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Diagnostic value of risk malignancy index in the preoperative evaluation of ovarian mass correlated with histopathology and comparison of conventional USG with other higher radio diagnostic modalities like CT, CECT and MRI in validating RMI: A prospective observational study in a tertiary care setting of Tamil Nadu

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Abstract
Background and Objectives: Ovarian cancer is one of the leading cancers in women and patients present with varied symptomatology and at different stages of the disease. Prognosis of the disease depends on the stage and time of intervention. Preoperative investigation and assessment forms an important part of treatment and there are many investigating modalities used for it and patients are being subjected to multiple investigations. This study is assessing the efficiency of these modalities and exploring the option of minimal preoperative investigation without affecting the quality of treatment.

Methods: A prospective study with 69 women who were admitted in gynaecology ward, with adnexal mass and not associated with pregnancy in the time period from May 2019 to April 2022. Data like CA125, Menopausal status and radiology report of USG, MRI, CECT, CT were collected and Risk Malignancy Index calculated with both USG and other modalities and a scoring done. A value more than 200 suggested malignancy and less than 200 suggested benign nature of the mass. These were compared with the definitive histopathology report and an analysis was made to find better modality in evaluation of adnexal mass.

Results: The relationship of RMI [U (USG)] and HPE report is -The sensitivity and specificity of RMI [U] in estimating malignancy was 80% and 98.4% respectively. The positive predictive value was 80% and negative predictive value 98.4%. There was significant association between RMI [U] and the findings, x^2= 42.45, p=0.001<0.05.

The relationship of RMI [C (CT, CECT, MRI)] and HPE report is - The sensitivity of RMI[C] in estimating malignancy was 60%, the specificity was 92.3%. The positive predictive value was 60% and negative predictive value was 92.3%. There was significant relationship of RMI [C]] with report, x^2=8.48, p=0.004<0.05.

Conclusion: Both USG and other higher investigations like CT, CECT, MRI could be used in the preoperative assessment of adnexal lesions, but proceeding with only USG is found to be efficient enough in comparison with CT and MRI and further avoids patient's going through unnecessary higher investigations, delay in definitive procedure, additional expenditure, radiation and contrast exposure.

Keywords: Adnexal mass, risk malignancy index, preoperative assessment of adnexal mass

Introduction
Ovarian cancer is one of the leading cancers in Indian women [1]. Symptoms that are associated with ovarian cancer are typically nonspecific and the association is often not recognized until the disease has advanced [2]. The stage of the disease at diagnosis is the most important prognostic factor [3]. There is no universal screening method for discrimination between benign and malignant adnexal masses yet, and combined diagnostic modality has come to practice in the form of Risk Malignancy Index (RMI) [4]. RMI is a simple scoring product based on ultrasound scores, menstrual status and absolute serum CA125 levels [5]. Though ultrasound is an important tool in evaluating nature of the tumour, it cannot assess the tumour spread and lymph node involvement precisely. CT, CECT and MRI imaging score over USG in this aspect [2].

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CT, CECT and MRI imaging have become the popular method in preoperative assessment of ovarian tumors [4].

Accurately characterizing the adnexal mass enables the surgeon to triage the patient with ovarian tumour appropriately as probably benign, intermediate and malignant, and diagnose in the earlier stages of the disease, also treat early resulting in better prognosis and survival. It also reduces unnecessary referral out for low risk patients.

The aim of this study is to determine RMI and correlate with histopathology and do a comparison of conventional USG with other higher radio diagnostic modalities like CT, CECT and MRI in validating RMI.

Study Design: Prospective observational study.

Study Setting: Department of Obstetrics and Gynaecology, Rajah Muthiah Medical College and Hospital, Chidambaram, Tamil Nadu.

Inclusion Criteria
All cases with adnexal mass and has suspicious clinical, radiological findings of ovarian tumour with USG, CT or CECT or MRI and CA125 reports.

Exclusion Criteria
1. Patients who received neoadjuvant chemotherapy
2. Pregnant women
3. Patient previously diagnosed with disease associated with elevated CA125
4. Patient on peritoneal dialysis
5. Patients who have not completed their family – for staging laparotomy
6. Patients not willing to participate in study.

Method of Study
Approval for the study was obtained from institutional ethical committee, informed consent obtained from study participants, and records were used after getting approval from the concerned authority of the institute. History was elicited from the patient and also was taken from records, examination was done and also findings were documented from records and the details were noted from reports, i.e. ultrasonography, Serum CA125, CT/ CECT/ MRI imaging and all these data were recorded using a standard proforma. With this information RMI score was calculated and independent RMI[C] values were derived from CT/ CECT/ MRI findings of each patient.

RMI was calculated using the formula:
RMI Score (U) = Ultrasound score x menopausal score x CA125 level in U/ml[6]
RMI Score (C) = CT/ CECT/ MRI score x menopausal score x CA125 level in U/ml

Ultrasound examination was performed using a 3.5-MHz abdominal convex transducer in patients with full bladder or 7.5-MHz vaginal probe in patients after empting the bladder. (Acuson X 300, Antares – M/S siemens)
Ultrasound score was assigned for the following features.
1. Multiloculations
2. Presence of solid elements
3. Bilaterality
4. Presence of ascites
5. Evidence of metastases

An ultrasound score (U) of 1 was given if none or one of the above features were found, and a score of 3was given if two or

more of these features were found.
CT/ CECT was performed using a 16 slice spiral CT scan (Toshiba Medical Systems Corporation) and MRI was performed using a MRI1.5 T AMIRA and a RMI [C] score was assigned for the following features based on the institutional guidelines.
1. Multiloculations
2. Presence of solid elements
3. Bilaterality
4. Presence of ascites
5. Evidence of metastases
6. Lymph nodes
7. Vascularity of lesion
8. Wall thickness > 3mm
9. Wall irregularity
10. Papillary projections
11. Necrosis
12. Fibro vascular septations

A RMI [C] of 1 was given if none or one of the above features were found, and a score of 3 was given if two or more of these features were found.
Postmenopausal status is defined as more than one year of amenorrhea or age older than 50 years for women who had undergone hysterectomy and were given a score M=3. All other patients who did not meet these criteria were defined in a premenopausal status and were scored M=1.
Serum CA 125 was determined by radioimmunoassay (SASTHA/ Hi-tech lab).
The absolute values of serum CA-125 were entered in the formula.
After the surgery, histopathological (HPE) findings of the specimen were traced in order to determine the

Statistical analysis
Results and discussion
In the present study the accuracy of USG RMI and CECT RMI is determined and compared with the HPE report of a total of 69 patients. The accuracy was estimated by evaluating sensitivity, specificity, positive and negative predictive values of the RMI [U] and RMI[C] in estimating malignancy in comparison with the gold standard HPE report. The other statistical tool used was Chi-square test of association. The entire statistical analysis was carried out using the statistical packages of social sciences (SPSS-21).

Table 1 (i): Age of the study group – Descriptive data

Age (years)	Mean	S.D
	33.48	11.69

Table 1 (ii): Age distribution of the study group

Age (years)	Frequency (N)	Percentage (%)
10-20yrs	11	15.9
21-30yrs	19	27.5
31-40yrs	19	27.5
41-50yrs	16	23.5
51-60yrs	4	5.8
Total	69	100

The data of the study group age is presented in Table 1. The Mean age of the study group is 33.48 ± 11.69 years, which represents the reproductive age group. The common age is in the range 21-30years (27.5%), followed by 31-40years (27.5%) and 41 -50years (23.5%).

Table 2: Presenting complaints of the study group

Presenting complaints	Frequency(N)	Percentage (%)
Abdominal pain	54	78.3
Excessive bleeding PV	5	7.2
Abdominal distension	3	4.3
Abdominal mass	2	2.9
Urinary retention and abdominal pain	1	1.4
Abdominal pain and leucorrhoea	1	1.4
Infertility	1	1.4
Abdominal pain and distension	1	1.4
Prolapse	1	1.4
Total	69	100.0

The main presenting complaint of the patients was abdominal pain in 78.3% of cases.
The most common age of menarche in the study group is 12, 13 and 14 years of age.

Table 3: Status of permanent sterilisation in the study group

Status	Frequency (N)	Percentage (%)
Unmarried/ family not complete	13	18.8
Sterlisation done	34	49.3
Not sterilised	22	31.9
Total	69	100.0

None of the study participants had any family history of carcinoma ovary, breast. One patient had history of CA colon in her mother and her HPE reported benign lesion.

Table 4 (i): Body composition of the study group

BMI	Mean	S.D
	33.48	11.69
BSA	1.44	0.21

Table 4 (ii): BMI distribution of the study group

BMI	N	%
Under weight	14	20.3
Normal	21	30.4
Over weight	29	42.0
Obese	5	7.2
Total	69	100

In Table 4, data regarding BMI and BSA is presented. It is inferred that overweight was the common BMI category (42%). The Mean BMI was 24.29 ± 5.30. The Mean BSA was 1.44 ± 0.21. Body surface area is calculated to ascertain the dosage of medications if patient turns to have malignant disease and chemotherapy is started. Otherwise most of the fall in the overweight category suggesting possibility of syndrome X, high estrogenic state related to peripheral oestrogen production.

Table 5: Comorbid status of the study group

Comorbidities	N	%
HTN	3	4.3
DM	1	1.4
Obesity	2	2.9
COPD	1	1.4
Asthma	1	1.4
Anaemia	20	29.0
Hypothyroidism	10	14.5
Other diseases	10	14.5

In Table 5, data regarding comorbid condition of the study group is presented. The most common comorbid condition was anaemia (29%). There were considerable proportions of hypothyroid (14.5%) as well, both of which are related to possibility of heavy menstrual bleeding which was the presenting complaints of few of the presenting complaints.

Table 6 (i): Haemoglobin status of the study group – descriptive data

HB	Mean	S.D
	11.18	1.50

Table 6 (ii): Haemoglobin status classification of the study group

HB	N	%
Normal (> 12g/dl)	26	37.7
Low (< 12g/dl)	43	62.3
Total	69	100

In Table 6, haemoglobin status of the study group is presented. Low haemoglobin was observed in 62.3% of the study patients. The mean haemoglobin was 11.18±1.50. The anaemia is probably represented lower than the existing status as many patients were prepared for laparotomy and anaemia was corrected preoperatively with either blood transfusion or iron sucrose injection. This suggests that the baseline haemoglobin is even lower in our area.

Table 7: HPE report of the study group

HPE Report	N	%
Borderline papillary serous cystadenocarcinoma	2	2.9
Bilateral malignant serous papillary cystadenoma of ovary	1	1.4
Papillary adenocarcinoma	1	1.4
Sex cord stromal tumor, granulosa cell tumor	1	1.4
Borderline mucinous cystadenoma	1	1.4
Benign serous cystadenoma	38	55.1
Benign papillary serous cystadenoma	1	1.4
Benign mucinous cystadenoma	11	15.9
Demoid cyst	5	7.2
Hemorrhagic corpus leuteal cyst	5	7.2
Endometriotic cyst of ovary	1	1.4
Corpus luteal cyst	1	1.4
Paratubal cyst	1	1.4
Total	69	100

In Table 7, HPE report of the study group is presented. The common finding was benign serous cystadenoma (55.1%) followed by benign mucinous cystadenoma (15.9%). 7.1% of the patients had malignancy, 1.4% had borderline tumour and 91.5% of them had benign tumour.

Table 8 (i): Data regarding menopausal status

	N	%
Attained menopause	8	11.6

Table 8 (ii): Association of malignancy in HPE with menopausal status

Menopausal status	HPE finding				Total (N/ %)
	Malignant		Benign		
	N	%	N	%	
Attained menopause	2	25	6	75	8(100)
Not attained menopause	3	4.9	58	95.1	61 (100)
Total	5	7.2	64	92.8	69 (100)

Table 8 (iii): Chi-square test of malignancy in HPE and menopausal status

	Value	P
Pearson's Chi-square	4.24	0.039*

In table 8, menopausal status and its relationship with malignancy is presented. The attainment of menopause was 11.6% in the study group. It is inferred from cross tabulation that 25% of the patients who attained menopause had malignancy and rest were benign and 4.9% of those who did not attain menopause had malignancy compared to 95.1% who had benign lesion. The Chi-square test of association was significant, x^2=4.24, p=0.039<0.05.

Table 9: The finding of RMI [U] and HPE report N=69

Finding	N	%
RMI [U]		
Suspected Malignant (RMI > 200)	5	7.2
Suspected Benign (RMI < 200)	64	92.8
HPE report		
Malignant	5	7.2
Benign	64	92.8

It is inferred from Table 9 that, RMI [U]shows suspicion of malignancy in 7.2% and the similar findings of malignancy rate was found in HPE reporting.

Table 10: RMI [U] and HPE report correlation

Pearson's Chi-square test	Value	P
	42.45	0.001*

Sensitivity = 80%
Specificity = 98.4%
Positive predictive value = 80%
Negative predictive value = 98.4%

The relationship of RMI [U] and HPE report is presented in Table 10. The sensitivity and specificity of RMI [U] in estimating malignancy was 80% and 98.4% respectively. The positive predictive value was 80% and negative predictive value 98.4%. There was significant association between RMI [U] and the findings, x^2= 42.45, p=0.001<0.05.

Table 11: The finding of RMI[C] and HPE report N=31

Finding	N	%
RMI[C]		
Suspected Malignant (RMI > 200)	5	16.1
Suspected Benign (RMI < 200)	26	83.9
HPE report		
Malignant	5	16.1
Benign	26	83.9

It is inferred from Table 11 that, malignancy was the findings in 16.1% in RMI[C]and the same reported in HPE report as well.

Table 12: RMI [C] and HPE report correlation

Pearson's Chi-square test	Value	P
	8.48	0.004

Sensitivity = 60%
Specificity = 92.3%
Positive predictive value = 60%
Negative predictive value = 92.3%

The correlation of RMI [C] with HPE report was studied by sensitivity and specificity analysis and is presented in Table 12. The sensitivity of RMI [C] in estimating malignancy was 60%, the specificity was 92.3%. The positive predictive value was 60% and negative predictive value was 92.3%. There was significant relationship of RMI [C] with report, x^2=8.48,

p=0.004<0.05.
Malignancy (HPE) was found in 16.1% of the study patients and rest 83.9% had benign condition.
Both RMI [U] and RMI [C] findings had significant correlation with the histopathology findings (HPE report).
RMI [U] had higher accuracy than RMI [C] in estimating malignancy with high sensitivity, specificity, positive and negative predictive value.

Conclusion
With the study results, we conclude that both USG and other higher investigations like CT, CECT, MRI could be used in the preoperative assessment of adnexal lesions, but proceeding with only USG is found to be efficient enough in comparison with CT and MRI and further avoids patient's going through unnecessary higher investigations, delay in definitive procedure, additional expenditure, radiation and contrast exposure. Also further studies needs to be done in the same area to substantiate the results which we obtained as there is difference in the number of cases with RMI[U] (69) and RMI[C] (31), included in the study, which could not be corrected due to the short study period and on going COVID 19 pandemic.

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