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Evaluation of Diagnostic Accuracy of Risk of Malignancy Index (RMI) and International Ovarian Tumour Analysis (IOTA) Simple Rules To Differentiate Between Benign and Malignant Ovarian Tumours

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Abstract
AIM:
To evaluate the diagnostic efficacy of Risk of Malignancy Index (RMI) and International Ovarian Tumour Analysis (IOTA) Simple Rules to differentiate between benign and malignant ovarian tumours.
Materials And Method:
This study was carried out in Sri Ramachandra Institute of Higher Education and Research, Chennai from August 2017 – December 2019.
RMI was calculated using the formula U(ultrasound scan score) x M(menopausal status) x CA 125.
Ultrasound examination was done for all patients and the masses were classified as benign and malignant based on the IOTA simple rules. The patients were then subjected to surgery. Gold standard was the postoperative histopathology of the ovarian mass.
Results:
220 patients were included in this study. Sensitivity and specificity Of IOTA were 100% and 99% which were significantly higher than RMI (33.3% and 95.6%) respectively.
Conclusion:
IOTA Simple Rules is considered to be the most reliable method in differentiating ovarian tumours into benign and malignant.
Keywords*:Ovarian mass, IOTA, RMI, Ultrasound, CA125*

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I. Introduction

Ovarian cancer has the leading mortality rate of all gynaecological cancers.[1] Preoperative estimation of benign or malignant character of an ovarian mass is essential as it will determine the treatment strategy and also impact significantly on the prognosis of the patient. Benign masses can be managed conservatively or removed by laparoscopy. Malignant masses need to be referred to surgical oncologists for proper staging and debulking.[2]

Hence several models were developed to differentiate between benign and malignant ovarian masses. This article evaluates the diagnostic accuracy of Risk of Malignancy index (RMI) and International Ovarian Tumour Analysis (IOTA) simple rules in differentiating benign and malignant tumours.

II. Materials And Methods

This study was carried out in the Department of Obstetrics and Gynaecology at Sri Ramachandra Institute of Higher Education and Research, Chennai from August 2017 – December 2019.
STUDY DESIGN: Prospective observational study
Women of any age with ovarian mass who subsequently underwent surgical removal were considered. Pregnancy was excluded.
A detailed history was obtained with regard to age, parity, menopausal status, family history and CA 125.

RISK OF MALIGNANCY INDEX:
RMI was calculated using the formula U(ultrasound scan score) x M(menopausal status) x CA 125.
The ultrasound result was given 1 point for each of the following characteristics: multilocular cysts, solid areas, metastases, ascites and bilateral lesions.

U = 0 for an ultrasound score of 0
U = 1 for an ultrasound score of 1 and
U = 3 for an ultrasound score of 2 – 5
Menopause is defined as one or more than one year of amenorrhoea or women who had undergone hysterectomy. Menopausal score was assigned M = 1 if premenopausal and M = 3 if postmenopausal.

Serum CA 125 levels were measured in IU/ml for all patients.
RMI < or = 200 were considered benign and RMI > 200 were considered malignant[3]

IOTA SIMPLE RULES (IOTA SR):
The IOTA SR were determined based on the 10 ultrasound features – 5 benign and 5 malignant features.
The mass was classified as benign if 1 or more B features were present with no M features. The mass was classified as malignant if 1 or more M features were present with no B features. If both B and M features were present or none was present, the mass was classified as inconclusive[4,5,9]

The patients were then subjected to surgery.
Gold standard was the postoperative histopathology of the ovarian mass.

III. Results

There were 220 patients in this study. The baseline characteristics of the patients were as shown in Table I.

TABLE I – BASELINE PATIENT CHARACTERISTICS

	VALUE
MEAN AGE (in years)	37.75 (12 – 85)
MENOPAUSAL STATUS	
Premenopausal	181 (82.3%)
Postmenopausal	39 (17.7%)
ULTRASOUND SCORE FOR RMI	
Score 0	157 (71.36%)
Score 1	34 (15.45%)
Score 3	29 (13.18%)
DEFINITIVE HISTOPATHOLOGY	
Benign	205
Malignant	15

Comparison of RMI and IOTA SR with definitive histopathology is shown in Table II.

TABLE II – COMPARISON OF RMI AND IOTA SR WITH DEFINITIVE HISTOPATHOLOGY

		DEFINITIVE HISTOPATHOLOGY	
	n (n = 220)	BENIGN	MALIGNANT
NATURE OF TUMOUR AS PER RMI			
<200 (benign)	206	196 (95.1%)	10 (4.9%)
> 200 (malignant)	14	9 (64.3%)	5 (35.7%)
NATURE OF TUMOUR AS PER IOTA SR			
Benign	203	203 (100%)	0
Malignant	17	2 (11.8%)	15 (88.2%)
Inconclusive	none		

The 9 tumours which were predicted malignant by RMI but were found to be benign in HPE were endometriotic cyst (7), serous cystadenoma (1) and serous cystadenofibroma (1)

The 10 tumours which were predicted benign by RMI but were found to be malignant in HPE were Granulosa cell tumour (2), serous borderline tumour (2), mucinous borderline tumour (2) and endometrioid CA (1)

The 2 tumours which were predicted malignant by IOTA but were found benign in HPE report were benign serous cystadenofibroma with features of irregular multilocular solid tumour and strong blood flow and Endometriotic cyst with features of irregular multilocular solid tumour.

Frequencies ofHistopathologicalevidence (HPE) of ovarian tumours is given in Table III.

TABLE III – HPE OF OVARIAN TUMOURS

BENIGN OVARIAN MASSES	**TOTAL NO OF PATIENTS (n = 205)**
SIMPLE CYST	56 (27.3%)
ENDOMETRIOTIC CYST	21 (10.24%)
MATURE CYSTIC TERATOMA	16 (7.8%)
CORPUS LUTEAL CYST	12 (5.85%)
BENIGN MUCINOUS CYSTADENOMA	14 (6.82%)
SEROUS CYSTADENOMA	41 (20%)
SEROUS CYSTADENOFIBROMA	25 (12.19%)
HEMORRHAGIC CYST	20 (9.75%)

MALIGNANT OVARIAN MASSES	**TOTAL NO OF PATIENTS (n = 15)**
GRANULOSA CELL TUMOUR	2 (13.33%)
SEROUS BORDERLINE TUMOUR	2 (13.33%)
MUCINOUS BORDERLINE TUMOUR	5 (33.3%)
ENDOMETROID CA	2 (13.33%)
CLEAR CELL CA	2 (13.33%)
MICROPAPILLARY SEROUS CA	1 (6.66%)
YOLK SAC TUMOUR	1 (6.66%)

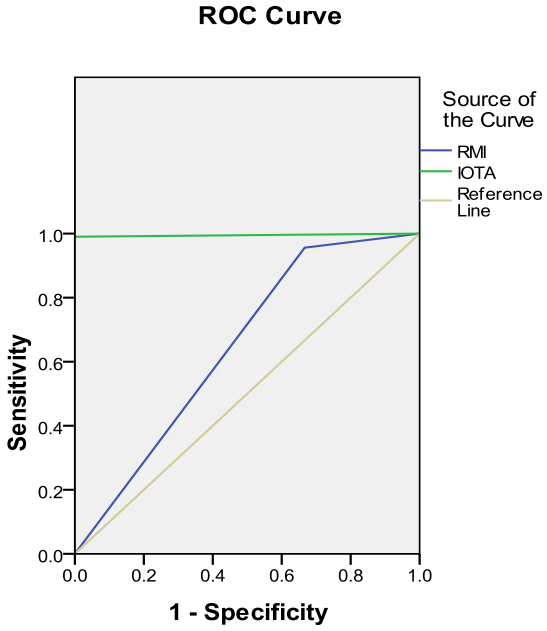
The sensitivity, specificity, positive predictive value and negative predictive values of RMI and IOTA SR were calculated which is shown in Table IV

TABLE IV – SENSITIVITY, SPECIFICITY, POSITIVE PREDICTIVE VALUE AND NEGATIVE PREDICTIVE VALUES OF RMI ANDIOTA SR

	SENSITIVITY	SPECIFICITY	POSITIVE PREDICTIVE VALUE	NEGATIVE PREDICTIVE VALUE
RMI	33.3%	95.6%	35.7%	95.1%
IOTA SR	100%	99%	88.2%	100%

Figure 1 shows the ROC curve, calculated for RMI and IOTA SR to compare the AUC of these models. The values for the AUC for RMI and IOTA SR are 0.645 and 0.995 respectively. The AUC of the IOTA SR was significantly higher than RMI ($P < 0.001$).

Figure 1: ROC curve showing the performance of RMI and IOTA SR.



Diagonal segments are produced by ties.

Test Result Variable(s)	Area under the curve	Standard. Error	Asymptotic Significance.	Asymptotic 95% Confidence Interval	
				Lower Bound	Upper Bound
RMI	.645	.086	.061	.477	.813
IOTA	.995	.004	.000	.000	1.000

IV. Discussion

This study compared RMI with IOTA Simple Rules in differentiating benign and malignant tumours in 220 patients. Results show that IOTA SR is more effective in distinguishing ovarian tumours[6,7,8,10] AUC of RMI is 0.645 and that of IOTA SR is 0.995 which is significantly higher.

RMI has very low sensitivity compared to IOTA SR (33.3% and 100%) which might result in missing malignant ovarian tumours which might result in inadequate treatment. This may be due to non epithelial and borderline tumours as described in previous studies. Addition of CA 19.9 may increase the sensitivity of this model. Incidence of false positives were also higher in RMI due to the elevated CA 125 levels in endometriotic cysts.

The strength of this study was that both RMI and IOTA SR were done in all patients, allowing the results of both the diagnostic tests to be compared. However this study had small number of included patients. Also the borderline tumours were classified as malignant for statistical purpose.

Everything considered IOTA Simple Rules is better in discrimination of ovarian mass before surgical treatment. Therefore the application of IOTA rules provide a basis for referral of patients with a mass classified as malignant to surgical oncologist.

V. Conclusion

IOTA Simple Rules were found to have higher sensitivity, specificity, positive predictive value and negative predictive values when compared to RMI. Hence IOTA Simple Rules is considered to be the most reliable method in differentiating the ovarian tumours into benign and malignant.

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