ISSN: 2091-2749 (Print)
2091-2757 (Online)

Submitted on: 19 Nov 2025
Accepted on: 22 Dec 2025

https://doi.org/10.3126/jpahs.v12i2.88955

Comparison of efficiency between risk malignancy index 1 and risk malignancy index 2 in diagnosing ovarian tumor

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Abstract

Introduction: The risk of malignancy index (RMI) is a validated clinical tool for stratifying risk of ovarian lesions. It is a scoring system based on menopausal status, ultrasound finding and CA-125 level. Various modifications have been made on scoring system to enhance its efficiency. The commonly used RMI is RMI 1 however recent studies suggest higher efficiency of RMI 2 over RMI 1. So, this study compares the efficiency of RMI 1 and RMI 2 on differentiating malignant ovarian tumor over benign one.

Method: This analytical cross-sectional study done at Patan hospital included 172 women who underwent operation for ovarian tumor. Both RMI 1 and RMI 2 were calculated using Ultrasound score, CA-125 value and menopausal status and compared with histopathological diagnosis. The cut-off value was 200 for both RMI 1 and RMI 2 in discriminating malignancy. Chi square test and Receiver Operator Characteristics (ROC) curves were calculated.

Result: Among 172 patients, 23 had malignant and 149 had benign ovarian tumor. The area under ROC curve for RMI 1 and RMI 2 was 0.973 and 0.969 respectively, which was statistically significant. The sensitivity and specificity of RMI 1 was 86.96% and 98.64%, whereas sensitivity and specificity of RMI 2 was 91.3% and 97.23% respectively. Similarly, positive predictive value (PPV) and negative predictive value (NPV) of RMI 1 was 90.9% and 97.98%, and that of RMI 2 was 84% and 88.63%, respectively.

Conclusion: RMI 1 has higher specificity, PPV and NPV whereas RMI 2 has higher sensitivity in diagnosing ovarian tumor.

Keywords: Nepal; Ovarian tumor; Risk Malignancy Index 1, Risk Malignancy Index 2

How to Cite: Budhathoki P, Shrestha P, Pradhan B. Comparison of efficiency between risk malignancy index 1 and risk malignancy index 2 in diagnosing ovarian tumor. J Patan Acad Health Sci. 2025 Dec;12(2):17-21.

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Introduction

Ovarian cancer is the seventh most common cancers among women, accounting for about 4% of all cancer cases.[1] Every year around 185,000 die from this disease.[2] In Nepalese women, ovarian cancer accounts for 5.1% of all cancers and 0.36% of total cancer deaths.[3] The incidence is higher among postmenopausal women, with 60% of ovarian tumors being malignant in this group.[4] Although relatively uncommon, it is the sixth leading cause of gynecological cancer-related death, largely because it often presents at an advanced stage due to nonspecific early symptoms.[5] Therefore, accurate and early diagnosis is critically important.[6] The risk of malignancy index (RMI) is one of the methods for differentiating benign and malignant ovarian tumors.

The RMI is based on menopausal status, ultrasound report and CA 125 level.[7] The most widely used index is RMI 1, which has demonstrated a sensitivity of 85% and specificity of 97%.[7] To improve diagnostic performance, RMI 2 and RMI 3 were introduced later.[8] Using the same cut-off value, RMI 2 showed a sensitivity of 80% and specificity of 92% and was reported to be more sensitive in detecting advanced-stage ovarian cancer. The principal differences among the indices lie in the scoring of ultrasound findings and menopausal status.[9,10]

Several studies have evaluated the diagnostic efficacy of different RMIs and have shown high accuracy in distinguishing malignant from benign ovarian tumors.[9–13] However, evidence comparing commonly used RMIs in routine clinical practice remains limited. Given the importance of accurate preoperative risk stratification, this study aimed to assess and compare the diagnostic accuracy of RMI 1 and RMI 2 in differentiating benign and malignant ovarian masses.

Method

This is an analytical cross-sectional study done in the department of Obstetrics and Gynaecology at Patan Academy of Health Sciences over a period of one year (August 2023 to July 2024). Sample size was calculated using Buderer's formula. This approach utilizes the calculation of sample size based on sensitivity and specificity for both RMI 1 and RMI 2. The sample size based on sensitivity and specificity for RMI 1 was 45 and 71 whereas the sample size based on sensitivity and specificity for RMI 2 was 71 and 171. So the sample size based on specificity for RMI 2 was the highest among all and was included in the study. A total of 171 patients who underwent laparotomy for ovarian mass were included in the study. During the study period, any admitted patient undergoing laparotomy for ovarian mass was identified and followed intraoperatively. If the intraoperative finding was suggestive of a tumor from ovarian origin, the patient would be included in the study. Patients who have a non-ovarian origin of adnexal mass, a known case of ovarian cancer under chemotherapy, and pregnancy with an ovarian tumor were excluded from the study. Following enrollment in the study, CA 125 value, menopausal status and ultrasound findings were noted. The ultrasound findings of ovarian tumor noted were multilocular, bilateral, ascites, solid areas and metastasis. RMI 1 and RMI 2 were calculated as below:

- RMI 1 = U x M x CA 125, where a total ultrasound score of 0 made U = 0, a score of 1 made U= 1, and a score of > 2 made U = 3: premenopausal status made M=1 and postmenopausal M = 3. The serum level of CA 125 in U/ml was applied directly to the calculation.[7]
- RMI 2 = U x M x CA 125, where a total ultrasound score of 0 or 1 made U = 1 and a score of >2 made U = 4; premenopausal status made M = 1 and postmenopausal M = 4. Serum level of CA 125 in U/ml was applied directly to the calculation.[7]

The cut off value for both RMI 1 and RMI 2 was set at 200. Final histopathology reports were traced by using patient's identification number. RMI1 and RMI 2 were then compared with patient's final histopathology report. The sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) of RMI 1 and RMI 2 was calculated. Chi square test was done for statistical significance. The study was approved by the institutional review committee before commencement (Ref. drs2506202029). The patient and patient party was well explained about the study and consent was taken. Confidentiality of study populations was maintained.

Result

A total of 171 patients were operated for ovarian tumor during the study period. Among which 23 cases were malignant ovarian tumor and 148 were benign. Among the malignant cases, 12 were postmenopausal and 11 were premenopausal, whereas among the benign ovarian tumor, 31 were postmenopausal and 113 were premenopausal, Table 1.

Table 1. Menopausal status of malignant and benign ovarian tumor

Obarian Tumor	Premenopausal n (%)	Postmenopausal n (%)	Total
Malignant	11(47.82)	12(52.17)	23
Benign	113(76.35)	31(20.94)	148

The most common malignant ovarian tumor was Serous cyst adenocarcinoma, whereas most common benign ovarian tumor was mature cystic teratoma.

The CA 125 value was generally higher among Malignant Ovarian tumor ranging from 13-204 U/ml. There was 1 case of Serous borderline carcinoma

Table 2. Types of malignant & ovarian tumors

Malignant Ovarian Tumor (N=23)	n (%)	Benign Ovarian Tumor (N=148)	n (%)
High grade serous carcinoma	8(34.78)	Mature cystic teratoma	36(24.32)
Immature teratoma	6(26.09)	Endometriosis	28(18.91)
Low grade serous carcinoma	4(17.39)	Mucinous cystadenoma	21(14.19)
Mucinous borderline carcinoma	2(8.70)	Brenner's tumor	3(2.03)
Serous borderline carcinoma	1(4.35)	Serous cystadenoma	11(7.43)
Mucinous adenocarcinoma	1(4.35)	Fibroma	12(8.11)
Granulosa cell tumor	1(4.35)	Corpus luteal cyst	14(9.46)
		Simple ovarian cyst	17(11.48)
		Follicular cyst	2(1.35)
		Hydatid cyst	1(0.67)
		Inclusion cyst	1(0.67)
		Tubo-ovarian abscess	2(1.35)

where the value was 13 U/ml. In the case of Granulosa cell tumor and Mucinous cystadenocarcinoma, the value was marginally increased up to 37 U/ml and 40 U/ml respectively. All other cases of malignant tumor had CA 125 level more than 2-fold of normal range. Regarding the benign ovarian tumor, the CA 125 value ranged from 1.5-252 U/ml. There were 19 cases which had increased value more than normal, among which 18 cases had increased value less than 2 fold above normal. Only 1 case of Mature cystic teratoma with necrotic inflammatory debris had high value of 252 U/ml. Regarding the USG finding among benign tumor, Multilocular cyst-73(49.3%), Solid areas-35(23.64%), Bilateral-12(8.1%), Ascites-4(2.7%), and Metastasis-0 were noted. Similarly, among malignant tumor Solid areas-18(78.26%), Multilocular cyst-15(65.21%), Bilateral-4(17.39%), Ascites-3(13.04%), and Metastasis-1(4.34%) were noted in the USG. There were 43 cases which had more than 1 USG findings among which 30(20.27%) were benign and 13(56.52%) were malignant tumor, Table 2.

In the index study, the cut off value for both RMI 1 and RMI 2 was set to 200 as per the standard guideline. There were 146 and 144 cases of benign tumor that had RMI value < 200 in accordance to RMI 1 and RMI 2 respectively. Similarly, there were 20 and 21 cases of malignant tumor that had RMI value ≥200 in accordance to RMI 1 and RMI 2, respectively. All these findings were statistically significant, Table 3.

Table 3. Chi square test of RMI 1 and RMI 2 for benign and malignant ovarian tumor

	RMI Value	Benign	Malignant	p value
RMI 1	<200	146	3	<0.0001
	>/=200	2	20	
RMI 2	<200	144	2	<0.0001
	>/=200	4	21	

The Sensitivity of RMI 2 is 91.3% which is higher than the sensitivity of RMI 1 which is 86.96% whereas the specificity of RMI 1 is 98.64% which is higher than the specificity of RMI 2 which is 97.23%. However the positive predictive value and negative predictive value of RMI 1 is higher than RMI2. The p value of both RMI 1 and 2 is statistically significant in diagnosing the disease with p value < 0.0001, Table 4.

The ROC (Receiver Operating Characteristic) curve of the test by plotting the true positive rate (sensitivity) against the false positive rate (1 - specificity) at

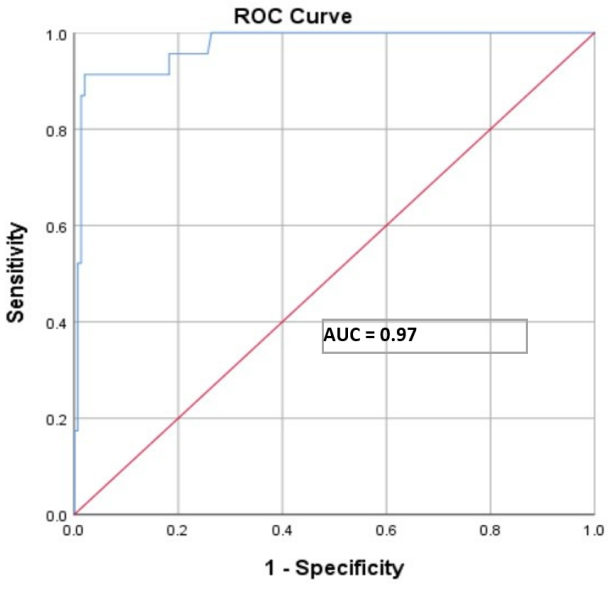

Figure 1. ROC curve of RMI 1 in differentiating benign and malignant ovarian mass

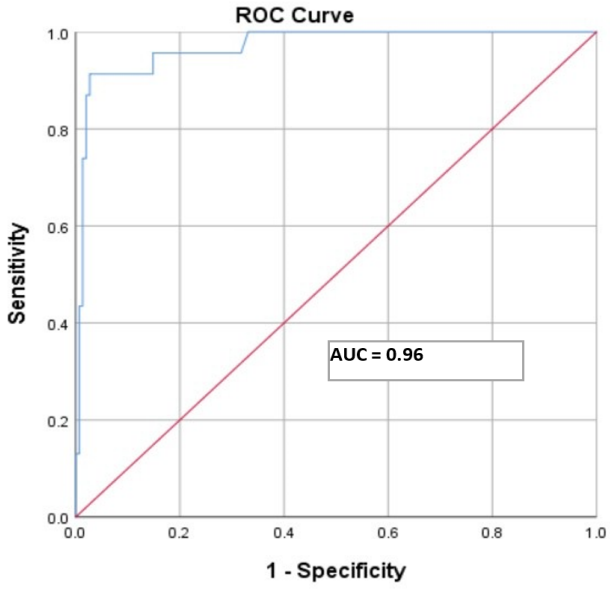

Figure 2. ROC curve of RMI 2 in differentiating benign and malignant ovarian tumor

Table 4. Sensitivity, specificity, PPV and NPV of RMI 1 and RMI 2

C	Sensitivity	Specificity	PPV	NPV	p value
RMI 1	0.8696	0.9864	0.909	0.9798	<0.0001
RMI 2	0.913	0.9723	0.84	0.8863	<0.0001

different cutoff point, Figure 1 and 2. Both RMI 1 and RMI 2 have high area under the curve (AUC) which is 0.97 and 0.96 respectively.

Discussion

This study compared the diagnostic efficacy of Risk of Malignancy Index 1 (RMI 1) and Risk of Malignancy Index 2 (RMI 2) in diagnosing malignant and benign ovarian tumors. It analyzed 171 patients with ovarian tumor who underwent surgical management. Both indices demonstrated high accuracy in preoperative evaluation, confirming their value as effective tools for ovarian tumor risk stratification. Hence both RMI indices can be very helpful in quickly assessing ovarian tumor at primary care and decide its best management approach.

The malignancy rate in our study was 13.5%, which is similar to the incidence (16.6%.) reported in a study done at Karnataka, India. [11] The most frequent malignant tumor among all the cases was serous cystadenocarcinoma whereas, the most frequent benign tumor was mature cystic teratoma which was also noticed by Runa et al. in their study.[14] The menopausal status is an important risk factor in evaluating ovarian tumor as postmenopausal status is an independent risk factor of common malignant ovarian tumors like surface epithelial tumor.[15] Similarly in this study the incidence of malignancy in postmenopausal women were 52.17% whereas the incidence of benign tumor in premenopausal status was 76.35%.

The risk of malignancy index (RMI) was developed in 1990, with the cut off value set at 200. They noted the sensitivity and specificity in discriminating ovarian tumor to be 85.45% and 96.9%, respectively.[7] With the same cutoff value, our study also found similar sensitivity and specificity of 86.96% and 98.64%, respectively with RMI 1. Since its development, the RMI has undergone several modifications to improve its diagnostic accuracy. Tingulstad in 1996 developed RMI 2 and found the sensitivity and specificity of 80% and 92% which was lower than RMI 1 developed by Jacobs et al. But the sensitivity increased to 90% when used in diagnosing ovarian cancer stage II and above.[8] Similar to this study, our study also had higher sensitivity of RMI 2.

In the index study, RMI 2 had higher sensitivity (91.3%) compared to RMI 1 (86.96%), reflecting its enhanced ability to correctly identify malignant tumors. This feature is critical in clinical practice to reduce missed malignancies that could delay treatment. Conversely, RMI 1 in comparison to RMI 2 demonstrated higher specificity (98.64% vs. 97.23%) and superior positive and negative predictive values. This means RMI 1 can diagnose malignancy with fewer false positive diagnoses and reduce unnecessary surgeries. This finding was similar to a study by Moolthiya, et al. where the sensitivity of RMI 2 was better than RMI 1 (80% vs 70.6%) whereas the specificity of RMI 1 was better than RMI 2 (78.2% vs 83.9%).[16] Similarly, Tantipalakorn, et al. and Lennox et al. also found RMI 2 to have better performance than RMI 1, consistent with the higher sensitivity observed in this study.[17,18]

Though there were some differences among RMI 1 and RMI 2 in terms of sensitivity, specificity, positive predictive value and negative predictive value, both the test had high accuracy in correctly diagnosing benign and malignant ovarian tumor. ROC curve analysis revealed excellent discriminatory power for both indices, with AUC values of 0.97 and 0.96 for RMI 1 and RMI 2, respectively — values that corroborate the strong diagnostic accuracy of RMIs reported in the literature. The AUC demonstrated by Håkansson et al. in their study was 0.94 which is similar to our findings.[19] The slight trade-off between sensitivity and specificity emphasizes the need to select the appropriate RMI based on clinical priorities, whether minimizing missed malignancies or reducing unnecessary interventions.

In contrast to our study, the study conducted at National University Hospital, Singapore in 2009 showed that there was no statistical difference in RMI 1 and RMI 2 scores between the benign and malignant ovarian tumor and also pointed that RMI is not a valuable triage tool for differentiating them.[20] The study was confounded by large cases of ovarian endometriotic cysts that presented as complex ovarian cysts with both high CA 125 levels and ultrasonographic scores. Such a confounding factor was not found in our study as only 28 case of ovarian endometriosis was detected and mean value of CA 125 was 43.94 U/ml.

The main limitation of the study was the smaller number of malignant ovarian tumors. There were only 23 cases of malignant ovarian tumors in comparison to 148 benign ovarian tumors. This difference can affect the statistical power and generalization of the findings, potentially limiting the precision of estimates related to diagnosing malignancy. This warrants validation through prospective, multicenter studies with a high number of malignant tumors in relation to benign. Another limitation of the study could be that the USG was done by different operators, which could lead to interobserver variations. This variation can affect the consistency and accuracy of ovarian tumor assessment.

Conclusion

In conclusion, both RMI 1 and RMI 2 are reliable and simple indices useful in preoperative ovarian tumor assessment. Their continued implementation into clinical practice can enhance diagnostic accuracy and guide optimal patient management. Future research could also evaluate modified RMI versions or integrate additional biomarkers to optimize diagnostic algorithms.

Conflict of Interest

None

Funding

None

Author Contribution

Concept, design, planning; PB, PS, BP; Literature: PB, PS; Data collection/analysis: PB; Draft manuscript: PS; Revision of draft: PS; Final manuscript: PS; Accountability of the work: PB, PS, BP.

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