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Predicting malignancy in adnexal masses by international ovarian tumor analysis (Simple rules) versus risk of malignancy index

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Abstract

Background: Ovarian cancers are 3rd most common cancers in females in India as of Globocan 2018. Preoperative differentiation between malignant and benign adnexal masses is necessary for choosing appropriate treatment for both. Risk of malignancy index (RMI) is a scoring system based on the combination of sonographic findings, menopausal status, and serum levels of CA 125. "IOTA Simple Rules" are a preoperative USG-based classification system for ovarian tumors, consisting of B-features, M-features.

Objective: To compare the diagnostic accuracy of International Ovarian Tumor Analysis (IOTA) simple rules and risk of malignancy index (RMI) scoring to discriminate between benign and malignant adnexal masses.

Methodology: A retrospective study, those women who fulfill the inclusion criteria were subjected to study. All recruited participants underwent either transabdominal or transvaginal ultrasound examination, or both prior to surgery. Ultrasound features of the adnexal masses used in the IOTA simple rules, RMI scoring, histopathology reports were retrospectively collected from the stored computerized database and the results were analysed.

Results: Of 75 adnexal masses, 70 (93.3%) were pathologically benign, 4 (5.3%) were malignant and 1 (1.3%) was borderline. The sensitivity and specificity of IOTA rules (100% and 97.14%, respectively) were significantly higher than RMI 1 (40% and 94%) respectively.

Conclusion: IOTA simple rules have good sensitivity and specificity when comparing with RMI, for identifying malignant adnexal masses. IOTA can be used in day today practice for assessing an adnexal mass.

Keywords: IOTA, RMI, adnexal mass

Introduction

Ovarian cancers are 3rd most common cancers in females in India as of Globocan 2018. Ovarian cancers stand 3rd for mortality also [1]. Preoperative differentiation between malignant and benign adnexal masses is necessary for choosing appropriate treatment for both. Benign cysts can be managed expectantly or by minimal access surgery like cystectomy either by open method or by laparoscopically. Malignant masses need to be treated by gynaecologic oncologist. Preoperative diagnosis is challenging in diagnosing adnexal masses. Risk assessment of ovarian masses are done by one of the following methods-tumor markers, RMI, Imaging (IOTA, IOTA-ADNEX), ROMA. Tumor markers most commonly used include CA-125, CA19-9, Alpha fetoprotein, Beta Human Chorionic Gonadotrophins, Lactate Dehydrogenase, Inhibin A and B. Risk of malignancy index (RMI) is a scoring system for the combination of various factors. It improves the diagnostic accuracy in predicting ovarian malignancy. It was developed by Jacob *et al.* [2], based on the combination of sonographic findings, menopausal status, and serum levels of CA 125. RMI has a sensitivity of 85.4% and specificity of 96.9%. Later, Tingulstad *et al.* [3] developed RMI 2 to increase diagnostic accuracy. They showed that RMI 2 was superior to RMI 1 in predicting malignancy, with sensitivity of 80% and specificity of 92% compared with RMI 1 which had sensitivity of 71% and specificity of 96%.

International Ovarian Tumor Analysis (IOTA) was found by Timmerman in 1999 to describe sonographic features of adnexal mass by simple rules [4]. Sensitivity was found to be 91% and specificity to be 93% [4, 5].

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“IOTA Simple Rules” are a preoperative USG-based classification system for ovarian tumors, consisting of five features typical for benign tumors called the B-features and five features typical for malignant tumors termed M-features. Based on B- or M-features, tumors are classified as benign, malignant, or inconclusive (if both B and M-features are present) [3]. “B features” included-unilocular, presence of solid components <7 mm, presence of acoustic shadow, smooth multilocular tumor with the tumor measuring <100 mm, and no blood flow on color Doppler (color score 1). “M features” included-irregular solid tumor, presence of ascites, at least four papillary structures, ascites, irregular multilocular solid tumor with the largest diameter ≥100 mm, very strong blood flow (color score 4).

Objective

To compare the diagnostic accuracy of International Ovarian Tumor Analysis (IOTA) simple rules and risk of malignancy index (RMI) scoring to discriminate between benign and malignant adnexal masses.

Materials and Methodology

Study Design: Retrospective study

Place of Study: Department of Obstetrics and Gynaecology, Vijaya Hospital, Chennai.

Study Period: January 2016 to June 2021

Inclusion Criteria: Women with adnexal masses diagnosed by Ultrasound planned for surgery

Exclusion Criteria: Known case of ovarian malignancy diagnosed prior to surgery, either by prior diagnostic laparoscopy or previous history of pelvic surgery or by histopathology.

Sample Size: 75

Methodology: Those women who fulfill the inclusion criteria were subjected to study. All recruited participants underwent either transabdominal or transvaginal ultrasound examination, or both prior to surgery. Ultrasound examinations were performed by an experienced sonographer. Ultrasound features of the adnexal masses used in the IOTA simple rules, RMI scoring, histopathology reports were retrospectively collected from the stored computerized database.

If one or more B-rules present in the absence of an M-rule, the mass was categorized as benign. If one or more M-rules present in the absence of a B-rule, the mass was categorized as malignant. If both B-rules and M-rules present, the mass was categorized as inconclusive.

Table 1: IOTA group simple rules to classify masses as benign (B-rules) or malignant (M-rules)

B-rules	M-rules
Unilocular cysts	Irregular solid tumor
Presence of solid components where the largest solid component <7mm	Ascites
Presence of acoustic shadowing	At least four papillary structures
Smooth multilocular tumor with a largest diameter <100mm	Irregular multilocular solid tumor with largest diameter ≥100mm
No blood flow	Very strong blood flow

RMI scoring, ultrasound features of the mass, menopausal status, and serum CA 125 levels were incorporated to score the mass. The ultrasound findings of solid area, multilocular cyst, bilateral masses, ascites, and intra-abdominal metastases were scored 1 point for each. A total ultrasound score (U) was calculated for each patient. Postmenopausal status (M) was defined as one year or more of missed menstruation; if this did not apply, the alternative status was classified as premenopausal. RMI was calculated for all patients, using a cut-off level of 200 for predicting malignancy.

RMI scoring² was calculated as follows: scores = U x M x serum CA 125, where a total ultrasound score of 0 gave U = 0, a score of 1 gave U = 1, and a score of greater than or equal to 2 gave U = 3; premenopausal status gave M = 1, postmenopausal status gave M = 3; and serum CA 125 level was multiplied directly into the formula.

The definite diagnosis of the adnexal masses were based on pathological reports. A comparison of the accuracy to predict benign or malignant masses between the IOTA and RMI methods was done.

Ethical Considerations: The study abides by the rules of the ethical committee. No intervention causing harm to patient mentally, physically or financially is being done.

- This study is conducted at Vijaya Hospital, Chennai.
- Women with inclusion criteria were selected and their information collected retrospectively from the stored computerized database.

Statistical Analysis: Statistical analysis is going to be done by the statistical software STATA 11.0. Continuous variables will be representing as ‘Mean (SD)’ and categorical variables are representing as ‘Frequency (percentage)’. Chi square test or Fisher’s exact test will be used to assess differences in categorical data. Student unpaired T-test/Mann Whitney U test will be used for differences in means of two independent data. The p value <0.05 will be considered significant.

Results

75 patients who fulfilled the inclusion criteria were included in the study. Among the 75 patients, premenopausal group were 55(73.3%) and postmenopausal group were 20(26.7%). Age of the patient ranges from 18 to 82 years. 15(20%) were nulliparous women.

Table 2: Menopausal status

	Menopause	
	Yes	No
Benign	16	54
Borderline/Malignant	4	1

Of 75 adnexal masses, 70 (93.3%) were pathologically benign, 4 (5.3%) were malignant and 1 (1.3%) was borderline. Benign Serous cystadenoma followed by Endometrioma were the most common adnexal mass, accounting for 44% (n=33) of all masses. According to IOTA simple rules, benign were 57(76%), inconclusive were 11 (14.6%) and malignant were 7(9.3%).

Table 3: Comparison of IOTA, RMI with Histopathology reports

	Histopathology	
	Benign	Malignant (Including borderline ovarian tumor)
IOTA –simple rules		
1. Benign- 57 patients	57	-
2. inconclusive- 11 patients	11	-
3. Malignant- 7 patients	2	5
RMI-1		
1. <200- 69 patients	66	3
2. >200- 6 patients	4	2

According to IOTA rules, none of the benign cases turned out to be malignant. Among the 11 inconclusive, all were benign by final histopathology report. Among the 7 malignant cases, 2 were false positive.

According to RMI 1, score more than 200 was considered to be significant. 6 patients had score more than 200, but only 2 turned out to be malignant. Even with score less than 200, 2 were malignant and 1 borderline.

The sensitivity and specificity of IOTA rules (100% and 97.14%, respectively) were significantly higher than RMI 1 (40% and 94%) respectively.

Discussion

Adnexal masses must be classified as benign or malignant to manage them. This differentiation has been achieved by clinical judgment, tumor markers, especially CA 125 or HE-4, sonographic morphology, sonography by an expert, spectral Doppler [6, 7, 8, 9] etc., RMI scoring system using a combination of age, menopausal status, tumor markers, and USG morphology has also been used to increase sensitivity and specificity in predicting malignancy in the adnexal masses. USG is a simple, noninvasive, nowadays widely available modality.

The main purpose of our study was to identify an accurate, simple, inexpensive, and practical method in differentiating benign and malignant adnexal masses. Because of high diagnostic performance, simplicity, and ease to learn with a short training course or practice under supervision, our study suggests that the IOTA rules should be used instead of RMI. However, the IOTA rules had a relatively high rate of inconclusive results, which must be taken into consideration for its wider use. In cases of inconclusive results, consultation from a specialist sonographer should be sought; if the mass is considered to be malignant, consultation with an oncologist or referral to a specialist center is recommended.

A disadvantage of RMI is that this scoring needs to measure tumor marker levels. But tumor markers are elevated in many non-malignant conditions like endometriosis, fibroid, pelvic inflammatory disease, adenomyosis and non gynaec condition like appendicitis, colitis etc.

Our findings showed that, the IOTA simple rules were more effective than RMI scoring at discriminating between benign and malignant adnexal masses. This finding was consistent with other studies [10, 11, 12, 13].

Conclusion

IOTA simple rules have good sensitivity and specificity when comparing with RMI, for identifying malignant adnexal masses. IOTA is becoming a single, cost-effective and feasible method, with a short learning curve to differentiate the adnexal mass from a benign or malignant. IOTA can be used in day today practice for assessing an adnexal mass.

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