

A Comparative Study of International Ovarian Tumor Analysis Simple Ultrasound Rules and Risk of Malignancy Index in Differentiating benign from Malignant Ovarian Masses Coming to Tertiary Care Hospital

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Abstract

Aims and Objectives: The main objective of our study was to determine the sensitivity and specificity of International Ovarian Tumor Analysis (IOTA) Simple Ultrasound Rules and Risk of Malignancy Index (RMI) in differentiating benign from malignant ovarian masses and to compare the results generated with histological diagnosis.

Materials and Methods: A total of 50 consenting patients with ovarian mass coming to the Department of Obstetrics and Gynecology of our college in reproductive and menopausal age group were enrolled over a period of nine months. Data was collected using a standardized pretested proforma. Detailed examination of the subjects was done following which ultrasonographic assessment was done by gynecologists. In the subsequent visit or post admission blood investigations including CA-125 was done. Patient management as per departmental protocol was continued.

Results: The sensitivity, specificity, Positive Predictive value and Negative Predictive Value of RMI 2 in our study was 75.75%, 64.7%, 80.6% and 57.8% respectively. The sensitivity, specificity, Positive Predictive value and Negative Predictive

Value of IOTA Simple Ultrasound rules in our study was 96.96%, 71.4%, 88.8% and 90.9% respectively.

Conclusion: In the present study we have seen that IOTA Simple USG Rules had better Sensitivity, Specificity, Positive Predictive Value and Negative Predictive Value than Risk of Malignancy Index (RMI 2). Though both the scoring systems have their own set of limitations IOTA Simple USG rules in our study seems to be a better scoring system; still we need to have a larger sample size, more Indian population-based studies to extrapolate the same results to Indian populations.

Keywords: IOTA Simple USG Rules; RMI 2; Ovarian mass; Histological Diagnosis.

Introduction

Ovarian cancer is the third most common cancer amongst Indian women with incidence varying between 5.4 and 8 per 100,000 populations in different parts of the country¹. India has the 2nd highest number of ovarian cancers (26,384) being reported annually next only to China (34,575); followed by the US². This highlights the need for timely diagnosis and intervention to provide optimal care to all patients.

In case of ovarian masses, the diagnostic difficulties arise from the heterogenic nature of the adnexal masses, presence of multiple functional changes, and lack of early symptoms. A definitive pre-surgical segregation cannot be performed using clinical features, ultrasonographic features, or tumour markers alone. No single test can be used conclusively to differentiate between malignant and non-malignant ovarian masses.

Amongst the various radiological modalities Ultrasonography has been used as screening tool since ages cost effectiveness and widespread availability being two major advantages. In this study we have attempted to compare 2 diagnostic algorithms International Ovarian Tumor Analysis (IOTA) Simple Ultrasound Rules^{3,4} with Risk of Malignancy Index (RMI 2).^{5,6}

Materials and Methods

This study is a prospective cross sectional study of 50 subjects enrolled in a tertiary care hospital over a period of nine months from June 2019 to February 2020. All consenting patients with ovarian mass size ≥ 5 cm in reproductive and menopausal age group were included in our study. Patients with ovarian cyst < 5 cm, pregnant patients with ovarian cyst and patients not willing to undergo surgery or radio-chemotherapy at our institute were excluded from our study.

Data was collected using a standardized pretested proforma. On first visit a detailed history was elicited followed by detailed examination and ultrasonographic assessment was done by gynecologists using Mindray DC-N3 ultrasonography machine in department. In the subsequent visit or post admission blood investigations including CA-125 were done. Patient management as per departmental protocol was continued. The data generated was analyzed using MS Excel (2011 version) and statistical analysis was done using Open Epi Software.

Discussion

In our study fifty consenting women presenting to the obstetrics and gynecology department of our college were included. The mean age of the subjects in present study was 49.34 years. The youngest subject was 18 years and oldest being 80 years. Malignancy was more common in the sixth decade of life. Malignancy was also seen more frequently in postmenopausal ladies (51.28%). RMI 2 classified 19 subjects as benign and 31 subjects as malignant as shown in Fig. 1. The sensitivity, specificity,

Positive Predictive value and Negative Predictive Value of RMI 2 in our study is 75.75%, 64.7%, 80.6% and 57.8% respectively.

Fig. 1: Comparison of RMI 2 Results with HPE.

	HPE Benign	HPE Malignant	Total
RMI Benign < 200	11	8	19
RMI Malignant ≥ 200	6	25	31
Total	17	33	50

Fig. 2: Comparison of IOTA Simple USG Rules result with HPE results.

	HPE Benign	HPE Malignant	Total
IOTA BENIGN	10	1	11
IOTA MALIGNANT	4	32	36
IOTA Indeterminate	3	0	3
Total	17	33	50

Fig. 3: HPE Distribution of study subjects and comparison of RMI 2 with IOTA Simple USG Rules.

HPE Diagnosis	Number of subjects	Number of subjects correctly identified by IOTA	Number of Subjects correctly identified by RMI 2
Non Neoplastic lesions of ovary	5	2	3
Epithelial Tumors of ovary	-	-	-
Benign	7	5	3
Malignant	27	27	21
Borderline	1	1	1
Germ cell tumor	-	-	-
Benign	2	2	2
Malignant	2	1	1
Sex Cord Stromal Tumor	2	1	2
Metastasis	3	3	2
Infective/Inflammatory conditions	1	0	1

In premenopausal age group the sensitivity was 61.5% and specificity was 88.8%; whereas in postmenopausal age group the sensitivity was 85% and specificity was 37.5%. IOTA Simple USG Rules classified 11 subjects as benign, 36 subjects as malignant and 3 subjects were classified as indeterminate as shown in Fig. 2. The sensitivity, specificity, Positive Predictive value and Negative Predictive Value of IOTA Simple Ultrasound rules in our study was 96.96%, 71.4%, 88.8% and 90.9% respectively. In premenopausal age group

the sensitivity was 92.3% and the specificity was 75%; whereas in postmenopausal age group the sensitivity was 100% and specificity was 66%. The histopathological diagnosis of subjects classified as indeterminate by IOTA Simple USG Rules were hemorrhagic ovarian cyst, hydatid cyst of ovary and serous cystadenoma of ovary.

As shown in Fig. 3 IOTA Simple USG rules correctly diagnosed all 27 of subjects with Malignant Epithelial Ovarian Tumors (100%) and all 3 subjects with metastasis (100%); whereas the diagnostic accuracy was poorest for Non-neoplastic lesions of ovary (40%), accuracy was also low for benign epithelial ovarian tumors (71%).

RMI 2 on the other hand correctly diagnosed 21 out of 27 subjects with Malignant Epithelial Ovarian Tumors (77.7%) and 2 of 3 subjects with metastasis (66.6%).

RMI 2 had a better diagnostic accuracy than IOTA Simple USG Rules for Non - neoplastic lesions of ovary (60%) and was also able to correctly classify infective conditions. Both the scoring systems couldn't correctly classify benign serous cystadenoma, endometrioma and residual yolk sac tumor. Thus as shown in Table 4 in our study IOTA Simple USG Rules is a better diagnostic criteria than Risk of Malignancy Index (2) having a better sensitivity, specificity, positive predictive value and negative predictive value.

Table 4: Comparison of IOTA and RMI 2 in terms of sensitivity, specificity, PPV and NPV.

Assessment	sensitivity	specificity	PPV	NPV
IOTA	96.96	71.4	88.8	90.9
RMI 2	75.75	64.7	80.6	57.8

Conclusion

Ovarian masses are known as the silent killer and need to be diagnosed early and treated well in time to prevent the associated risk of mortality and morbidity. Since no single criteria and modality

has till date been able to correctly diagnose ovarian mass pre-operatively; a number of diagnostic models combining multiple parameters have been put forth. In the present study we have seen that IOTA Simple USG Rules had better Sensitivity, Specificity, Positive Predictive Value and Negative Predictive Value than Risk of Malignancy Index (RMI 2). Hence we have concluded that IOTA Simple USG Rules is a simple, easy to apply and better performing diagnostic algorithm than RMI 2.

Limitations

The sample size of our study was small.

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