheral color flow.

The advantage of IOTA rules over subjective evaluation is that they are easy to apply and are more objective and reproducible hence can be used as a screening tool by less experienced sonographers.

Subjective evaluation requires expertise, however, its advantage over IOTA rules is that it is more specific in establishing the diagnosis and characterization of adnexal masses. Subjective evaluation by experts after years of experience not only differentiates benign and malignant tumors but also enables establishing a specific pathologic diagnosis in some adnexal masses. In adnexal masses for which the rules yielded an inconclusive result, subjective assessment of ultrasonic findings added to the diagnostic yield of ultrasound in the present study.

The present study has several strengths and limitations. The strengths of the study include the prospective nature of the study; close follow-up till final diagnosis without any lost case, blinding of the sonographers as well as the pathologist to the results of the simultaneous assessments.

The main limitation is that it is a single-center study, and there was no borderline ovarian malignancy in our study population.

CONCLUSION

In conclusion, IOTA rules are highly sensitive and specific and its inherent simplicity makes it ideal for use by less experienced sonographers with the potential to improve the management of patients with adnexal masses even at a primary health care facility. Therefore, we recommend the use of IOTA rules at a large scale for early detection of malignant masses and thereby facilitating timely management and referral of patients with malignant adnexal masses. In adnexal masses for which the rules yield an inconclusive result by simple IOTA rules, we can use simple IOTA rules as a triage test and expert subjective evaluation as the next step for establishing the diagnosis.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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