Asian Oncology Research Journal

4(1): 24-31, 2021; Article no.AORJ.65804

Diagnostic Accuracy of Risk of Malignancy Index (RMI) in Ovarian Masses

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Authors' contributions

This research work was carried out in collaboration with between both authors. Author JA designed the study, performed the statistical analysis, wrote the protocol and wrote the first draft of the manuscript. Author SP managed the analyses of the study and the literature searches. Both the authors have read and approved the final manuscript.

Article Information

Editor(s):
(1) Dr. Ramesh Gurunathan, Sunway Medical Center, Malaysia.
Reviewers:
(1) I.V. Renuka, DR. N.T.R University of Health Sciences, India.
(2) Voinea Silviu Cristian, University of Medicine Carol Davila Bucharest, Romania.
Complete Peer review History: http://www.sdiarticle4.com/review-history/65804

Original Research Article

Received 20 December 2020
Accepted 25 February 2021
Published 15 March 2021

ABSTRACT

Aims: To determine the diagnostic accuracy of RMI in ovarian mass.
Study Design: Prospective, observational study.
Place and Duration of Study: Between November 2017-March, 2019 in the Department of Obstetrics and Gynaecology of Lady Hardinge Medical College and Smt. Sucheta Kriplani Hospital, New Delhi.
Methodology: We included a total of 50 women with ovarian masses coming to our OPD. Initial investigations were done and the RMI score was calculated based on Ultrasound score (U), Menopausal status (M), and CA-125 levels. The final diagnosis was made after the histopathological report and the RMI score at appropriate cut-off was evaluated by sensitivity, specificity, positive predictive (PPV), negative predictive (NPV), and diagnostic accuracy values concerning the ability to distinguish malignant from benign masses.
Results: In our study, benign ovarian masses were found in 64% and malignant in 36% based on histopathology. The majority of malignant mass was observed in the age group of 41-50yrs whereas benign in 21-30yrs. The mean RMI score was significantly higher in women with malignant ovarian

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masses compared to benign masses (1603.3±4093.1 vs. 18.95±21.62, p=0.032). A Standard cut-off of 200 and a lower cut-off of 100 calculated based on ROC curve was compared. Sensitivity, Specificity, and Diagnostic accuracy at 200 was 33.3%, 95.8%, and 69% respectively, whereas at 100 was 44.4%, 90.6% and 74%.

Conclusions: RMI is a simple multimodal scoring system with higher accuracy in predicting ovarian malignancy in preoperative evaluation. In our study, the diagnostic accuracy of RMI at cut-off 100 was better.

Keywords: Ovarian Mass; RMI; accuracy.

ABBREVIATIONS

RMI- Risk of Malignancy Index; ROC curve- Receiver operating characteristic curve

1. INTRODUCTION

Ovarian cancer is the second most common gynaecologic cancer and accounts for 6% of all deaths in women. The annual incidence is 5.1 per 100,000 women and increases with age [1], with the peak incidence at about 56 to 60 years of age [2]. Women with ovarian cancer are often asymptomatic in the early stage or have vague and non-specific symptoms leading to delay in diagnosis, 60% are diagnosed at an advanced stage with 5-year survival rate as low as 10%. If the disease is diagnosed at stage I (confined to the ovaries), the 5-year survival is in excess of 90%. This suggests that early detection of ovarian cancer may improve long-term survival [3,4]. Up to 24% of ovarian tumors in premenopausal women are malignant and up to 60% are malignant in postmenopausal women [5-7].

A recent report indicated an increasing incidence of ovarian cancers in the developing world, compared to the developed countries [8]. The preoperative determination of whether a mass is malignant or not, cannot always be made with all the current diagnostic modalities, making the plan of surgery difficult. An improved method for preoperative discrimination of ovarian mass which has better sensitivity and specificity would result in more women receiving first-line therapy from appropriately trained and experienced personnel [9,10].

The risk of malignancy index (RMI) was the first diagnostic model to combine demographic, sonographic, and biochemical data for the assessment of patients with ovarian mass. The RMI is the product of the ultrasound scores (U), the menopausal score (M), and the absolute value of serum CA-125 levels: RMI=U × M × CA-125.

For RMI 1, abnormal ultrasound findings (U) include multilocular cystic lesion, solid lesion, bilateralism, ascites, and metastasis. If nothing abnormal is found, U is regarded as zero (U=0); if a single abnormality is seen, it will be U=1; and if 2 or more abnormal findings are seen, it will be U=2. Menopausal status (M) is either post-menopausal (at least one year of amenorrhea not related to other condition or age>50 if hysterectomy for any reason) (M=3) or pre-menopausal (M=1). The serum concentration of CA125 is directly entered into the formula. In previous studies, a cut-off value of 200 for RMI 1 was suggested as the best discrimination point for segregation of benign and malignant pelvic masses, with high sensitivity and specificity levels [11].

The main advantage of RMI is that it's a simple scoring system which can be applied directly into clinical practice without the introduction of any expensive or complicated methods (such as computed tomography [CT] scan, magnetic resonance imaging [MRI], and whole-body positron emission tomography [PET]). It can also be applied in less specialized centers.

1.1 Objective

To determine the diagnostic accuracy of RMI in ovarian mass

2. MATERIALS AND METHODS

A prospective, Observational study was carried out on 50 women from November 2017- March 2019 in the Department of Obstetrics and Gynaecology, Lady Hardinge Medical College, and Smt. Sucheta Kriplani Hospital, New Delhi. All women with incidental or symptomatic ovarian mass not treated before were included in the study. Women who have received chemotherapy

for ovarian malignancy, had inflammatory masses like endometriotic cyst, were pregnant, or on ovulation induction drugs were excluded.

RMI score was calculated based on Ultrasound score (U), Menopausal status (M), and CA-125 levels. Ultrasound was performed with TOSHIBA Nemio XG Diagnostic Ultrasound System, using a 3.5-MHz abdominal convex transducer in women with full bladder or 7.5-MHz vaginal probe after emptying the bladder. Preoperative measurement of serum CA-125 levels was performed by using an electrochemiluminescent immunoassay (ECLIA). The women were operated (laparoscopic/laparotomy) and the final diagnosis was made after the histopathological report. Diagnosis based on RMI scores and histopathology was compared to reach the objective of the study. Statistical analysis was done using SPSS software (latest version). The diagnostic performances of each test were reported as sensitivity, specificity, positive predictive value, and negative predictive value with a 95% confidence interval.

3. RESULTS

The histopathological examination report revealed benign ovarian masses in 64% with serous cystadenoma (16%) and mucinous cystadenoma (16%) being the commonest and malignant masses in 36% of the women, maximum being epithelial tumours where serous adenocarcinoma accounted for 14% of total cases, followed by mucinous carcinoma (6%). Eight out of 32 benign tumours were normal parenchyma, endometriotic cyst, and haemorrhagic cyst; so these cases were excluded from further results. (Table 1)

The distribution of women according to age in benign and malignant ovarian mass shows that women with malignant masses were comparatively older than women with benign masses (46.72±10.45 vs. 33.04±13.65, p=0.002) (Table 2). The majority of malignant mass was observed in the age group of 41-50yrs whereas benign was seen mainly in 21-30yrs.

Out of 35 premenopausal women, 22 (63%) women had benign masses and 13(37%) had malignant, while with 7 postmenopausal women, 5 (72%) had malignant tumours. Thus it was concluded that postmenopausal women were more likely to have malignant masses. Most common symptom with which the women presented in both benign and malignant group was pain abdomen (80%) followed by menstrual irregularity (38%) and abdominal distension (18%). The mean serum CA-125 Levels in malignant ovarian mass were significantly higher than benign ovarian mass (195.24±429.89 vs. 41.56 ±128.55, p=0.017). The USG score was between 2-5 in women with malignant ovarian mass compared to benign masses (61% and 4%) (Table 3).

Table 1. Distribution of masses according to histopathology

S.NO.	HISTOPATHOLOGY	No. of patients	% of total(50)
Benign tumors			
1	Mucinous cystadenoma	8	16
2	Serous cystadenoma	8	16
3	Normal parenchyma with inclusion gland	4	8
4	Mature cystic teratoma	4	8
5	Endometriosis	3	6
6	Serous cystadenofibroma	2	4
7	Hemorrhagic/necrotic cyst	1	2
8	Thecoma ovary	1	2
9	Ovarian leiomyoma	1	2
Malignant tumors			
1	Serous carcinoma	7	14
2	Mucinous carcinoma	3	6
3	Proliferative mucinous tumor with micro invasion	2	4
4	Atypical borderline mucinous tumor	2	4
5	Granulosa cell tumor	2	4
6	Serous borderline tumor	1	2
7	Immature teratoma grade 2	1	2

The mean RMI score was significantly higher in women with malignant ovarian masses compared to benign masses (1603.3±4093.1 vs. 18.95 ±21.62, p=0.032). In the majority of the women (95%) with benign mass, the RMI-1 was <100 though it varied from 0-1923, whereas an equal proportion of women (56% and 44%) with malignant ovarian mass had RMI score less than 100 and more than 100 with as low as 3.65 to as high as 15840 (Table 4).

For the women with ovarian malignancy, the ROC curve generated for RMI-1, an area under the curve was 0.823 (p=<0.001; SE + 0.062; CI=0.701-0.945). The cut-off threshold values with the highest sensitivity and specificity were obtained and two cut off values were almost near to each other, they were 200 and 100 for RMI-1 (Fig.1).

After calculating all indices for prediction of malignancy in ovarian mass for RMI at the cut-off of 100 and 200, it was observed that sensitivity and diagnostic accuracy were more with lower cut-off (Table 5).

Table 2. Distribution of women according to age in benign and malignant ovarian mass

Age (years)	Benign (24)		Malignant (18)		Chi-square test	
	N	%	N	%	χ2	p-value
≤ 20	4	16.7	0	0	14.120	0.002
21 – 30	9	37.5	1	5.6		
31 – 40	3	12.5	4	22.2		
41 – 50	5	20.8	9	50.0		
51 – 60	3	12.5	1	5.6		
>60	0	0	3	16.7		
Mean	33.04± 13.65		46.72±10.45			

Table 3. Comparison of variables in benign and malignant ovarian masses (n=42)

Variable	Malignant		Benign		Statistical comparison	
Menopausal status	**N**	**%**	**N**	**%**	**χ2**	**p-value**
Premenopausal	13	72.22	22	91.66	4.973	0.043
Postmenopausal	5	27.78	2	8.34		
USG Score						
0 – 1	7	38.9	23	95.83	12.963	0.001
2 – 5	11	61.1	1	4.17		
CA-125 Levels						
<= 35	10	55.6	22	91.7	6.445	0.017
> 35	8	44.4	2	8.3		

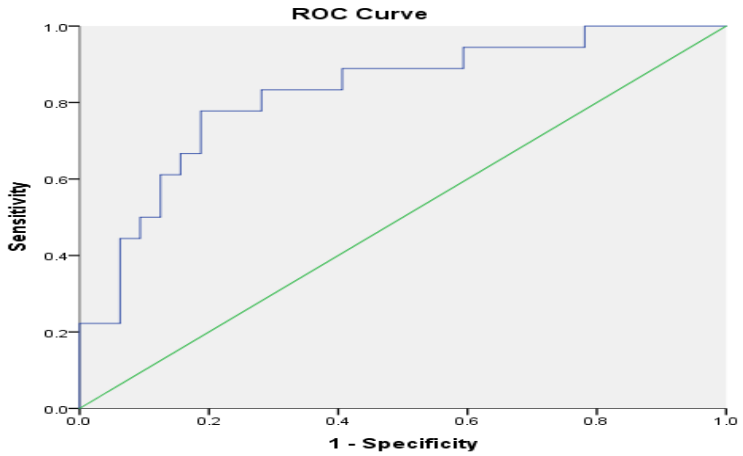

Fig. 1. ROC analysis for RMI for diagnosing malignancy

Table 4. Distribution of RMI -1 score in benign and malignant ovarian masses (N=42)

RMI-1 score	Benign (N=24)		Malignant (N=18)		P-value
	N	%	N	%	
0-50	21	87.5	7	38.88	
51-100	2	8.33	3	16.67	
101-200	0	0	2	11.11	
>200	1	4.17	6	33.34	
Mean ±SD	18.95 ±21.62		1603.3±4093.1		
Range	0 – 1923		3.65 – 15840		0.032

Table 5. Comparison of RMI at different cut-off

Predictive indices	200 cut-off	100 cut-off
Sensitivity	33.3	44.4
Specificity	95.8	90.6
PPV	85.7	72.7
NPV	65.7	74.4
Diagnostic Accuracy	69	74
Odds Ratio	11.5	18.4
95% CI	0.701-0.945	0.701-0.945

4. DISCUSSION

In India, Ovarian mass is the fourth most common malignancy among females [1]. The outcome for women with ovarian cancer is generally poor as they present late, with an overall 5-year survival rate of less than 35%. It is estimated that surgery needed for a suspected ovarian tumour in women was performed in 5-10% of their lifetime. Among these, Malignancy is detected in only 13-21% of the women [2]. Therefore it is of great importance to discriminate between benign and malignant tumour preoperatively to reduce the number of surgeries performed in self-limiting conditions and also the referrals to higher centres. Hence there is a need for greater awareness and also for better initial investigations in primary and secondary care to enable earlier referral and optimum treatment.

The histopathological diagnosis was considered the gold standard for the definite outcome and revealed benign ovarian masses in 64% commonest being mucinous and serous cystadenoma(25% each) and malignant masses in 36% of the women with serous cystadenocarcinoma being commonest(38.8%) followed by mucinous carcinoma (16.7%). (Table 1) Similar results were found in the study by Shintre SA et al. [12] where benign ovarian mass was found in 76% and commonest being serous (24.49%) followed by mucinous cystadenoma (22.45%). In malignant lesions, serous carcinoma (20%) was most common followed by mucinous carcinoma (13.33%). Bouzari et al. [13] reported a case series of 181 women with 87.3% benign and rest malignant ovarian tumours commonest being papillary adenocarcinoma (35.7%). In contrary to the present study, Chopra et al. [14] in a retrospective study of 100 women with adnexal masses observed a high preponderance of malignant adnexal masses compared to benign (61% and 39%).

Age is an important factor in ovarian mass diagnosis and any postmenopausal or advanced age group women presenting with adnexal mass should be evaluated seriously (Table 2). The study by Dora et al. [15] showed the average age of the patients with benign and malignant tumours was 37.12 ± 13.05 years and 47.30±11.43 years, respectively. A similar observation was reported by Karimi-Zarchi et al. [16] with the majority of benign ovarian tumour occurring in women between 21-40 years while malignant ovarian tumour was between 61-83 years. In contrast, G.O. Abdulrahman Jr et al. [17] observed the occurrence of both benign and malignant ovarian lesions in the older age group (56.96 ± 17.991 years and 60.16±15.6 years).

It was observed that women who were postmenopausal mostly had malignant ovarian mass compared to benign (Table 2). A similar result was obtained by Bouzari et al. [13] who reported a higher proportion (70%) of malignant ovarian tumour in postmenopausal women. Insin P et al. [18] also observed 2.54 fold higher

increased risks for malignant and borderline ovarian tumours in postmenopausal women compared to premenopausal women.

The mean serum CA-125 Levels though not much elevated but significantly higher in malignant ovarian mass compared to in benign ovarian mass (195.24±429.89 vs. 41.56 ±128.55, p=0.017). However, almost half of the women exhibited a normal value of less than 35U/ml. This could be because of the small sample size, higher number of cases with benign and low stage disease, and serum CA-125 has a limited role in mucinous carcinomas [19] and non-epithelial tumour like dysgerminoma, immature teratoma, sex cord stromal tumour. Similar results were found in the study of Javdekar et al. [19] who showed that mean serum CA 125 level in the malignant disease was comparatively more than that in benign disease (395 U/ml vs. 33 U/ml). Insin P et al. [18] showed that when serum CA-125 levels were ≥ 35 U/ml a women's risk for malignant tumour increased 3.64 times. Also, Y. Yamamoto et al. [20] found that the mean serum CA-125 was significantly higher among women with malignancy (670.4 U/ml) when compared to benign pelvic mass (54.4U/ml). Park JW et al. [21] compared women with benign disease to malignant disease, and a significantly higher mean level of serum CA-125 was observed with malignancy (507 U/ml vs. 35 U/ml).

The detection of ovarian malignancy by USG based on certain features has been studied extensively. In the present study majority of malignant ovarian lesions had a higher USG score (2-5) compared to benign lesions (61% and 4%) (Table 3). Yelikar KA et al. [22] showed that 80% of the women with malignant ovarian lesions had USG score >3 while those with benign lesions 83% had a very low USG score of 0 or 1. Insin P et al. [18] showed that women with USG score >1 had 8.89 times increased risk for malignancy compared to a USG score of 0.

A scoring system that can predict ovarian malignancy can also improve the chance of better preoperative counseling, preoperative preparation, and wherever needed appropriate referring the patients to a specialized centre. Herein we report that the multiparametric RMI score including menopausal status, CA-125 level, and USG score can be a useful tool in the prediction of malignant ovarian disease, in low-resource settings.

Jacobs et al. [23] first described RMI-1 at a cut-off level of 200, with a sensitivity of 85% and a specificity of 97%. Since then it has become a tool for diagnosing malignancy in ovarian tumours. In the present study, the mean RMI-1 score was significantly higher in women with malignant ovarian masses compared to benign (1603.3 vs. 18.95, p=0.032) (Table 4) In the majority of the women (95%) with benign mass the RMI-1 was <100 whereas an equal proportion of women (56% and 44%) with malignant ovarian mass had RMI-1 score < 100 and >100. Based on the ROC curve plotted for RMI-1, two cut-off values were chosen (200 and 100), their diagnostic accuracy was calculated (Table 5). On comparing both, RMI 1 with 100 as cut off showed better accuracy in predicting ovarian malignancy**.** To date, many studies have been done to prove the performance of RMI-1 at different cut-off values (Table 6). Shintre SA et al. [12] in a cross-section study calculated the effectiveness of RMI for predicting malignancy and observed the RMI 1 score was <200 in 68.75% of the women and ≥ 200 in 31.25% of the women. Their mean RMI scores of the total

Table 6. Comparison of rmi-1 in previous studies with the present

Study	No.	Year	Cut off	Sn	Sp	PPV	NPV	Accuracy
Jacobs et al.[23]	143	1990	200	85	97			
Clarke et al. [24]		2009	120	72	87			
Y Yamamoto et al. [20]	253	2009	200	80	86.4	52.5	95.8	
Bouzari et al.[13]	181	2011	265	91	96	78	99	
Park JW et al.[21]	547	2012	150	77.9	81.1	51.7	93.4	80.4
Insin P et al. [18]	255	2013	200	62	80	66	77	
Abdulrahman et al.[17]	247	2014	120	74	84	70	85	
Aziz et al. [25]	283	2015	250	54.05	93.4	55.5	93.06	
Yelikar KA et al. [22]	102	2016	250	85.71	85.07	75	91.93	82.29
Present study	42	2019	200	33.3	95.8	85.7	65.7	69
			100	44.4	90.6	72.7	74.4	74

population were 1485.48±5835.41. The sensitivity and specificity RMI 1 at the cut-off of 200 in predicting malignant lesions was 93.33% and87.76%. Our study has shown a high specificity but a low sensitivity of RMI 1. This can be due to small sample size, less number of malignant lesions, more mucinous tumours altering CA-125 level, etc.

5. CONCLUSION

It may be concluded that RMI is definitely useful as a simple scoring system and would aid the surgeon in preoperative management of ovarian masses. In a resource-poor setting, for any women presenting with an ovarian mass seeking medical care, RMI should be applied to predict malignancy at a lower cutoff of 100.

Since the specificity of the Risk of malignancy index is high, there is a potential role for this in the selection of cases for conservative or minimally invasive surgery for benign cases.

However, due to the small sample size, there is weak statistical significance in this study, thus further studies are required with more cases to conclude and determine the appropriate cutoff of RMI to differentiate the ovarian mass into benign and malignant.

CONSENT

As per international standard or university standard, patient's written consent has been collected and preserved by the authors.

ETHICAL APPROVAL

As per International standard or university standard written ethical approval (LMHC/ECHR/2017/134) has been collected and preserved by the authors.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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Peer-review history:
The peer review history for this paper can be accessed here:
http://www.sdiarticle4.com/review-history/65804