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EVALUATION OF IOTA SIMPLE ULTRASOUND RULES AND HISTOPATHOLOGY TO DISTINGUISH BETWEEN BENIGN AND MALIGNANT OVARIAN TUMORS : A DESCRIPTIVE STUDY

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ABSTRACT **Introduction:** Ovarian masses present with very vague symptoms and thus it is imperative to establish a quick diagnosis at the first point of contact. Pre-operative diagnosis of an ovarian mass and its classification as benign or malignant helps in timely referral to specialized gynecologist/oncologist and proper surgical/medical management. IOTA simple Rules provides one such criteria for pre-operative classification of ovarian mass and has proved to be reliable, accurate and highly reproducible in all settings. **Methods:** a hospital based prospective study was done on 100 patients. Initial pre-operative classification was done using IOTA Simple Rules and the findings were compared to histo-pathological findings after surgery which were considered gold standard. **Results:** Out of the 100 masses under study, 86% could be classified according to IOTA Simple Rules with a sensitivity of 96.36% and specificity of 91.4%. The positive predictive value was 80.3% and the negative predictive value was 94.1%. The accuracy was 85%. **Conclusion:** Thus, IOTA Simple Rules is a cost-effective, simple, reliable, accurate scoring system with excellent sensitivity and specificity that is easily applicable in primary evaluation of patients with ovarian masses in clinical practice. Only unclassified masses on IOTA Simple Rules need further evaluation. Use of these rules in discriminating the masses will help in timely referral of the patient to specialized gynecologist /oncologist to receive optimal management.

KEYWORDS :

INTRODUCTION

Adnexal masses are one of the most frequent cases witnessed in a Gynecology Out-Patient Department. According to GLOBOCAN 2020 estimates, ovarian cancers amount to 6.7% of the cancer in Indian women. (1) This makes it the third most common gynecological malignancy in India.

As the symptoms of ovarian cancer are vague like bloating, pelvic or abdominal pain, poor appetite, feeling full quickly, urinary urgency, it is imperative to establish a quick diagnosis at the first point of contact. (2) Silent occurrence and slow progression of ovarian tumors, added to the fact that there are few effective methods for early diagnosis has made its mortality rate highest among gynecological malignancies. Ovarian cancers do not have a pre-invasive stage (as in cervical cancers) or well-defined symptoms (like endometrial cancers) making screening a non-viable option. Thus, there is a need for diagnostic techniques and protocols which facilitate early detection of neoplasms so as to reduce morbidity and mortality associated with the disease. (3) The most efficient diagnostic techniques revolve around ultrasonography. Malignant masses can be referred to an oncology center and benign masses can be managed conservatively, thereby preserving fertility and avoiding extreme surgery. But USG based procedures depend on the expertise of the clinician or the radiologist and thus have a high interobserver variability. To address these issues International Ovarian Tumor Analysis group developed standardized terms and definitions (4) for pre-operative characterization of ovarian masses. The group prospectively analyzed a large cohort of patients with persistent adnexal masses and published the IOTA Simple Rules (5) which are based upon a set of five ultrasound features indicative of benign tumor (B features) and five ultrasound features indicative of malignant tumor (M features). If one or more benign features are found in the absence of any malignant features then the tumor is said to be benign. If one or more malignant features are found in the absence of any benign features then the tumor is defined as malignant. If no features are seen or if both malignant and benign features are observed then the tumor is labelled as unclassified or inconclusive.

A large number of studies have been performed to examine the external validity of these rules and to establish it as a pre-operative diagnostic technique. Clinical application, reproducibility of these rules and their establishment as a diagnostic protocol however, requires further evaluation. This study was performed to truly establish the diagnostic utility of these rules in our country and to estimate and compare the sensitivity and specificity of given rules with histopathological diagnosis and establish their use as a tool in early diagnosis of ovarian malignancy.

MATERIALS AND METHODOLOGY:

The present study was a hospital-based descriptive study (validation study) conducted in the Dept. of Obstetrics and Gynecology, SMS Medical college Jaipur. This study was done on 100 patients with suspected ovarian mass presenting to the Gynecology OPD during the period of April 2021 to December 2022, who consented to undergo a transvaginal/transabdominal USG followed by surgery and histopathological examination. Pregnant females, patients with co-morbidities not allowing surgical intervention and patients unwilling for surgery were excluded. Transvaginal sonography was done for all patients except virgins where Transabdominal ultrasound was done. The findings were noted in accordance with the IOTA Simple Rules and masses were classified as Benign- those following only B rules, Malignant- those following only M rules and inconclusive when masses followed both B and M rules. The patients underwent suitable surgery within 120 days of diagnosis. Ascitic fluid and peritoneal washings were also sent for sampling. Reports of the ultrasound and histopathological reports were corelated and HPR reports were considered gold standard. The specificity, sensitivity, PPV and NPV were calculated. Statistical analysis was done using unpaired T test, one way ANOVA and Pearson co-relation factor. Ethical clearance was taken from the concerned institutional ethics committee.

RESULTS:

Out of the 100 patients evaluated, 52 masses were classified as benign according to the IOTA rules, 34 were classified as malignant and 14 masses could not be classified according to the IOTA rules. On Histopathology, 55 masses were Benign and 45 masses were malignant.

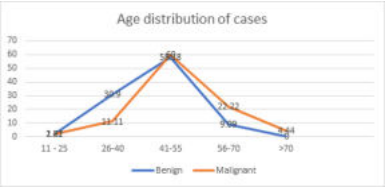
- Majority of the patients (59%) belonged to the 41–55-year age group. The mean age of the patients in the study was 47.71 years suggestive of increased incidence of ovarian masses in the reproductive age group especially the peri-menopausal age group. The mean age was lower for a benign ovarian mass (45.38 yrs.) as compared to those with a malignant ovarian mass (50.55 yrs.). The difference between the 2 groups w.r.t age was statistically significant.

Table 1. Distribution of cases with respect to age of the patients

Age group	Benign		Malignant		Total	P value
	N	Percentage	N	Percentage	N	
11-25	1	1.81	1	2.22	2	0.045
26-40	17	30.9	5	11.11	22	
41-55	32	58.18	27	60	59	
56-70	5	9.09	10	22.22	15	
>70	0	0	2	4.44	2	
Total	55	100	45	100	100	

The p-value was significant suggesting that there was a statistical difference in the average age for benign and malignant ovarian masses with respect to age.

FIGURE 1: Distribution of cases according to age.



- There was no significant difference between patients with benign ovarian tumors and malignant ovarian tumors according to religion, geographical distribution, socio-economic status, and parity.
- Pain abdomen was the most common complaint in all patients with ovarian masses (78%). 76% of patients with benign masses and 77% of patients with malignant masses presented with pain abdomen. The second most common symptom in patients with ovarian masses was lump abdomen. 34% of patients with benign masses and 67% of patients with malignant masses presented with lump abdomen.

Table 2. Distribution of cases according to symptoms

Symptoms	Benign		Malignant		Total
	N	%	N	%	
Abdominal Pain	42	76.37	35	77.78	78
Abdominal Lump	19	34.55	30	66.67	49
Menstrual abnormalities	18	30.91	7	13.34	25
Abdominal Bloating	1	1.82	2	4.45	3
Post-menopausal bleeding	1	1.82	0	0	1
Incidental finding	1	1.82	0	0	1
Dysmenorrhea	1	1.82	0	0	1
Anorexia	0	0	1	2.23	1

- When classified using the IOTA Simple Rules, out of the 100 masses, 86% masses could be classified. 52% followed B rules and were classified as benign and 34% followed M rules and were classified as malignant.

Rules for predicting a malignant tumor (M-rules)	Rules for predicting a benign tumor (B-rules)
M1 Irregular solid tumor	B1 Unilocular
M2 Presence of ascites	B2 Presence of solid components where the largest solid component has a largest diameter<7mm
M3 At least four papillary structures	B3 Presence of acoustic shadows
M4 Irregular multilocular solid tumor with largest diameter >100mm	B4 Smooth multilocular tumor with largest diameter<100mm
M5 Very strong blood flow (color score 4)	B5 No blood flow (color score 1)

Table 3. Classification of cases according to IOTA rules

IOTA classification of benign or malignant		
	Frequency	Percent
Benign (follow B rules)	52	52
Malignant (follow M rules)	34	34
Indeterminant (follow both B and M rules)	14	14
Total	100	100

The B Simple Rules followed by the Benign masses were further evaluated and the following findings were noted. A high number of masses (75%) followed B5 which is a score of 1 on color doppler scan signifying minimal blood flow. This is followed by B4 (46%) which signifies presence of a smooth multilocular lesion but with a diameter less than 10 cm and B1 (46%) which signifies the presence of a smooth unilocular lesion. B3 i.e., presence of acoustic shadows or a sonolucent mass was seen in 19 cases (36%) and B2, presence of solid components less than 7 mm in diameter, was seen in 7 cases (13%).

Table 4. Distribution of masses classified as benign according to the B rules followed

B rule	Number	Percentage of benign masses according to IOTA (n=52)
B1	24	46.15
B2	7	13.46
B3	19	36.53
B4	24	46.15
B5	39	75.00

- According to our study, out of the masses classified as malignant according to the IOTA rules, maximum number of masses were positive for M2 (91%) which indicates presence of ascites. This was followed by M5 (color doppler score 4) (47%), M4 i.e., an irregular multilocular tumor with diameter more than 10 cm (44%) and M1 i.e., presence of an irregular solid tumor in 41% cases. Fewer masses were positive for M3 (14%) which signifies presence of papillary structures.

Table 5. Distribution of cases classified as malignant according to the M rules followed

M rule	Number	Percentage of malignant masses according to IOTA (n=34)
M1	14	41.17
M2	31	91.17
M3	5	14.7
M4	15	44.11
M5	16	47.05

- Out of the 14 masses that could not be classified using IOTA rules, 4 masses were benign in nature. On histopathology, 2 masses were found out to be mucinous cystadenoma, 1 was mixed sex cord stromal cell tumor of ovary and 1 was a serous cystadenoma. They were mostly large multiseptated masses with size large than 10 cm but less to minimal blood flow. 5 masses had borderline malignancy along with either omental metastasis or positive peritoneal washings. For convenience of classification and calculation they were classified under malignant masses. The rest 5 masses were malignant- mostly papillary or mucinous cystadenocarcinoma which were well differentiated with low blood flow on doppler.
- Highest number of inconclusive masses had presence of ascites and papillary structures (M features) and had minimal to no blood flow on color doppler scan (B feature).

Table 6. Distribution of Indeterminant masses according to M and B rules (N=14)

M rules			B rules		
M1	1	7.14%	B1	0	0 %
M2	5	35.71%	B2	1	7.14%
M3	5	35.71%	B3	1	7.14%
M4	9	64.28%	B4	5	35.71%
M5	2	14.28%	B5	12	85.71%

- When using the IOTA guidelines, 52 masses were predicted as benign as per the B rules. Out of these 49 masses turned out to be benign on histopathology. But 3 masses were wrongly classified and turned out to be malignant on histopathology. The masses were multicystic with size around 10 cm and had minimal blood

flow. All 3 masses that were mis-diagnosed were cases of mucinous cystadenoma with borderline malignancy with peritoneal and omental spread.

- Out of 34 masses that were classified as malignant according to IOTA rules, 32 masses were found to be malignant on histopathology. 2 masses were benign which were wrongly classified as malignant. One was a large mucinous cystadenoma with presence of ascites and the other was mixed sex cord stromal tumor of the ovary with high blood flow on color doppler scan.

Table 7: Correlation between the IOTA classification results and histopathological report

	Predicted	Actual	Percentage
Benign	52	49	94.23
Malignant	34	32	94.11

Thus, on the basis of the basis of the above findings, after exclusion of unclassified masses according to IOTA simple rules, the following values were calculated

Sensitivity	96.364%	87.474% to 99.557%
Specificity	91.42%	85.685% to 96.634%
Positive Predictive Value	80.303%	71.992% to 86.607%
Negative Predictive Value	94.118%	80.209% to 98.442%
Accuracy	85.000%	76.469% to 91.355%

- The most common benign ovarian mass found in patients of the study was serous cystadenoma (29%) followed by Mucinous cystadenoma (27.27%). Simple cyst (21%) and corpus luteal cyst (5.45%) were also common.

- The most common Histo-pathological finding in malignant masses was serous cystadenocarcinoma. (71.11%) followed by mucinous cystadenocarcinomas (11.11%). Borderline malignancies were seen with mucinous tumors (11.11%).

DISCUSSION

- The mean age for benign masses was 45.38 (16-70) years. The mean age for malignant masses was 50.55 (16-75) years. The median age for the benign masses was 42 years and that for the malignant masses was 46 years. Since extreme values of age are present (range from 16-75) thus median values are more relevant. The p value was 0.045 which implies there was statistical difference between the average age of patients having a benign and a malignant mass. These findings are similar to Phinyo et al where the mean age for benign masses was 40.6 ± 11.0 (29.6- 51.6) years and that for the malignant masses was 45.4 ± 14.8 (30.6 -60.2) years. (6) The malignant masses were more common in an older age group ($p<0.001$). The distribution of age is also similar to Soo Young Jeong et al where the mean age for benign masses was 42 years and that for malignant masses was 59 years. (7) The mean age of all the patients was 43.05 years. Similarly, the mean age was 37.5 years for benign masses and 47.6 years for malignant masses according to Shetty et al (8). The mean age for all the patients in this study was 37.5 years. According to Sugandha et al, malignancy was more common in the 6th decade age group. And the mean age of all the patients was 42.5 years. (9)

- Pain abdomen was the most common complaint in all patients with ovarian masses (78%). 76% of patients with benign masses and 77% of patients with malignant masses presented with pain abdomen. These observations are similar to Patel-Lippmann et al where the most common presenting complaints were abdominal pain, bloating and fullness (46.8%), followed by abnormal menstrual bleeding (15.4%). (10)

- 86% of the ovarian masses in the study could be classified according to the IOTA rules. 14 % of the masses could not be classified. 52% masses were benign and 34% masses were malignant according to the IOTA rules. This is similar to the observation made by Hartge et al where IOTA simple rules could be used to classify 81% masses.(11) This is also similar to Karlsen where 83% of the masses could be classified according to simple rules.(12) The classification rate was higher as compared to Charuwan Tantipalakorn where IOTA rules could classify 80.1% masses and 19.9% masses could not be classified.(13) Out of the masses which could be classified, 66.4 % masses were benign and 33.6 were classified as malignant. The percentage of masses that could be classified using IOTA rules in a study by Dr. R. Nigam et al was 97.1%. (14) The number of lesions classified as benign was higher (84.2%) as compared to our study (55%). The number of lesions classified as malignant was lower in their study (12.9%) as compared to our study (34%).

- When the Benign masses according to IOTA Simple Rules were assessed, maximum number followed B5(75%) followed by B4(46%) and B1 (46%). B3 was positive for 36% masses and B2 for 13% masses. This is similar to the observations of Phinyo et al where highest number of lesions (88.9%) were positive for B5, followed by B1 (50.6%), B4(23.4%), B3(19.8%), and least no. of cases were positive for B2 (5.1%). (6) This is also similar to the observations of Sugandha Garg et al where B5 was positive for the highest number of benign masses (40%) followed by B1 (34%), B3 and B4 (12%) and least number of masses were positive for B2(4%). (9)

- When the Malignant masses according to IOTA Simple Rules were assessed, maximum number followed M2 (91%) followed by M5 (47%) and M4(44%). M1 was positive for 41% masses and M3 for 14% masses. The rates were slightly higher as compared to Sugandha et al where only 50 % masses were positive for M2. (9) The statistics were similar for M1 and M4 where 50 % masses were positive for these rules followed by M5 (25%). Similar to our study, the least number of masses were positive for M3 (6%). According to Phinyo et al, M1 was positive for 50 % masses, M2 for 23.5%, M3 for 22.1 %, M4 for 74% and M5 for 66% masses. (6)

- Out of the 14 inconclusive masses, 4 masses were benign in nature, 5 were malignant and 5 had borderline malignancy. Highest number of inconclusive masses had presence of ascites and papillary structures (M features) and had minimal to no blood flow on color doppler scan (B feature). In a study by Sugandha et al, 3 out of 5 indeterminate masses (60%) were benign and 2 out of 5 (40%) were malignant. (6) According to Dr.R. Nigam et al, 2 masses out of 70 were unclassified and both of them were benign. (14) According to Patel-Lippman et al, 65 out of 764 (8%) masses could not be classified according to the IOTA guidelines. (10) Out of this, 10 % were malignant masses, 15 % were benign neoplasms and rest were functional cysts. As observed by Phinyo et al, 18% masses were inconclusive according to IOTA guidelines. (6) The percentage of inconclusive results in benign and malignant masses were comparable.

- These findings were compared to studies along the same line and the following comparisons can be made.

Author and year of study	Patients with rules applicable	Prevalence of malignancy	Sensitivity	Specificity
Nunes N et al (2012) [15]	237	44.3%	89%	89%
Charuwan et al, 2014 [13]	319	33.6%	82.9%	95.3%
Sugandha et al, 2017 [9]	45	28%	91.66%	84.84%
Shetty et al, 2019 [8]	183	25.36%	92.8%	92.9%
Patel-Lippmann et al, 2019 [10]	651	4.8%	90%	96.5%
Dr.R. Nigam et al, 2020 [14]	59	12.9%	90%	100%
Phinyo et al 2021[6]	479	30.3%	93.1%	75.1%
Present study	86	47.05%	96.36%	91.42%

- The most common benign ovarian mass found in patients of the study was serous cystadenoma (29%) followed by Mucinous cystadenoma (27.27%). Simple cyst (21%) and corpus luteal cyst (5.45%) were also common. The findings are similar to Nigam et al where benign serous tumors were most common (38%) followed by endometriotic cysts (22%). (14) This was followed by mucinous tumors (10.16%). This is different from the findings of Shetty et al where the most common pathology is an

endometrioma (28.7%) followed by serous cystadenoma (15.7%) and mucinous cystadenoma (10.7%). (8) This was followed by functional cyst (8%) and dermoid cyst (8.7%).

- The most common Histo-pathological finding in malignant masses was serous cystadenocarcinoma. (71.11%) followed by mucinous cystadenocarcinomas (11.11%). Borderline malignancies were seen with mucinous tumors (11.11%). These findings are similar to Nigam et al where malignant serous tumors were more prevalent (77.77%) followed by malignant mucinous tumors (11.11%). (14) This is also similar to Shetty et al where the most common Histopathological finding was serous cystadenocarcinoma (64%) followed by mucinous cystadenocarcinoma (20%). (8)

Limitations of the study:

One of the limitations of our study is its small sample size due to short study period. A larger multi-centric prospective study in the Indian scenario is recommended to validate IOTA Simple Rules. Furthermore, our center is a tertiary referral center and thus the percentage of malignant tumors in the study is higher.

CONCLUSION

The prevalence of ovarian neoplasms has been rising during the last decades. Silent occurrence, slow progression and lack of effective pre-operative diagnosis protocols makes its mortality rate the highest among gynecological malignancies. There is no universal screening method to discriminate between benign and malignant ovarian tumors yet thus leading to introduction of methods for early diagnosis of malignant ovarian masses by various parameters. These may be earliest clinical features, tumor markers, imaging studies, or cytology. A pre-set protocol for determining the nature of an ovarian mass helps in appropriate selection of the surgical management technique and follow up. The present study demonstrated that IOTA Simple Rules have proved to be an effective technique to easily discriminate between the benign and malignant masses pre-operatively. The sensitivity was found to be 96.3% and the specificity was 91.4%. Use of pre-operative diagnostic techniques such as IOTA SR are multi-fold. Firstly, accurate differentiation between benign and malignant tumors can lead to referral of patients with malignant tumors to gynecological oncology centers for further diagnosis or staging, followed by debulking surgery and/or administration of systemic therapy. This is an important factor that positively influences prognosis. Benign ovarian masses can be managed expectantly or by conservative surgical management with reduced morbidity and fertility preservation. Secondly, optimal treatment of adnexal malignancies depends on the type of tumor. Borderline tumors can be treated with less aggressive techniques than invasive tumors, which is of interest when fertility preservation is desired. IOTA guidelines also define the criteria for discrimination very specifically thus avoiding inter and intra-observer variability and increase the reproducibility of results.

Thus, IOTA Simple Rules is a cost-effective, simple, reliable, accurate scoring system with excellent sensitivity and specificity that is easily applicable in primary evaluation of patients with ovarian masses in clinical practice. Only unclassified masses on IOTA simple rules need further evaluation. Use of these rules in discriminating the masses will help in timely referral of the patient to specialized gynecologist /oncologist to receive optimal management.

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