Section: Obstetrics and Gynaecology

Original Research Article

COMPARISON OF THE DIAGNOSTIC ACCURACY OF THE IOTA – SIMPLE RULES WITH THE RMI INDEX TO DISTINGUISH BETWEEN BENIGN AND MALIGNANT ADNEXAL MASSES

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Abstract

Ovarian cancer is the 3rd most common cancer and 5th most frequent cause of death in women. As there are no ideal screening methods for ovarian malignancy, primary prevention is difficult. Secondary prevention is early diagnosis and treatment. Our aim is to diagnose and distinguish the adnexal lesions as benign and malignant. To diagnose ovarian malignancy in early treatable stage so that complete cure could be offered to these patients who will improve their quality of life and their life expectancy. A precise characterization of the adnexal masses is required for optimal patient management. Hence the tools I have chosen to characterize the lesion are Risk of Malignancy Index 2(RMI-2) and International Ovarian Tumor Analysis-Simple Rules (IOTA-SR).

INTRODUCTION

Aim

To compare Risk of Malignancy Index (RMI 2) and the International Ovarian Tumor Analysis (IOTA-Simple rules) in the accurate diagnosis of benign and malignant ovarian masses Pre-operatively.

MATERIALS AND METHODS

This study is conducted at Institute of Obstetrics and gynaecology (IOG). 200 patients with adnexal lesions were subjected to Transvaginal ultrasound to determine RMI Index and IOTA – Simple Rules. RMI Score 2 is used. IOTA – SR differentiates lesion as B-Features and M-Features. If patient had only benign features, then they were subjected to conservative surgeries. If in case USG Features are suggestive of malignancy, then patients are sent to surgical oncologist opinion and posted for staging laprotomy and more radical surgeries. After surgery, the specimens were sent for histopathology. Tissue diagnosis is gold standard. Results of RMI Score 2 and IOTA-SR is compared with Histopathogical diagnosis. Sensitivity, specificity, positive and negative predictive values for both RMI Index and IOTA-Simple rules are calculated and compared with each other.

RESULTS

Large number of physiological and benign lesions occur in 30-50 years of age, most of the ovarian pathologies are. Malignancy is common in elderly patients. Roughly 50% of cancer cases occur in people aged 65 years or older.

Parity among the study participants: Majority of the study participants were multiparous. Nulliparous women constituted 18.5% of the study population. (Table 2/Fig 2)

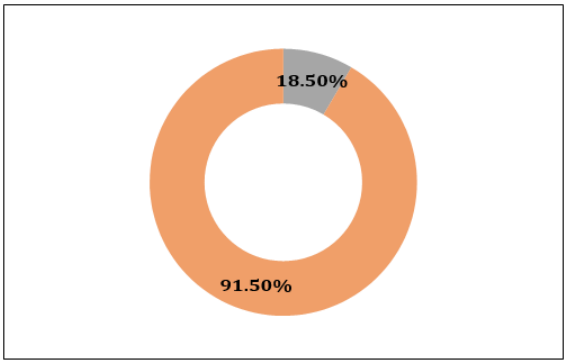

Figure 1: Parity among the study participants

Menopausal status of the study participants

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In the present study we observed that more than half (68%) of the study participants were pre-menopausal. Post-menopausal women comprised of 32% of the study population.

Malignancy is higher among Post menopausal age group. Epithelial ovarian tumors are higher among post menopausal women.

Family History among the study participants

In the present study, more than half (67.5%) of the study participants had reported to have a family history of carcinogenic lesions. Negative family history was reported by 32.5% of the study population.

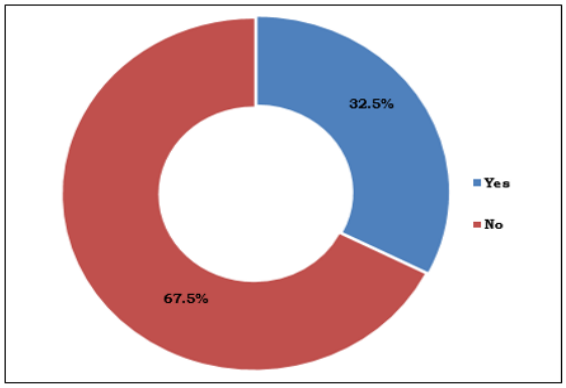

Figure 2: Family History among the study participants

Histopathology findings

Histopathological reports of the observed samples showed that three types of lesions namely, Benign, Borderline and Malignant were present. Benign (47%) lesion appeared to be more common as compared to malignant (23.5%) and borderline (29.5%) lesions.

Cancer antigen 125 (CA-125) levels among study participants

In the present study the cutoff values of CA-125 was kept at 35 u/ml. It was found that 34% of the study population had CA 125 values more than 35 units per ml while 66% of the study participants had CA 125 level of less than 35 units per ml.

Risk Malignancy Index among study participants

Risk Malignancy Index 2 was taken in the present study. The study population study participants with Risk Malignancy Index cut off values above and equal to 200 were 56 in number, this constituted 28% of the study population. Whereas those with cutoff values less than 200 constituted 72% of the study population.

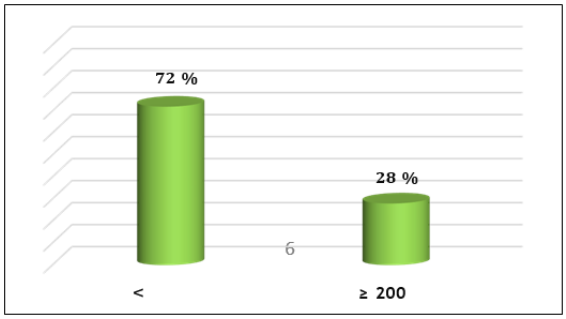

Figure 3: Risk Malignancy Index among study participants

International Ovarian Tumor Analysis-Simple Rules (IOTA-SR) USG finding among study participants

USG finding of the patients was categorized into Benign(B-FEATURES) indicating benign and Malignant(M-FEATURE) indicating malignancy. In the present study patients with B-FEATURE constituted 71% of the study population. While those with M-FEATURE constituted 29% of the study population

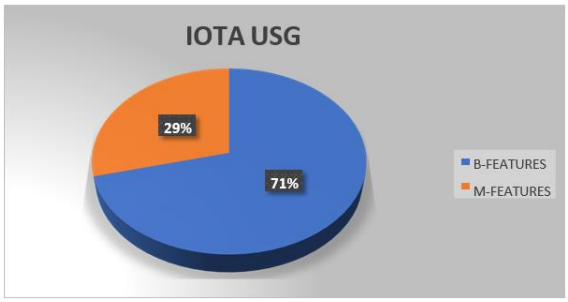

Figure 4: USG finding among study participants

Histopathological examination – Benign Tumors

In the present study, our results showed 94 benign lesions among the study participants. The commonly observed benign lesions were serous cyst adenoma (34%), Simple serous cyst (25.5%), Mucinous cystadenoma (13.8%), Dermoid (5.3%).The other benign lesions like Endometriotic cyst (9.6%), Corpus luteal cyst (5.3%) and Follicular cyst (6.4%) were also observed.

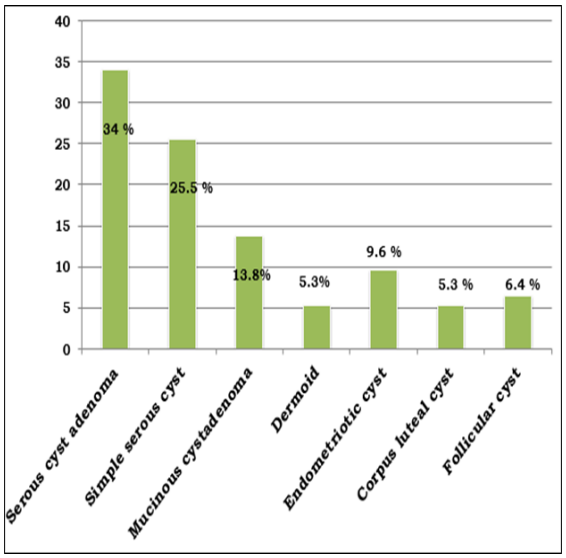

Figure 5: Benign Tumors among study participants

Histopathological examination – Malignant Tumors

In the present study, our results showed 47 malignant lesions among the study participants. The commonly observed malignant lesions were serous adenocarcinoma (55.3%), Mucinous cyst adenocarcinoma (38.3%) and Granulosa cell tumor (2.1%). The other malignant lesions like Clear cell

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carcinoma (2.1%), and Germ cell tumor (2.1%) were also observed.

Correlation between IOTA-SR and Histopathology examination finding

In our study, we observed the correlation between IOTA-SR and Histopathology examination finding. Our findings showed that patients with benign lesions had significantly higher number of USG Score I. We also found that the USG Score III was significantly more in participants with malignant lesions.

RMI index and Histopathology examination finding

In our study, we observed the correlation between RMI index and Histopathology examination finding. Our findings showed that patients with RMI values less 200, there was significantly more benign lesions. We also found that the patients with RMI values more than or equal to 200 had significantly more malignant lesions.

Table 1: Age distribution of participants (n=200)

Age Group	Frequency (n=200)	%
<20	4	2%
21-30	13	6.5%
31 – 40	64	32%
41 – 50	71	35.5%
51 – 60	40	20%
>60	8	4%

Table 2: Parity among the study participants --Incidence of Ovarian malignancy is higher in Nulliparous women compared to multiparous women.

Parity	Frequency (n=200)	%
Nulliparous	17	18.5
Multiparous	183	91.5

Table 3: Menopausal status of the study participants

Menopausal	Frequency (n=200)	%
Pre-menopausal	136	68 %
Post-menopausal	64	32 %

Table 4: Family History among the study participants

Family History	Frequency (n=200)	%
Yes	65	32.5%
No	135	67.5%

Table 5: Histopathology findings among the study participants

Histopathology	Frequency (n=200)	%
Benign	94	47
Borderline	59	29.5
Malignant	47	23.5

Table 6: Cancer antigen 125 (CA-125) levels among study participants

CA 125	Frequency (n=200)	%
< 35 u/ml	146	73%
≥ 35 u/ml	54	27%

Table 7: Risk Malignancy Index among study participants

RMI cutoff	Frequency (n=200)	%
< 200	144	72
≥ 200	56	28

Table 8: USG finding among study participants

USG	Frequency (n=200)	%
B-FEATURES	142	71%
M-FEATURES	58	29%

Table 9: Benign Tumors among study participants (n=94)

Benign Tumors	Frequency	Percentage
Serous cyst adenoma	32	34
Simple serous cyst	24	25.5
Mucinous cystadenoma	13	13.8
Dermoid	5	5.3
Endometriotic cyst	9	9.6
Corpus luteal cyst	5	5.3
Follicular cyst	6	6.4

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Table 10: Malignant Tumors among study participants (n=47)

Malignant Tumors	Frequency	Percentage
Serous adenocarcinoma	26	55.3
Mucinous cyst adenocarcinoma	18	38.3
Granulosa cell tumor	1	2.1
Clear cell carcinoma	1	2.1
Germ cell tumor	1	2.1

Test of Significance - Chi Square Test (χ^2)

Table 11: Correlation between IOTA-SR and HPE finding (n=200)

IOTA-SR	Benign	Borderline	Malignant	p value
B-FEATURE	93	46	3	0.00001
M-FEATURE	1	13	44	

*p value <0.05 was considered to be statistically significant Correlation between

Table 12: Correlation between RMI index and HPE finding (n=200)

RMI index	Benign	Borderline	Malignant	p value
< 200	83	23	12	0.00001
≥ 200	11	36	35	

*p value <0.05 was considered to be statistically significant

DISCUSSION

A cohort study was conducted to compare the IOTA SR and RMI index in assessing the malignant adnexal mass from benign. The study was conducted among 200 patients admitted at IOG, Chennai.[1]

The results of the study are given below, 64 participants(32%) were aged between 31 - 40 years, 71 participants(35.5%) were aged between 41 and 50 years. Among the study population 20% were aged between 51 to 60 years. 4% were aged more 60 years of age. Participants aged less than 30 years of age and more than 60 years of age constituted 8.5% and 4% respectively.[2]

Majority of the study participants were multiparous. Nulliparous women constituted 18.5% of the study population.

More than half (68%) of the study participants were pre-menopausal. Post- menopausal women comprised of 32% of the study population. More than half (67.5%) of the study participants had negative family history. Only 32.5% of the study population reported family history of malignancy.[3]

Histopathological reports of the observed samples showed that three types of lesions namely, Benign, Borderline and Malignant were present. Benign (47%) lesion appeared to be more common as compared to malignant (23.5%) and borderline (29.5%) lesions.[4]

The cutoff values of CA-125 was kept at 35 u/ml. It was found that 34% of the study population had CA 125 values more than 35 units per ml while 66% of the study participants had CA 125 level of less than 35 units per ml.[5]

Risk Malignancy Index 2 was taken in the present study. The study population study participants with Risk Malignancy Index cut off values above and equal to 200 were 56 in number, this constituted 28% of the study population. Whereas those with cutoff values less than 200 constituted 72% of the study population.[6]

For USG (IOTA-SR) - patients was categorized into B-Features and M-Features. B-Feature indicating benign and M-Feature indicating malignancy. In the present study patients with B-Feature constituted 71% of the study population. While those with M-Feature constituted 29% of the study population.[7]

94 benign lesions among the study participants. The commonly observed benign lesions were serous cyst adenoma (34%), Simple serous cyst (25.5%), Mucinous cystadenoma (13.8%), Dermoid (5.3%). The other benign lesions like Endometriotic cyst (9.6%), Corpus luteal cyst (5.3%) and Follicular cyst (6.4%) were also observed

47 malignant lesions among the study participants. The commonly observed malignant lesions were serous adenocarcinoma (55.3%), Mucinous cyst adenocarcinoma (38.3%) and Granulosa cell tumor (2.1%). The other malignant lesions like Clear cell carcinoma (2.1%), and Germ cell tumor (2.1%) were also observed

The correlation between IOTA-SR and Histopathology examination finding. Our findings showed that patients with benign lesions had significantly higher number of B-Feature. M-Feature was significantly more in participants with malignant lesions The correlation between RMI index and Histopathology examination finding. Our findings showed that patients with RMI values less 200, there was significantly more benign lesions. We also found that the patients with RMI values more than or equal to 200 had significantly more malignant lesions.

The sensitivity, specificity, PPV and NPV of IOTA SR is 87.8%, 94.3%. 94.2% and 87.5% whereas for RMI index is 85.1%, 84.4%, 84% and 85.5%. Both the IOTA SR and RMI index has good diagnostic predictive value with IOTA SR having superior sensitivity in diagnosis adnexal mass malignancy.

CONCLUSION

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The sensitivity, specificity, Positive predictive Value and Negative predictive value of IOTA-SR is 87.8%, 94.3%, 94.2% and 87.5% whereas for RMI Index 2 is 85.1%, 84.4%, 84% and 85.5%. Both the IOTA-SR and RMI Index has good diagnostic predictive value with IOTA-SR having superior sensitivity and specificity in the diagnosis of adnexal malignancy. RMI Index is useful and superior in diagnosing serous malignancy, but IOTA-Simple Rules is able to diagnose all tumors such as serous, mucinous tumors, sex cord stromal tumors, and germ cell Tumors as IOTA-SR is independent of CA-125. Use of IOTA-SR widely has chances to reduce inter-observer and Intra-observer variation.

Hence we recommend the use of IOTA-SR widely in order to streamline the diagnosis of ovarian malignancies in an early detectable stages so that we will be able to give cancer patients better quality of life and longer life expectancy.

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