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Original Research Article

IOTA Simple Ultrasound Rules for Triage of Adnexal Mass

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Abstract

Introduction: Adnexal mass affects younger population more often, the prevalence of these masses in the range of 0.17%–5.9% in asymptomatic women and 7.1%– 12% in symptomatic women. As these masses presents with very non-specific symptoms the differential diagnosis can include a long list of diseases ranging from benign conditions all the way to malignancies. The IOTA group also developed '*Simple Rules*' that may be applied to a mass based on the presence or absence of five benign and five malignant ultrasound features. So, this study was performed to establish the diagnostic utility of these rules diagnosing ovarian malignancy.

Aims and objectives: (a) To assess the ability of simple ultrasound rules to discriminate adnexal masses as benign or malignant. (b) To calculate the diagnostic accuracy of simple ultrasound rules from IOTA in diagnosing benign and malignant adnexal masses when compared against histopathology results.

Material and methods: It was a cross-sectional observational study conducted from October 2019 till October 2021 in Department of Obstetrics and Gynecology, MKCG Medical College and Hospital, Berhampur, Odisha; India over 100 consecutive patients basing on following inclusion and exclusion criteria. Clinical information like chief complaints, menstrual history, and obstetric history, history of past illness and personal history were noted followed by per speculum, per vaginal and per rectal examination. Tumor markers like CA-125 were ordered for all patients after ultrasonography. IOTA classification done for all cases and placed for surgery as required. Histopathological examination was sent for the resected adnexal mass following surgery.

Results: Majority of cases i.e., 66 cases (66%) were in the age group of 20 to 40 years. Out of 100 cases, 81 cases (81%) were pre-menopausal, and 19 cases (19%) were post-menopausal. The most common presenting complaint was abdominal pain in 52 cases (52%) followed by abdominal mass in 27 cases (27%) and abnormal vaginal bleeding in 3 cases (3%). Nonspecific complaints were presented in 18 cases (18%). Based on IOTA simple rules, in 92 patients (92%), multiple features in combination were found among which B-5 was the most common presentation in benign conditions in 68% of cases, while M-4 was the most common among malignant conditions in 22% of cases. Out of all cases studied, 77 cases (77%) of the patients had benign lesions and rest 23 cases (23%) had malignant lesions. Among benign lesions, serous cystadenoma in 25 cases (25%) was the most common. Among the malignant lesions, serous cystadenocarcinoma was the most common. The overall diagnostic accuracy of CA-125 was of 84.5 % and overall diagnostic accuracy of RMI scoring was 85 %. The overall diagnostic accuracy of IOTA simple rule for adnexal mass was 86%.

Conclusion: This overall diagnostic accuracy of IOTA simple rule was higher than that of CA-125 and RMI. IOTA simple rules have good sensitivity and specificity for identifying malignant adnexal masses and differentiating benign from malignant.

Keywords: Adnexal mass, IOTA, Benign, Malignant

Background

Adnexal mass affects younger population more often, the prevalence of these masses in the range of 0.17%–5.9% in asymptomatic women and 7.1%– 12% in symptomatic women [1]. As these masses presents with very non-specific symptoms the differential diagnosis can include a long list of diseases ranging from benign conditions all the way to malignancies. Different forms of ultrasonography like transabdominal sonography (TAS), transvaginal sonography (TVS) and Color Doppler have been used so as to differentiate benign from malignant lesions. Advanced imaging techniques like computer tomography and magnetic resonance imaging have also been used to diagnose the lesions as well as to differentiate benign from malignant masses [2]. Ultrasonography (USG) is able to detect lesions arising from the uterus, ovaries, endometrium and adnexa as well. It also helps to guide the needle so as not to injure the surrounding areas to collect fluid which is examined to clinch the diagnosis in these cases. A clear guideline on terminology and classification for the USG based description of the adnexal masses were lacking [3]. To homogenize and standardize the quality, description, and evaluation of ultrasonography across different centers, and thereby increase diagnostic accuracy worldwide, the IOTA (International Ovarian Tumor Analysis) group first published a consensus paper on terms and definitions to describe adnexal lesions in 2000. The IOTA group also developed '*Simple Rules'* that may be applied to a mass based on the presence or absence of five benign and five malignant ultrasound features. These rules can be applied to about 80% of adnexal masses, with the rest being classed as inconclusive [4].

As many ovarian masses can be recognized relatively easily, the IOTA group also proposed four '*Simple Descriptors'* of the features typical of common benign lesions and two suggestive of malignancy, which can give an 'instant diagnosis' and reflect the pattern recognition that is a key part of ultrasonography. These are applicable to about 43% of adnexal masses. A three-step strategy, consisting of the sequential use of Simple Descriptors, Simple Rules, and subjective assessment by an expert, had high accuracy for discriminating between benign and malignant adnexal lesions [5]. Although numerous studies are available proving the efficacy of these rules, however a prospective study directly applying these diagnostic rules to the patient is lacking. So, this study was performed to establish the diagnostic utility of these rules diagnosing ovarian malignancy.

Aims and Objectives

- To assess the ability of simple ultrasound rules to discriminate adnexal masses as benign or malignant.
- To calculate the diagnostic accuracy of simple ultrasound rules from IOTA in diagnosing benign and malignant adnexal masses when compared against histopathology results.

Material and Methods

It was a cross-sectional observational study conducted from October 2019 till October 2021 in Department of Obstetrics and Gynecology, MKCG Medical College and Hospital, Berhampur, Odisha; India over

100 consecutive patients basing on following inclusion and exclusion criteria.

Inclusion criteria

- Women with unilateral/bilateral adnexal masses
    - In case of bilateral adnexal masses, mass with the most complex ultrasonic morphology were included
    - If both the masses had similar morphology on ultrasound, the one which is most easily accessible by TVS or the largest one is included.
- Patients who were operated for adnexal mass in our department.

Exclusion Criteria

- Pregnancy with adnexal mass
- Patient who failed to undergo surgery within 120 days of ultrasound examination
- Patients planned for conservative management.

Initially the sociodemographic information of the patients was followed by clinical information like chief complaints, menstrual history, and obstetric history, history of past illness and personal history were noted. Findings of general physical examination were noted, including per speculum, per vaginal and per rectal examination. Routine laboratory investigations like complete blood count, blood grouping, liver and renal functional testing, electrolytes and vital markers were sent for all patients. Tumor markers like CA-125 were ordered for all patients after ultrasonography. All adnexal masses were categorized finally into two groups - benign and malignant, in accordance with the IOTA simple rules protocol. The benign features are: B1-unilocular cyst, B2-presence of solid components (largest diameter < 7 mm), B3-presence of acoustic shadowing, B4-smooth multilocular tumor with largest diameter < 100 mm, B5-no blood flow (Color score 1). The malignant features are: M1-irregular solid tumor, M2-ascites present, M3-at least four papillary structures present, M4- irregular, multilocular solid tumor with largest diameter ≥ 100 mm, M5-very strong blood flow (Color score 4). At the end of the examination, the mass was classified as benign if one or more B features were present in the absence of M features. The masses were classified as malignant if one or more M features were present in the absence of B features. If both B rules and M rules were applied or none were present, the mass was classified as inconclusive. Serum CA-125 level was determined by radioimmunoassay. Serum CA-125 >200 IU/ml in premenopausal &>35 IU/ml in postmenopausal women were considered together as high risk of ovarian malignancy. Risk of Malignancy Index (RMI): U x M x Serum CA-125 level where U is ultrasound scoring: It was based on one point for each of the following, 1-bilateral lesion 2-multilocular cyst or septation 3-evidence of solid areas 4-evidence of metastasis 5-presence of ascites. (USG Score, U = 1 for 0-1 USG finding U = 3 for >2 USG finding. Ultrasound scoring was done within two weeks prior to laparotomy. M is the menopausal score (premenopausal woman have score 1 and postmenopausal woman have score 3). If the score < 25, it was considered as low risk, if the score 25-250, it was considered as moderate risk and if the score > 250, it was considered as high risk. The type of surgical procedure was decided by the operating surgeon. Histopathological examination was sent for the resected adnexal mass following surgery. All analysis was done using SPSS software, version 24.0 after tabulation of all data.

Results

In the present study conducted over 100 cases in the Department of Obstetrics and Gynecology of MKCG Medical College, Berhampur, Odisha; India resulted as follows: The mean age of the patients was 36.6 ± 6.49 years, ranging from18 to 76 years. Majority of cases i.e., 66 cases (66%) were in the age group of 20 to 40 years. Out

of all 77 cases (77%) were multiparous and 23 cases (23%) were nulliparous. Out of 100 cases, 81 cases (81%) were pre-menopausal, and 19 cases (19%) were post-menopausal. Among all cases studied, 26 cases (26%) of the patients had a family history of ovarian cancer. The most common presenting complaint was abdominal pain in 52 cases (52%) followed by abdominal mass in 27 cases (27%) and abnormal vaginal bleeding in 3 cases (3%). Nonspecific complaints were presented in 18 cases (18%). (Figure-I).

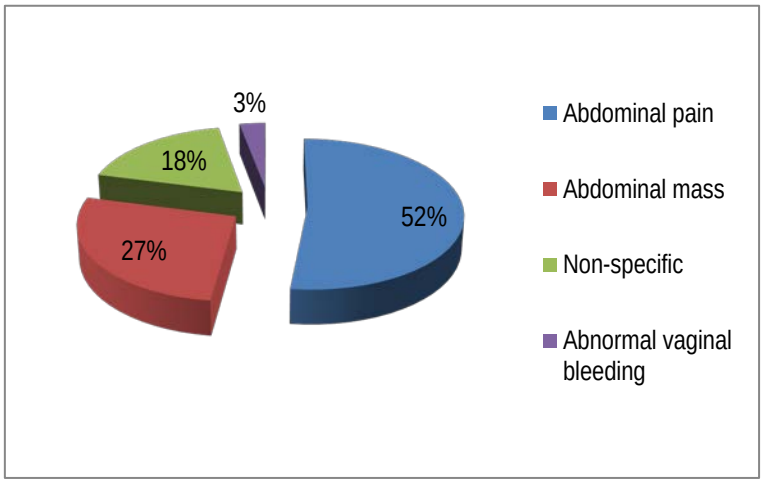

Figure 1: Clinical complain of patients with adnexal mass

History of diabetes mellitus, hypertension, hypothyroidism and cardiovascular diseases was reported by 23 cases (23%), 19 cases (19%), 5 cases (5%) and 3 cases (3%) of the patients respectively. Based on IOTA simple rules, B-5 feature were found in 5 cases (5%) whereas M-3 features found in 3 cases (3%). In 92 patients (92%), multiple features in combination were found. Among which B-5 was the most common presentation in benign conditions in 68% of cases, while M-4 was the most common among malignant conditions in 22% of cases. Other benign conditions were B-1 in 59 cases (59%), B-3 in 24 cases (24%), B-4in 23 cases (23%) and B-2 in 16 cases (16%) and other malignant presentations were M-1 in 21 cases (21%), M-5 in 21 cases (21%), M-2 in 20 cases (20%) and M-3 in 19 cases (19%). Based on IOTA simple rules (IOTA-SR), it was found 69 cases (69%) of the cases with benign lesion having at least 1 B feature, 22 cases (22%), malignant lesions having at least 1 M feature and 9 cases (9%) were inconclusive lesions having either no or both B and M features. (Table-I)

Table 1: USG findings according to IOTA Simple rule

	IOTA simple rules	Frequency	%		IOTA simple rules	Frequency	%
Benign	B1	59	59	Malignant	M1	21	21
	B2	16	16		M2	20	20
	B3	24	24		M3	19	19
	B4	23	23		M4	22	22
	B5	68	68		M5	21	21

Out of all cases studied, 77 cases (77%) of the patients had benign lesions and rest 23 cases (23%) had malignant lesions. Among benign lesions, serous cystadenoma in 25 cases (25%) was the most common diagnosis followed by mature teratoma in

20 cases (20%), endometrial cyst in 12 cases (12%), corpus luteal cyst in 7 cases (7%), mucinous

cystadenoma in 6 cases (6%), tubal cyst in 5 cases (5%) and mesonephric cyst in 2 cases (2%). Among the malignant lesions, serous cystadenocarcinoma was the most common in 11 cases (11%) followed by mucinous cystadenocarcinoma in 6 cases (6%), mucinous borderline in 3 cases (3%), granulosa cell tumor in 2 cases (2%) and immature teratoma in one case (1%). (Table-II)

Table 2: Histopathology report of Adnexal mass

	Pathology	No of Cases	%		Pathology	No of Cases	%
Benign(n=77)	Corpus luteal cyst	7	7	Malignant(n=23)	Granulosa cell tumor	2	2
	Endometrial cyst	12	12		Immature teratoma	1	1
	Mature teratoma	20	20		Mucinous borderline	3	3
	Mesonephric cyst	2	2		Mucinous cystadenocarcinoma	6	6
	Mucinous cystadenoma	6	6		Serous cystadenocarcinoma	11	11
	Serous cystadenoma	25	25				
	Tubal cyst	5	5				

Among 23 cases (23%) with malignancy on HPR (Histopathology Report), 18 cases (18%) had high CA-125 level and 5 cases (5%) had low CA-125 level whereas among 77 cases (77%) with benign HPR lesions, 7 cases (7%) had high CA-125 level and 70 cases (70%) had low Ca-125 level. Operating characteristics were measured as sensitivity: 78.2%, specificity: 90.9%, positive predictive value: 72% and negative predictive value: 93.3%. The overall diagnostic accuracy was of 84.5%. (Table-III).

Table 3: Diagnostic accuracy of CA-125 when compared against Histopathology Report

		HPR impression		Total	Operating characteristics	Value	95% CI (confidence interval)
CA-125		Malignant	Benign		Sensitivity	78.20%	56.3 to 92.5%
	High	18	7	25	Specificity	90.90%	82.1 to 96.2%
	Low	5	70	75	Positive predictive value	72.00%	55.1 to 84.2%
	Total	23	77	100	Negative predictive value	93.30%	86.5 to 96.8%
					Accuracy	84.50%	79.9 to 91.4%

Out of 23 cases (23%) with malignancy on HPR, 17 cases (17%) had RMI > 250 and 6 cases (6%) had RMI ≤ 250 whereas among 77 cases (77%) with benign HPR lesions, 9 cases (9%) had RMI > 250 and 68 cases (68%) had RMI < 250. Operating characteristics were measured as sensitivity: 73.9%, specificity: 88.3% and positive predictive value: 65.3% and negative predictive value: 91.8%. The overall diagnostic accuracy was of 85 %. (Table-IV).

Table 4: Diagnostic accuracy of RMI Score when compared against histopathology report

		HPR impression		Total	Operating characteristics	Value	95% CI (confidence interval)
MI score		Malignant	Benign		Sensitivity	73.90%	51.5 to 89.7%
	> 250	17	9	26	Specificity	88.30%	78.9 to 94.5%
	≤ 250	6	68	74	Positive predictive value	65.30%	49.3 to 78.5%
	Total	23	77	100	Negative predictive value	91.80%	85 to 94.7%
					Accuracy	85.00%	76.4 to 91.3%

Inconclusive cases on IOTA simple rules were classified as malignant for analysis purposes. Among 23 cases (23%) with malignancy on HPR, 16 cases (16%) were malignant on IOTA, 4 cases (4%) were inconclusive, and 3 cases (3%) were benign. Among 77 cases (77%) with benign HPR lesions, 6 cases (6%) were malignant on IOTA, 5 cases (5%) were inconclusive, and 66 cases (66%) were benign. Operating characteristics were measured as sensitivity: 86.9%, specificity: 85.7%, positive predictive value: 64.5% and negative predictive value: 95.6%. The overall diagnostic accuracy was of 86 %. (Table-V)

Table 5: Diagnostic accuracy of IOTA simple rules when compared against histopathology report

		HPR impression		Total	Operating characteristics	Value	95% CI(confidence interval)
IOTA Simple rules		Malignant	Benign				
	Malignant	16	6	22	Sensitivity	86.90%	66.4 to 97.2%
	Inconclusive	4	5	9	Specificity	85.70%	75.8 to 92.6%
	Benign	3	66	69	Positive predictive value	64.50%	50.7 to 76.2%
	Total	23	77	100	Negative predictive value	95.60%	88.6 to 98.4%
					Accuracy	86.00%	77.6 to 92.1%

Discussion

This cross-sectional observational was conducted in the Department of Obstetrics and Gynecology, MKCG Medical College and Hospital, Behrampur, Odisha; India which included women with unilateral/bilateral adnexal masses, who eventually underwent laparotomy in our department. All patients underwent ultrasound examination for classifying patients using IOTA simple rules.

In our study, the mean age of cases was 36.6 ± 6.49 years, ranging from 18 to 76 years and 66% of the cases were in the age group of 20 to 40 years which was similar to Shetty *et al* having mean age of 37.5 (range 15–72 years [6]. Out of all studied, 26% of the patients had a family history of ovarian cancer which is not concurrent to Shetty *et al* (4.9%). The most common presenting complaint was abdominal pain (52%) followed by abdominal mass (27%) and abnormal vaginal bleeding (3%). only 18% of the patients were asymptomatic which is concurrent to Mohan *et al* having 56% of cases had pain abdomen as their presenting

complaint [7]. Out of all, 77% of cases were multiparous and 23% cases were nuliparous which is similar to that of Mohan *et al* having 72% cases of multiparous and 28% cases of nuliparous. Among all cases studied, 81% of cases were pre-menopausal and 19% cases were postmenopausal which is not similar to Mohan *et al* having 38% cases belonging to postmenopausal age. In this study it was found that 50% of cases had co morbidities, detailed as e.g., past history of diabetes mellitus, hypertension, hypothyroidism and cardiovascular diseases in 23% cases, 19% cases, 5% cases and 3% cases respectively which is similar to that of Mohan *et al* having 54% of cases having the above co morbidities.

Based on IOTA simple rules, B-5 was the most common presentation among benign presentations in 68% of cases followed by B-1 (59%), B-3 (24%), B-4 (23%) and B-2 (16%) which is concurrent to that of Sujata *et al* having B-5 as the most common benign presentation in 82.9% of cases [8]. M-4 was the most common among malignant presentations followed by M-1 (21%), M-5 (21%), M-2 (20%) and M-3 (19%) which is not similar to that of Sujata *et al* who found M-5 as most common malignant presentation in 15.8% of cases. So, 69% of cases had benign lesions, 22% of cases had malignant lesions and 9% cases had inconclusive lesions. Out of all, 77% cases had benign lesions and 23%cases had malignant lesions which was nearly similar to study of Mohan *et al* who found 60% of the cases having benign tumors and 40% of the cases having malignant tumors (including 8% borderline tumors).

Among benign lesions, serous cystadenoma (25%) was the most common diagnosis followed by mature teratoma (20%), endometrial cyst (12%), corpus luteal cyst (7%), mucinous cystadenoma (6%), tubal cyst (5%) and mesonephric cyst (2%). Among the malignant lesions, serous cystadenocarcinoma was the most common (11%) followed by mucinous cystadenocarcinoma (6%), mucinous borderline (3%), granulosa cell tumor (2%) and iimmature teratoma (1%). This is similar to study of Sujata *et al* having serous cystadenoma accounted (30.1%) as the most common finding among benign conditions followed by mature teratoma (23.8%) and endometriotic cyst (17.4%); so also, serous cystadenocarcinoma (46.1%) as the most common condition in malignant conditions followed by mucinous cystadenocarcinoma (23%).

Among 23 cases (23%) with malignancy on HPR (Histopathology Report), 18 cases (18%) had high CA-125 level and 5 cases (5%) had low CA-125 level whereas among 77 cases (77%) with benign HPR lesions, 7 cases (7%) had high CA-125 level and 70 cases (70%) had low Ca-125 level. The operating characteristics for CA-125 were measured as sensitivity: 78.2%, specificity: 90.9%, positive predictive value: 72% and negative predictive value: 93.3%. The overall diagnostic accuracy was 84.5% which indicates a comparatively low accuracy with respect to IOTA-SA. Similar study conducted by Jacobs *et al* over 101 cases of benign pelvic mass and 42 cases of malignant pelvic mass using serum CA-125 level of 30 U/ml and found sensitivity: 81 %, specificity: 75%. Keeping RMI cut off level of 200, the sensitivity was 85% and specificity was 97% i.e., no significant advantage of Serum Ca-125 over RMI in classifying pelvic mass (p-value is 0.338591 or $p<0.05$).

Table 5

	Serum CA-125	RMI	Marginal Row Totals
Sensitivity (%)	81 (76.62) [0.25]	85 (89.38) [0.22]	166
Specificity (%)	75 (79.38) [0.24]	97 (92.62) [0.21]	172
Marginal Column Totals	156	182	338 (Grand Total)

In addition, the operating characteristics for RMI were measured as sensitivity: 73.9%, specificity: 88.3%, positive predictive value: 65.3%, negative predictive value: 91.8% and an overall diagnostic accuracy: 85%. Which is similar to Mulder *et al* (sensitivity and specificity of RMI were 72.0% and 90.7%, respectively) [9]. The sensitivity and specificity of the IOTA SR were 90.0% and 68.6%, respectively in his study which is not concurrent to present study (low sensitivity: 73.9% and high specificity: 88.3%).

In our study, operating characteristics for IOTA simple rules were measured as sensitivity: 86.9%, specificity: 85.7%, positive predictive value: 64.5%, negative predictive value: 95.6% and an overall diagnostic accuracy: 86%. Sharma *et al* observed the similar finding by using IOTA SA for detecting malignancy in adnexal mass and found as; sensitivity: 92.8%, specificity : 93%, positive predictive value : 81.2% and negative predictive value : 97.5% and the accuracy : 92.9% [10]. Sujata *et al* found that higher sensitivity and relatively low specificity as 93.7% and 76.9% respectively among benign conditions whereas sensitivity and specificity as 81.8% and 97% respectively among malignant conditions applying IOTA-SR.

Solanki *et al* also reported a higher sensitivity of IOTA-SR as compared to that in our study and found IOTA simple rules had a sensitivity of 96.67% (95% confidence interval 82.78–99.92), specificity of 92.36% (95% confidence interval 86.74–96.1), PPV of 72.5%, NPV of 99.25% [11]. In the study by Shetty *et al*, IOTA simple rules had sensitivity, specificity, PPV and NPV of 92.8%, 92.9%, 70.2% and 98.6% respectively. In their study, approximately 10% were inconclusive results, which needed further evaluation by pattern recognition. Dakhly *et al* found that simple rules were true positive in 88.0% and true negative in 90.9% of cases, whereas they were false positive in 9.1% and false negative in 12.0% of cases which is similar to the results obtained by pattern recognition with true positive and true negative values of 88.3% and 92.7%, respectively in current study [12].

Auekitrungrueng *et al* found using IOTA rules as follows: 28 cases (19.3% of malignant masses) and 59 cases (17.7% of benign masses) masses were finally diagnosed as malignant and benign, respectively [13]. The sensitivity and specificity of IOTA rules (83.8% and 92.0%, respectively) were significantly higher than RMI 1 (77.2% and 86.8%; P=0.013 and P=0.006, respectively) and RMI 2 (82.1% and 82.6%; P=0.065 and P=0.011, respectively) which indicates the importance of IOTA-SA as compared to other methods like RMI. This is similar to our findings i.e., higher sensitivity of IOTA-SR as compared to that of RMI. The sensitivity and specificity of IOTA were 100% and 99% which were significantly higher than RMI (33.3% and 95.6%) respectively in current study.

Conclusion

IOTA simple rules had a sensitivity of 86.9%, specificity of 85.7%, positive predictive value of 64.5%, negative predictive value of 95.6%, with an overall diagnostic accuracy of 86%. This overall diagnostic accuracy was higher than that of CA-125 and RMI. Correctly classifying the nature of ovarian pathology is a common diagnostic problem in gynecology, and accurate identification of cancer in these cases is the key to ensure patients access appropriate treatment. IOTA simple rules have good sensitivity and specificity for identifying malignant adnexal masses and differentiating benign from malignant. With the available evidence, IOTA is emerging as a single modality, cost-effective, feasible, with a short learning curve to differentiate the adnexal mass from a benign or malignant, thus priding the patients a chance for early diagnosis, treatment, and better survival rate. IOTA

may be incorporated in clinical practice as a tool for assessing an adnexal mass.

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