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Original Research Article

Effectiveness of Risk of Malignancy Index to Differentiate benign from Malignant Ovarian Masses - A Cross Sectional Study

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ABSTRACT

Background and objectives: Diagnostic dilemma exists in differentiating benign from malignant ovarian lesions making treatment difficult. CA125, USG scoring have been used for differentiating these lesions, however significant overlap exist in these test. RMI is a simple, cost-effective method that can be used by gynecologist even at less specialized center to differentiate malignant from benign ovarian masses.
Materials and methods: One year sectional study involving ovarian lesions on sonography were analysed in KLE's Dr Prabhakar Kore hospital and Medical Research Centre, in Belgaum, Karnataka. During the study period 74 women satisfied the selection criteria, however 10 women were not operated hence only 64 cases were finally analysed. RMI was calculated by combining USG score, CA125 and Menopausal status i.e. (RMI = U×CA125 × M) where cut-off value of ≥200 as malignant and finally compared with gold standard HPR. Sensitivity, specificity, positive and negative predictive value was calculated to predict the effectiveness of the RMI.
Results: Out of 64 cases analysed 20 had RMI of ≥200 of which 14 cases were malignant and 6 benign on HPR. And 44 cases who had RMI <200 out of which only 1 turned out to malignant on HPR. The sensitivity is 93.3%, specificity is 87.7%, PPV is 70%, and NPV is 97.7%.
Conclusions: The RMI was accurate in differentiating benign from malignant ovarian lesions in majority of the cases. Also RMI is a simple scoring system with higher accuracy and high potential in selection of cases for conservative management or minimal invasive surgery. And hence it can be the test of choice in preoperative evaluation of ovarian masses.
Keywords: Benign Ovarian tumor; Ovariant tumor; Ovarian cancer; Risk of malignancy index (RMI);

INTRODUCTION

Ovarian tumors frequently present as adnexal masses and are quiet frequent reasons for referral to gynaecologist. Ovarian cancer is the leading cause of death in women with female genital cancers in developing countries. A woman's lifetime risk has been estimated to be about 1 in 55, which represents an increase from the 1970 figure of 1 in 70. [1] In the year 2005, an estimated 22,220 new cases of ovarian cancer were diagnosed in the US alone, with 16,210 deaths predicted. [2]

Prior to surgery and Histopathological reporting, it is very difficult to differentiate benign from malignant ovarian lesions. 39-69% of the ovarian masses diagnosed after menopause

are malignant as compared to 21-24% prior to menopause. Ovarian cancer is a disease with a poor prognosis. Women commonly have diagnoses of stage III and IV disease, for which 5-year survival rates are around 27% and 16%, respectively. It has been the hope that early detection of early-stage disease could have a positive impact on the prognosis of this dreaded disease. There has been no universally available test with high sensitivity and specificity for ovarian cancer. Up to 70% of the ovarian cancers are detected at advance stages because of its bizarre and atypical behaviour like abdominal bloating, pain, indigestion, urinary frequency and constipation. Thus a high index of suspicion is required for diagnosis of ovarian cancer. [3]

The prognosis worsens with the late diagnosis. With advanced ovarian disease the mortality rate increases to 70% within 2years and 90% within 5 years. [3] Pre-operative assessment of adnexal mass/ovarian lesions is thus a challenge for gynaecologist. This encouraged us to research on ovarian lesions.

The quality of primary cyto-reductive surgery is one of the most important prognostic factors. The extent of cyto-reductive surgery is associated with the specific skills and experience of well-trained gynaecologic oncologists. The discrimination between benign and malignant ovarian masses is thus important in selective referral of relevant patients to specialized cancer centers. [4]

Until currently, there has been no effective screening method for ovarian cancer and because the lesions are usually asymptomatic until they have metastasized, patients have advanced disease at diagnosis in more than two-thirds of the cases and the prognosis is therefore poor. Several attempts have been made to distinguish benign from malignant conditions.

At the present, one clinical feature provides inadequate performance in discriminating benign and malignant ovarian tumour. For ultrasonographic techniques, the sensitivity and specificity in diagnosis of malignant condition were 62% and 73%, respectively. [5,6] Serum CA 125 is another promising tool. Elevation of serum CA 125 concentrations is documented in 85% of epithelial ovarian cancers. [6,7] At the cut-off level of 35 U/ml, the sensitivity was 83.1%; but specificity was only 39.3%. [7] The risk of malignancy index (RMI) is a scoring system of the combination of various clinical features. It has been developed to improve diagnostic accuracy for ovarian malignancy. Jacob et al. [8] (1990) originally developed the RMI based on ultrasonographic findings, menopausal status, and serum levels of CA 125. By using the RMI at a cut-of level of 200 to indicate malignancy, so called RMI 1, sensitivity and specificity were 85.4% and 96.9%, respectively. [8] Tingulstad et al. [9] (1996) then developed RMI 2. A direct comparison showed that RMI 2 was significantly better at predicting malignancy than RMI 1 (p value < 0.001). The RMI 2 gave sensitivity of 80%, specificity of 92% and positive predictive value (PPV) of 83% while RMI 1 gave sensitivity of 71%, specificity of 96%, and PPV of 89%. It is a simple and cost effective method and can be used by gynaecologist even at less specialized centres to diagnose benign and malignant ovarian lesions.

Considering the high burden of the disease and diagnostic difficulties in differentiating benign and malignant lesions the present study was planned to assess the diagnostic value of RMI in discriminating benign from malignant ovarian diseases.

METHODOLOGY

This cross-sectional study was undertaken under the Department of Obstetrics and Gynaecology, KLES Dr. Prabhakar Kore Charitable Hospital, Belgaum, Karnataka, India a 1800 bedded tertiary care teaching hospital situated in North Karnataka attached to Jawaharlal Nehru Medical College, Belgaum, Karnataka, India from January 2012 to August 2012. Considering the sensitivity of RMI as 80%, standard error as 10% the

minimum effect sample size was calculated as 64. Women suspected to have ovarian mass on sonography with either one of the parameters RMI above 5 cm were included in the study. Women with previous bilateral salpingo-oophorectomy and previously treated carcinoma were excluded from the study. Prior to the commencement the study ethical clearance was obtained from the Institutional Ethical committee, Jawaharlal Nehru Medical College, Belgaum. Women fulfilling selection criteria were explained about the nature of the study and a written informed consent was obtained (Annexure I) prior to the enrolment. After the enrollment demographic data and obstetric history were obtained. Further these women were subjected to thorough clinical examination. These findings were recorded on a predesigned and pretested proforma.

The selected women underwent investigations such as serum CA125 and ultrasound. Transabdominal / transvaginal scan was performed by single observer (Sonologist) using the 3.5 Mhz curvilinear probe of PHILIPS HD II machine to calculate USG score. RMI combines three pre-surgical features viz Serum CA125 (Measured in IU/mL) – May vary between zero and hundreds or even thousands (CA125); Menopausal status (M) which is interpreted as 1 = pre-menopausal and 3 = post-menopausal; and Ultrasound score (U) – Which is interpreted based on New weighted scoring system (Learner et al). [10]

Parameters	0	1	2	3
Wall structure	Smooth/ small irregularites <3mm	-	Solid or non applicable	Papillarities ≥ 3mm
Shadowing	Yes	No	-	-
Septa	None or thin < 3mm	Thick ≥ 3 mm	-	-
Echogenicity	Sonolucent or low level echo or echogenic core	-	-	Mixed or high

Based on the New weighted scoring system the ultrasound score (U) is further interpreted as 0 for an ultrasound score of 0; 1 for an ultrasound score of 1; and 3 for an ultrasound score of ≥ 2 Based on these variables RMI index is calculated as RMI = U x M x CA125 Based on the RMI 1 index values the lesions were interpreted as benign if the RMI score was < 200 and malignant if the score was > 200.

Ovary tissue specimens were received in 10% formalin. Ovarian tissue was grossly examined first and findings were noted. The laterality, size, consistency, cystic content and presence of solid areas, necrosis, hemorrhage and papillae and any other suspicious appearing areas.

Statistical analysis

The data obtained was coded and entered into Microsoft Excel Worksheet. The categorical data was expressed as rates, ratios and proportions and continuous data was expressed as mean ± standard deviation (SD). The categorical data was analysed using chi-square test. The accuracy of RMI in differentiating benign and malignant lesions was determined by sensitivity, specificity, positive predictive value and negative predictive value. Kappa agreement was used to correlate the agreements. A 'p' value of less than or equal to 0.05 was considered as statistically significant.

RESULTS

During the study period a total of 74 women suspected to have ovarian tumours. However, of the 74 women, 10 (13.51%) were not operated and histopathological reports were available in the remaining 64 (87.67%) women. Hence 64 cases were studied. Most of the women (29.69%) presented with age 41 to 50 years and the mean age was 38.41 ± 15.71 years. Majority of the women (96.88%) presented with pain abdomen followed by with mass per abdomen (56.25%). The history of pelvic surgery was noted among 25% of the women. Majority of the women (73.44%) reported multi parity. Nearly two thirds (64.06%) of the women presented with pre menopausal status. With regard to CA125 levels, 70.31% of the women had serum CA 125 levels of < 35 and mean serum CA125

levels were 178.10 ± 646.56. Among 67.19% of the women USG score of three was noted and the mean USG score of was 3.08 ± 2.32. Most of the women (68.75%) had RMI score of <200 and 31.25% of the women had RMI score of ≥ 200 (Graph 1). The mean RMI score was 1485.48 ± 5835.41. In the present study the histopathological reports showed benign lesions in majority of the women (76.56%) (Graph 2).

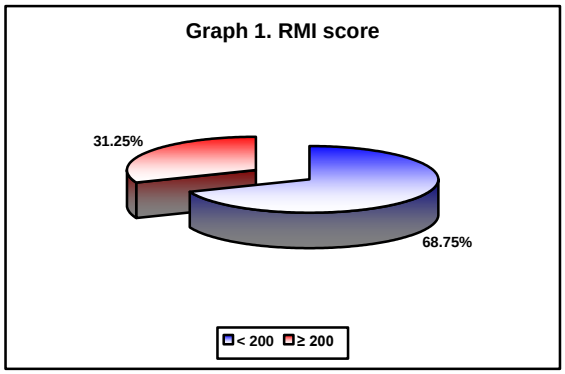
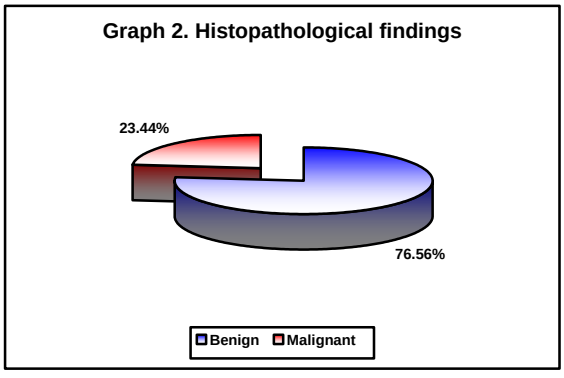


Table 1. Histopathological findings – Benign lesions

Type of lesion	lesions	Distribution (n=49)	
		Number	Percentage
Benign	Serous cystadenoma	12	24.49
	Mucinous cystadenoma	11	22.45
	Serous cyst	5	10.20
	Ovarian serous cyst	3	6.12
	Ovarian haemorrhagic cyst	3	6.12
	Simple cyst	2	4.08
	Dermoid cyst	2	4.08
	Ovarian dermoid cyst	2	4.08
	Ovarian cystadenofibroma	1	2.04
	Ovarian mucinous cystadenoma	1	2.04
	Mesenteric tumour	1	2.04
	ovarian serouscystadenoma	1	2.04
	Ovarian simple cyst	1	2.04
	Papillary serous cystadenoma	1	2.04
	Mass of unknown origin	1	2.04
	Mixed serous and mucinous cystadenoma	1	2.04
	Granulosa cell tumor	1	2.04
	Total	49	100.00
Malignant	Papillary adenocarcinoma	3	20.00
	Mucinous cystadeno carcinoma	2	13.33
	Ovarian adenocarcinoma	2	13.33
	Serous papillary adenocarcinoma	2	13.33
	Ovarian papilary serous tumor	1	6.67
	Ovarian serous adenocarcinoma	1	6.67
	Brenner tumor	1	6.67
	Ovarian dysgerminoma	1	6.67
	Tube adenocarcinoma	1	6.67
	Yolksac tumor	1	6.67
	Total	15	100.00



The commonest diagnosis in the benign lesions was serous cystadenoma in (24.49%) while mucinous cystadenoma was noted in 22.45% of the women. The distribution of other lesions is as shown in Table 1. The most common diagnosis in the malignant lesions was papillary adenocarcinoma (20%) followed by mucinous cystadenoma carcinoma, ovarian adenocarcinoma and serous papillary adenocarcinoma (13.33% each). The distribution of other malignant lesions is as shown in table 1. Of the 15 malignant lesions on histopathology, 14 had RMI score ≥ 200 while 1 woman had RMI score of < 200. The sensitivity of RMI in predicting malignant lesions as compared to histopathology was 93.33% with 87.76% of

specificity (Table 2). Of the 41 women with premenopausal status RMI findings showed 7.32% women with RMI ≥200 while 92.68% had RMI score of <200. This difference was statistically significant (p<0.001) (Table 3).

Table 2. Accuracy of RMI Index in comparison to histopathology

RMI Index	Histopathology		Total
	Malignant	Benign	
≥ 200	14	6	20
< 200	1	43	44
Total	15	49	64

Kappa=0.727 (Substantial agreement) p < 0.001

Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
93.33	87.76	70.00	97.73

Table 3. Comparison of menopausal status and HPR

Menopause	RMI findings				Total	
	≥ 200		< 200			
	No	%	No	%	No	%
Premenopausal	3	7.32	38	92.68	41	100.00
Post menopausal	12	52.17	11	47.83	23	100.00
Total	15	23.44	49	76.56	64	100.00

p < 0.001

Table 4. Accuracy of CA 125 in comparison to histopathology

Histopathological report	CA125		Total
	≥ 35	< 35	
Malignant	13	2	15
Benign	6	43	49
Total	19	45	64

Kappa=0.681 p < 0.001

Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
86.67	87.75	68.42	95.56

Table 5. Accuracy of USG scoring in comparison to histopathology

Histopathological report	USG score		Total
	≥ 5	< 5	
Malignant	10	5	15
Benign	10	39	49
Total	20	44	64

p < 0.001

Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
66.66	79.59	50.00	88.63

Out of 19 women with CA125 score of ≥ 35, 13 had malignant lesions on histopathology while 6 women had benign lesions. The sensitivity of CA125 in predicting malignant lesions as compared to histopathology was 86.67% with 87.75% specificity (Table 4). In 20 women with USG score of ≥ 5, 10 each had malignant and benign lesions on histopathology. The sensitivity of USG score in predicting malignant lesions as compared to histopathology was 66.66% with 79.59% specificity (Table 5). Among the 20 women with CA125 score ≥35, 90% of the women had RMI score of ≥200 and 10% had RMI scores of <200. This difference was statistically significant (p<0.001).

DISCUSSION

In this study the commonest age group was 41 to 50 years (29.69%) followed by 21 to 30 years (26.56%) and the mean age was found to be 38.41 ± 15.71 years. These results were in agreement with the findings in literature stating that, the ovarian tumors can occur at any age but their peak incidence is in the reproductive age group. [11]

In the present study of the 64 women studied, 96.88% of the women presented with pain abdomen and 56.25% with mass per abdomen. With regard to obstetric history, most of the women (73.44%) reported multi parity. The history of pelvic surgery was present in 25% of the women.

In the present study almost two thirds of the women (64.06%) reported pre menopausal status followed by post menopausal state (35.94%) The serum CA125 levels were < 35 in 70.31% of the women and 29.69% had ≥ 35 with mean serum CA125 levels being 178.10 ± 646.56. Based on USG findings the score of one was found in 32.81% of the women while 67.19% had USG score of three with mean USG scores being 3.08 ± 2.32.

In this study RMI 1 score was calculated to be <200 in 68.75% of the women and in 31.25% of the women it was ≥ 200. The mean RMI scores were 1485.48 ± 5835.41.

In the present study, 76.56% of the women had benign and 23.44% had malignant lesions. A similar study to verify the effectiveness of the RMI in the discrimination between benign lesions and malignant adnexal masses in clinical practice reported benign tumor in 62.96% and malignant in 37.04% of the patients. [12] Another prospective study from Turkey to evaluate the ability of four risks of

malignancy indices (RMI) to detect malignant ovarian tumors on 100 women reported that, 80% had benign and 20% had malignant disease. [13]

In this study, the commonest diagnosis in the benign lesions was serous cystadenoma seen in 24.49% followed by mucinous cystadenoma seen in 22.45% of the women while, the commonest diagnosis in the malignant lesions included papillary adenocarcinoma (20%) and, mucinous cystadenoma carcinoma, ovarian adenocarcinoma and serous papillary adenocarcinoma (13.33% each). A prospective study from Turkey also reported mucinous cystadenocarcinoma as the commonest diagnosis in malignant cases (10 out of 20) and endometriosis in benign cases (27 out of 80). [13]

Risk of malignancy index (RMI) is recommended in assessment of patients with adnexal masses. In this study, of the 15 women with malignant lesions on histopathology, 14 women had RMI 1 score ≥ 200 while 1 woman had RMI 1 score of <200. The sensitivity of RMI 1 in predicting malignant lesions as compared to histopathology was 93.33% with 87.76% of specificity. Also of the 19 women with CA125 score of ≥ 35, 13 had malignant lesions on histopathology while 6 women had benign lesions. The sensitivity of CA125 in predicting malignant lesions as compared to histopathology was 86.67% with 87.75% specificity. Similarly, of the 20 women with USG score of ≥ 5, 10 each had malignant and benign lesions on histopathology. The sensitivity of USG score in predicting malignant lesions as compared to histopathology was 66.66% with 79.59% specificity.

In the 1990s, Jacobs et al. [8] originally developed the RMI, which is now termed RMI 1. Tingulstad et al. [9] developed their version of the RMI in 1996 and it is known as RMI 2. In 1999, Tingulstad et al. [14] modified the RMI, which is termed RMI 3. Yamamoto et al. [15] created their own model of a malignancy risk index. They added the parameter of the tumor size (S) to the RMI and have termed it the RMI 4. The RMI was originally developed by Jacobs et al. [8] and subsequently the same group reproduced the results in a second patient group, establishing the superiority of RMI over the individual parameters. [16]

Jacobs et al. [8] in his study assessed age, ultrasound score, menopausal status, a clinical impression score and serum CA 125 level to see how they could best distinguish between patients with benign (n=101) and malignant (n=42) pelvic masses. Each criterion used alone provided statistically significant discrimination. The most useful individual criteria were a serum CA 125 level of 30 U/ml (sensitivity 81%, specificity 75%) and an ultrasound score of 2 (sensitivity 71%, specificity 83%). Three criteria could be combined in a risk of malignancy index (RMI) which is simply calculated using the product of the serum CA 125 level (U/ml), the ultrasound scan result (expressed as a score of 0, 1 or 3) and the menopausal status (1 if premenopausal and 3 if postmenopausal). This index was statistically virtually as effective a discriminant between cancer and benign lesions as more formal methods. Using an RMI cut-off level of 200, the sensitivity was 85% and the specificity was 97%. Patients with an RMI score of greater than 200 had, on average, 42 times the background risk of cancer and those with a lower value 0.15 times the background risk. These findings were comparable with the present study where the sensitivity of RMI 1 in predicting malignant lesions as compared to histopathology was 93.33% with 87.76% of specificity.

Similar results were reported in recent study where sensitivity of RMI was 83.33%, specificity 94.12%, positive predictive value was 89.29% and negative predictive value was 90.57% using RMI cut off value of 200. [12]

The RMI has been evaluated by several studies since its description by Jacobs et al. [8] in 1990. Jacobs et al. [8] described a cut-off level of 200, with a

sensitivity of 85% and a specificity of 97%. 12 However, most studies evaluate a range of cut-off levels varying between 25 and 250. When 200 was used as cut-off level, the pooled estimate for sensitivity was 78% (95% CI 71–85%) for a specificity of 87% (95% CI 83–91%). At a cut-off level of 50, the pooled estimate for sensitivity was 91% (95% CI 85–97%) for a specificity of 74% (95% CI 69–80%). [17]

In 1996, Tingulstad et al. [9] described an adjustment of the Risk of Malignancy Index, named RMI II.54 RMI II is based on the same product as RMI I except that the score for menopause is 1 for premenopausal status and 4 for postmenopausal status and the ultrasound score is expressed as 1 or 4. The score of RMI II varies between 1 and infinity. RMI II is evaluated in other studies. When 200 was used as cut-off level, the pooled estimate for sensitivity was 79% (95% CI 71–87%) for a specificity of 81% (95% CI 72–90%). [17]

Finally, an RMI III and RMI IV also have been developed.67,68 RMI III and RMI IV both apply different ultrasound scores compared with RMI I and RMI II. RMI III is evaluated in one study and showed at validation a sensitivity and specificity of 74% and 91%, respectively.53 RMI IV has not been validated in other studies.

In 2001 Manjunath et al. [18] compared RMI 1, RMI 2, and RMI 3 with each other and also confirmed that there was no statistical difference between these three indices in benign - malignancy discrimination.

In a study by Clarke et al. [19] using a cut-off of 120, found that RMI 1 had a sensitivity of 72% and a specificity of 87%; RMI 2 had a sensitivity of 76% and a specificity of 81%; RMI 3 had a sensitivity of 74% and a specificity of 84%.

In 2009 Yamamoto et al. [15] developed their own RMI by using tumor size and called it RMI 4. Their study confirms that, at a cut-off level of 450, the accuracy of the RMI 4 was better than RMI 1 (p=0.0013), RMI 2 (p=0.0009) and RMI 3 (p=0.0013) with a cutoff level of 200. They observed that at a cutoff level of 450 the sensitivity, specificity, positive predictive value, negative predictive value and accuracy were respectively, 86.8%, 91.0%, 63.5%, 97.5%, and 90.4%.

A review [17] reported that, when the Risk of Malignancy Index was applied with a sensitivity of 78% and a specificity of 87% to a woman with an adnexal mass and a prior probability of disease of 10%, the posttest probability for a woman with an Risk of Malignancy Index above the threshold of 200 would have a probability of malignancy of 40%, whereas a woman with an Risk of Malignancy Index below this threshold would have a probability of disease of 2.7%. However it should be consider that this test already combines information on CA 125 level, ultrasound scan result, and menopausal state, thus limiting the possibility of differentiation of the prior probability of disease. However, a distinction between a probability before surgery of 2.7% compared with 40% is clinically useful.

Overall, the RMI is a simple method that can be used by general gynecologists to aid in selecting a patient for referral to cancer centres for primary surgery.

CONCLUSION

The sensitivity of RMI 1 in predicting malignant lesions as compared to histopathology was 93.33% with 87.76% of specificity it may be concluded that, the RMI is a simple scoring system with higher accuracy in predicting adnexal masses and useful in clinical practice. Therefore it may be the test of choice in the preoperative evaluation of the adnexal mass under primary settings.

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