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Original Research Article

Evaluation of the risk of malignancy index in preoperative diagnosis of ovarian masses

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ABSTRACT

Background: Ovarian cancer possesses a challenge to screening tests due to its anatomical location, poor natural history, lack of specific lesion, symptoms and signs and low prevalence. Authors shall be considering RMI 2 and RMI 4 (forms of RMI) and comparing them with histopathology report to derive the sensitivity, specificity and other parameters of these tests.
Methods: A prospective study was conducted from September 2016- September 2017 at Mazumdar Shaw Hospital, Narayana Hrudayalaya, Bangalore.73 patients met the inclusion criteria. RMI 2 and RMI4 were calculated for all the patients and these scores were compared to the final histopathology reports.
Results: In present study of 73 patients RMI2 showed a sensitivity of 86.6%, specificity of 86.5 %, Positive predictive value of 81.25% and negative predictive value of 90.24 %. Whereas RMI4 showed a sensitivity of 86.6%, specificity of 86.5 %, Positive predictive value of 83.87 and negative predictive value of 90.48 %. These results are comparable to other studies conducted. The risk of malignancy index 2 and 4 are also almost comparable with each other and so either can be used for determining the risk of malignancy in patients with adnexal masses. These results were derived in an Indian population across all age groups showing that authors can apply this low-cost method even in resource limited settings.
Conclusions: Authors found that Risk of malignancy index is a simple and affordable method to determine the likelihood of a patient having adnexal mass to be malignant. This can thus help save the resources and make the services available at grass root level.

Keywords: Adnexal masses, CA 125, RMI2, RMI4, Screening

INTRODUCTION

Ovarian cancer is the fifth most common cancer in women and the fourth most common cause of death from malignancy in women.[1] It is one of the deadliest cancer of the female reproductive system. The annual percentage of increase in age standardized incidence rates ranged from 0.7% to 2.4%.[2]

Ovarian cancer is known as the silent killer as it is generally diagnosed in later stages due to non-specificity of the symptoms and absence of any specific screening test.

Malignant tumors of the ovaries occur at all ages with variation in histological subtype by age. In women younger than 20 years of age, germ cell tumors predominate, while borderline tumors typically occur in women in their 30s and 40s, 10 or more years younger than in women with invasive epithelial ovarian cancers, which generally occur after 50 years of age. Approximately 23% of gynecologic cancers are ovarian

in origin, but 47% of all deaths from cancer of the female genital tract occur in women with ovarian cancer. Overall, epithelial ovarian cancer accounts for 4% of all new cancer diagnoses in women and 5% of all cancer-related deaths. However, this incidence rate increases proportionately with age. The largest number of patients with epithelial ovarian cancer is found in the 60–64 years age group.[3]

Gynaecological cancers have increased in India and are estimated to be around 182,602 by the year 2020 constituting about 30% of the total cancers among women in India. Ovarian cancer being contributing about 19.8% of the total cases.[3]

In Bangalore as per the population-based cancer registry survey, incidence of ovarian cancer is 6.5 per 1,00,000.[3] According to the Population based cancer registries at Bangalore (5.53%), Chennai (3.81%), Delhi (3.55%) and Mumbai (2.73%) have showed a statistically significant increase in age adjusted rate over time.[3]

The 5-year survival of the patient of ovarian cancer is directly influenced by the stage of cancer. Usually ovarian cancers are diagnosed at a later stage due to their silent nature which results in poor prognosis in most cases. This directly increases the morbidity and mortality. Therefore, in a country like India strained for its healthcare resources authors need to adopt a feasible and economical test to screen the female population for presence of the disease, its early detection and management. To solve this problem and to better classify benign and malignant tumours pre-operatively, various methods have been devised. These methods are a combination of a number of clinical parameters. They take into account various findings including ultrasonograms, CT scans, tumour markers pertaining to the specific organs and genetic karyotyping. Most of these findings are compiled together to obtain a specific score which may suggest the possibility of malignancy in ovaries and need for further evaluation. All these tests are known as screening tests.

Screening is the identification of unrecognized disease in apparently asymptomatic population by use of tests, examinations or other procedures that allow earlier diagnosis of disease than if it had presented clinically.[4] Screening tests need not necessarily identify the exact diagnosis but are helpful to apply in general population to find out the people who are most likely to develop or have the disease. In cancer screening tests the main goal is to reduce mortality from the disease by either preventing it or by diagnosing it earlier when the treatment is more effective.

Ovarian cancer possesses a challenge to these screening tests due to:

- Anatomical location: the ovaries are located well inside peritoneum making them less accessible
- Poor natural history
- Lack of specific lesion, symptoms and signs
- Low prevalence
- Contraindication for biopsy of ovarian mass
- Lack of good screening test.

Thus, in view of all this, authors have decided to evaluate a low cost, easily available and reproducible scoring system known as Risk of malignancy index (RMI) in Indian population.

Authors shall be considering RMI 2 and RMI 4 (forms of RMI) and comparing them with histopathology report to derive the sensitivity, specificity and other parameters of these tests. Authors further wish to see if these tests, found useful can be applied in present low resource setting for setting up a better diagnosis, referral and management system.

METHODS

The study was located at Mazumdar Shaw Hospital, Narayana Hrudayalaya, Bommasandra Industrial Area, Bangalore. Study population included any woman who presents to Narayana Hrudayalaya, Bommasandra Industrial Area, Bangalore with diagnosis of ovarian mass. Time period was September 2016 to September 2017. Study design was prospective observational study type. The subjects consist of all women who present with ovarian mass to Narayana Hrudayala who will be followed up till after surgery and will be taken into cohort once the histopathology report is available. Category for proving the test: validation.

Inclusion criteria

All consenting women who have an ovarian mass on presentation will be recruited in study and they will be recruited in cohort on getting operated and getting a histopathology report done.

Exclusion criteria

All women with

- simple luteal cyst
- abdominal mass other than ovarian mass
- ectopic mass
- patients who are not operated.

Data collection

Patient presenting to OPD or inpatient in Narayana Hrudayala with adnexal mass will be evaluated with the help of Proforma helping data collection on the risk factors of carcinoma ovary, as well as investigation of CA 125, Ultrasonography findings of adnexal mass and their menstrual status. Also, the post-operative

histopathological report will be collected. Both the reports will be then compared.

Method of collecting data

Consecutive

Patient data will be collected from OPD patients as well as inpatients. General information of the patient including her age, menstrual history, obstetric history, and other significant medical history will be collected. Other reports like ultrasonography scan report and CA-125 levels will be collected

Calculation of risk of malignancy index

Risk of Malignancy Index 2 = U × M × CA125.

Ultrasound score of 0 or 1 considered as U = 1, and a score of 2 considered as U = 4.

Premenopausal status will be considered as M = 1 and postmenopausal status will be considered as M = 4.

The serum CA125 level was used directly in the calculation

Reference level for malignancy cut-off: Risk of Malignancy Index score of 200 and

Risk of Malignancy Index 4 = U × M × CA125 × S.

Ultrasound score of 0 or 1 considered as U = 1, and a score of 2 considered as U = 4.

Premenopausal status will be considered as M = 1 and postmenopausal status will be considered as M = 4.

The serum CA 125 level was used directly in the calculation.

S is size of tumour if <7cm S=1, if >7 cm S= 2.

Reference level for malignancy cut-off: Risk of Malignancy Index score of 450.

Ultrasound scoring

1 point each is given for:

- Multilocular cyst
- Solid areas
- Bilateral lesions
- Ascitis
- Intra-abdominal lesion.

Scoring

0 or 1 feature = 1.

2 or more features = 4.

Menstrual score

Pre-menopausal = 1.

Post–menopausal = 4.

If hysterectomised, age greater than 50 years to be considered post-menopausal.

Sample size

The sensitivity of Risk of Malignancy Index 80%, precision 10% and with 90% confidence interval the sample size required 61 diseased subjects. The following formula has been used for the sample size calculation.

Formula

Sample size $n = \{[Z_{1-\alpha/2}]^2 p(1-p)\}/d^2$

Where,

p: Sensitivity of the new test

d: Precision

Z1-α/2: Desired Confidence level.

Calculation

Sample size $n = [1.96^2 * 0.80(1-0.80)]/ (0.1)^2$

$= 61.40$

$= 61$

Statistical analysis

The statistical analysis will be performed by SPSS 22.0 version. Categorical variables will be described as frequency and percentage. Continuous variables will be described as mean and standard deviation. Normality will be checked by using Shapiro-Wilk test. To validate the findings between Risk of Malignancy Index 2 and Risk of Malignancy Index 4, sensitivity and specificity, Positive and negative predicted values will be used $P<0.05$ will be considered as statistically significant.

Ethical clearance: The study was conducted after receiving approval from the Narayana Health Institutional Review Board (IRB) and Academic Ethics Committee.

RESULTS

In present study, authors have studied a total of 73 subjects with adnexal masses shown on ultrasongraphy. CA-125 levels were done on each of the subjects. A

detailed history was also taken. All the subjects included in the study underwent a surgical excision/biopsy along with histopathological evaluation of the tissue. Finally, RMI 2 and RMI 4 were calculated for the subjects and compared with their final histopathological report.

Table 1: Age specific distribution.

Age (years)	Benign	Malignant
<20	2	1
21-30	13	1
31-40	8	1
41-50	11	12
51-60	7	9
>60	2	6
Total	43	30

The histopathological reports show that there were 43 benign lesion and 30 malignant lesions.

Most common benign lesion was mature cystic teratoma consisting of 18.6 % of cases followed by Mucinous cystadenoma consisting of 11.6% of cases.

In Malignant lesion high grade serous cell carcinoma formed the most common lesion of the ovary.

Table 2: Menstrual status.

Menstrual status	Benign	Malignant	Total
Pre-menopausal	32	11	43
Menopausal	11	19	30
Total	43	30	73

Table 3: RMI 2.

Benign		Malignant	
Histopathology	**N=43**	**Histopathology**	**N=39**
Benign serous cystadenoma	1 (2.3%)	Adenocarcinoma (peritoneal)	1 (3.3%)
Benign serous papillary cystadenoma	1 (2.3%)	Adult granulosa cell tumour	3 (10%)
Benign epithelial cyst	1 (2.3%)	Clear cell carcinoma	1 (3.3%)
Benign mesothelial cyst	1 (2.3%)	Clear cell carcinoma, epithelial	1 (3.3%)
Benign mucinous cystadenoma	1 (2.3%)	Endometroid carcinoma of ovary	2 (6.6%)
Benign mucinous/ seromucinous cystadenoma	1 (2.3%)	Epithelioid tumour	1 (3.3%)
Benign ovarian cyst	2 (4.7%)	Granulosa cell tumour	1 (3.3%)
Mucinous borderline tumour	1 (2.3%)		
Mucinous cystadenoma	5 (11.6%)		
Ovarian borderline cystadeno fibroma	1 (2.3%)		
Ovarian dermoid cyst	1 (2.3%)		
Serous cystadeno fibroma	2 (4.7%)		
Serous cystadenoma	3 (7%)		

Table 4: RMI 2.

	RMI 2		Total
	Benign	**Malignant**	
RMI 2 <200	38	3	41
	5	27	32
Total	43	30	73

RMI 2 correctly identified 38 cases as benign and 28 cases as malignant while missing out 3 malignant cases and wrongly identifying 5 benign cases as malignant.

Thus, for a cut off value of 200 it showed 86.67% sensitivity and specificity of 86.05%.

Table 5: RMI 4.

	RMI 4 prediction		Total
	Benign	**Malignant**	
RMI 4 <450	40	2	42
	3	28	31
Total	43	30	73

RMI 4 correctly identified 38 cases as benign and 28 cases as malignant while missing out 2 malignant cases and wrongly identifying 3 benign cases as malignant. Thus, for a cut off value of 450 it showed 86.67% sensitivity and specificity of 88.37.

Table 6: CA 125.

CA 125	Malignant	%	Benign	%
>35	5	16.66	36	83.72
35-50	3	10	2	4.65
51-100	0	0	2	4.65
101-150	0	0	0	0
151-200	0	0	0	0
201-250	1	3.33	1	2.32
251-300	3	10	1	2.32
301-350	1	3.33	0	0
351-400	1	3.33	0	0
401-450	0	0	0	0
451-500	1	3.33	0	0
>500	15	50	2	4.65
Total	30	100	43	100

RMI 2 and RMI 4 were calculated using the formula and compared with the histopathology report which was taken as the gold standard. It was found that RMI 2 showed a sensitivity of 86.67% with specificity of 86.05% and PPV of 81.25% and NPV of 90.24%. RMI 4 showed equal sensitivity of 86.67 % while specificity of 88.37 %, PPV of 83.87% and NPV of 90.48%. At extremes of age there is a chance of missing malignant cases while using risk of malignancy index while in perimenopausal age group authors may wrongly classify a benign mass as a malignant. Reason for this may be increase in CA 125 levels due to benign conditions and also presence of benign cyst being more common in reproductive age group.

Table 7: RMI 2 and RMI 4.

	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
RMI 2	86.67	86.0	81.25	90.24
RMI4	86.67	88.37	83.87	90.48

While pelvic mass index shows the highest sensitivity of 90.3% its specificity is quite low at 80.6% on the other hand ultrasonography which shows a specificity of 95 % has low sensitivity for malignancy of 75%. The table 1 shows that most of the benign cases are common during the reproductive age group while malignancies are more likely to occur in extremes of age. RMI 2 correctly identified 38 cases as benign and 28 cases as malignant while missing out 3 malignant cases and wrongly identifying 5 benign cases as malignant. Thus, for a cut off value of 200 it showed 86.67% sensitivity and specificity of 86.05%.

DISCUSSION

In present study authors have compared 73 patients presenting with adnexal masses visiting MSH. This population consists of mostly Indian population belonging across all age groups. These patients are mostly referred from other centres or an adnexal mass is incidentally detected on ultrasonography.

As ovarian malignancies tend to grow silently till reaching an advanced state authors need a method to detect them at the earliest. Also, almost more than half of the adnexal masses present are benign tumour which can be treated with a minor intervention thus decreasing morbidity and in cases of malignancy appropriate treatment may be given like staging laparotomy. Taking into consideration all these factors various methods of screening have been devised. But none of these screening tests are able predict the probability of malignancy in ovarian masses. Therefore, histopathology report still remains the gold standard to detect nature of the disease.

From a cost-effectiveness and public health point of view, it is important to limit the workload of gynaecology oncologists to preselected cases with high risk of malignancy.

Therefore, there has been much interest in developing scoring systems to distinguish benign masses from the malignant ones. These include using colour and pulsed Doppler ultrasound and multiple tumour markers.[5] However these methods require more expensive technology and laboratory resources in contrast to the simplicity of RMI.

In premenopausal patients, the preoperative differentiation between benign and malignant adnexal lesions often might only be of secondary importance. In many situations, the severity of accompanying clinical symptoms in such patients (for example: Pain in acute adnexitis or an ovarian torsion) necessitates a prompt surgical intervention which is usually carried out via a laparoscopy. In such cases it may be necessary for a pre-operative investigation to rule out the chance of malignancy and thus preventing mismanagement or incomplete management of the people.

Thus, Risk of malignancy index turns out to be is a low cost, easily reproducible, fast and reliable method to screen for ovarian malignancies in women of all age groups including premenopausal women which can be made universally available.[6]

Table 8: Comparison of different methods.

	Sensitivity	Specificity
Risk of malignancy index	85.4	96.9
ROMA	74.1	95.2
HE4	79.6	87.1
Ultrasonography[7]	75	98.3
Pelvic mass score[7]	90.3	80.6

While pelvic mass index shows the highest sensitivity of 90.3% its specificity is quite low at 80.6% on the other hand ultrasonography which shows a specificity of 95 % has low sensitivity for malignancy of 75%.[7]

Thus, only Risk of malignancy index and ROMA have a balance between sensitivity and specificity and Risk of malignancy is the cheaper of the two and easily applicable at grass root level setup.[7,8]

Table 9: On comparing the Risk of malignancy index sensitivity for RMI 2 and RMI 4.

Study	Year	Total patients	RMI 2	RMI 4
Yamamoto Y[9]	2014	296	81.1	89.6
Karimi-Zarchi M[14]	2015	200	77.79	66.66
Yamamoto Y[11]	2009	253	90	86.8
Ozbay PO[10]	2015	191	67.4	67.4
Insin P[13]	2013	255	71	69
Aktürk E[12]	2011	100	75	84
Present study	2017	73	86.67	86.67

The sensitivity in various studies ranges between 67% to 90 % for RMI 2 and RMI 4. The highest sensitivity is shown by Yamamoto Y study as 90% for RMI 2 and 86.6% for RMI4.[9] Present study shows a sensitivity of 86.67% for both RMI 2 and 4 which is comparable to the studies Yamamoto Y.

Table 10: On comparing the Risk of malignancy index specificity for RMI 2 and RMI 4.

Study	Year	Total patients	RMI 2	RMI 4
Yamamoto Y[9]	2014	296	89.6	92.3
Karimi-Zarchi M[14]	2015	200	81.03	82.75
Yamamoto Y[11]	2009	253	80	91
Ozbay PO[10]	2015	191	89.7	92.4
Insin P[13]	2013	255	77	78
Aktürk E[12]	2011	100	85	87
Present study	2017	73	86.5	88.3

The specificity in various studies ranges between 77 % to 92 % for RMI 2 and 4. Highest specificity was 89.3% and 92.4 % for RMI 2 and RMI 4 respectively in a study by Ozbay PO.[10] Present study shows a specificity of 86.5 % for RMI 2 and 88.3% for RMI 4 which is comparable studies by Ozbay PO and Yamamoto Y.[11]

Table 11: On comparing the Risk of malignancy index positive predictive value for RMI 2 and RMI 4.

Study	Year	Total patients	RMI 2	RMI 4
Yamamoto Y[9]	2014	296		
Karimi-Zarchi M[14]	2015	200	68.29	82.22
Yamamoto Y[11]	2009	253	49.3	63.5
Ozbay PO[10]	2015	191	67.4	73.8
Insin P[13]	2013	255	61	66
Aktürk E[12]	2011	100	55	60
Present study	2017	73	81.25	83.87

The positive predictive value in various studies ranges between 55 % to 69% for RMI 2 and 60% to 83% for RMI 4. The highest is shown by a study by Karimi-Zarchi M in 2015 with positive predictive value of 68.29% and 82.22 % for RMI2 and RMI4 respectively.[14] Present study shows a positive predictive value of 81.2% for RMI 2 and 83.8% for RMI 4 which is comparable to Karimi-Zarchi M.

The negative predictive value in various studies ranges between 80 % to 97% for RMI 2 and 80% to 97% for RMI 4. Highest Negative predictive value is 93% and 95 % for RMI 2 and RMI 4 in a study by Erhan Akturk.[12] Present study shows a negative predictive value of 90.2% for RMI 2 and 90.4.8% for RMI 4 which is comparable to the same study.

Table 12: On comparing the Risk of malignancy index negative predictive value for RMI 2 and RMI 4.

Study	Year	Total patients	RMI 2	RMI 4
Yamamoto Y[9]	2014	296		
Karimi-Zarchi M[14]	2015	200	80.35	87.68
Yamamoto Y[11]	2009	253	97.8	97.5
Ozbay PO[10]	2015	191	89.7	89.4
Insin P[13]	2013	255	80	80
Aktürk E[12]	2011	100	93	95
Present study	2017	73	90.24	90.48

Thus, in present study of 73 patients, to this authors have got a sensitivity of 86.6%, specificity of 86.5 %, Positive predictive value of 81.25% and negative predictive value of 90.24 % RMI 2.

Authors have got a sensitivity of 86.6%, specificity of 86.5 %, Positive predictive value of 83.87 and negative predictive value of 90.48 RMI 4. These results are comparable to other studies to which authors have compared.

This shows the applicability of RMI in Indian population as these results were derived in an Indian population across all age groups. Thus, authors can apply this low-cost method even in resource limited settings.

Also comparing between RMI 2 and RMI 4 both prove to be almost equally useful for determining the probability of malignancy in the patients with adnexal mass.

The advantage of this is that even if authors are not able to make out the exact size of lesion still authors can calculate the RMI and have reasonable accuracy for determining the nature of disease.

CONCLUSION

Authors found that risk of malignancy index is a simple and affordable method to determine the likelihood of a female having adnexal mass to be malignant. This can thus help save the resources and make the services available at grass root level. The RMI 2 with cut-off at 200 shows a Sensitivity, Specificity, Positive predictive value and Negative predictive value of 86.67, 86.05, 81.25 and 90.24% respectively. While the RMI 4 with cut-off at 450 shows a Sensitivity, Specificity, Positive

predictive value and Negative predictive value of 86.67, 88.37, 83.87 and 90.48% respectively.

The risk of malignancy index 2 and 4 are almost comparable and either one can be used for determining the risk in patients. Therefore, both of them can be used to determine the necessity for further investigation, referral and to plan out the further management of the patient. Thus, RMI can be used as a low cost, reliable screening test in rural sector in India for better healthcare and wellbeing.

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