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Risk of malignancy index and its implication in clinicopathological evaluation for ovarian mass

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Abstract:
Accurate pre-operative differentiation of benign, borderline and malignant ovarian masses is essential for appropriate treatment planning and patient outcomes. Therefore, it is of interest to evaluate the diagnostic performance of the risk of malignancy index in 155 ovarian mass cases over 1 year, using ultrasound findings, menopausal status and serum cancer antigen 125 levels, with histomorphological examination as the reference standard. Ovarian-adnexal reporting and data system ultrasound classification will also be assessed to improve pre-operative diagnostic accuracy. The study will determine the risk of malignancy index to stratify ovarian masses linking with histological findings. Thus, we describe a practical and economical approach to pre-operative ovarian mass stratification and decision-making.

Keywords: Risk of malignancy index (RMI), ovarian mass, cancer antigen 125 (CA-125), ovarian-adnexal reporting and data system (O-RADS), histopathology, menopausal status

Background:
A large number of gynecological cases seen in clinical practice include ovarian masses, which may range from harmless cysts to very aggressive cancerous tumors. It is still quite difficult to tell benign ovarian tumors from malignant ones, especially because early-stage ovarian cancer generally doesn't cause any symptoms or only causes vague ones like bloating, stomach pain, or irregular periods **[1]**. As a result, many cases are detected after they have progressed significantly, leading to significant rates of illness and death globally **[2]**. Ovarian cancer ranks seventh among female cancers worldwide and ranks high among cancer-related fatalities owing to delayed diagnosis and inadequate screening methods **[3]**. Optimum surgical planning, avoidance of needless treatments and improvement of survival results depend on proper pre-operative assessment of ovarian tumors. Clinical examination, imaging methods like ultrasonography and tumor markers such as cancer antigen 125 (CA-125) are examples of traditional diagnostic procedures. The sensitivity and specificity of these modalities are not without their limits, however **[4]**, composite scoring methods like the Risk of Malignancy Index (RMI) were created to address these constraints. For a more comprehensive assessment of malignancy risk, the Risk of Malignancy Index (RMI) combines three important parameters: ultrasonographic findings, menopausal status and serum CA-125 levels. Previous studies have demonstrated that this composite index can effectively differentiate benign from malignant ovarian masses, supporting its role as a simple and cost-effective tool for preoperative risk stratification **[5]**. Several iterations of RMI have been suggested since its inception; nevertheless, RMI-I has enjoyed the lion's share of use owing to its simplicity and practicality in clinical settings. In ordinary clinical practice, RMI has shown to be a beneficial tool due to its high sensitivity and specificity in distinguishing benign ovarian tumors from malignant ones **[6]**. When evaluating masses in the ovaries, ultrasonography is crucial. The Ovarian-Adnexal Reporting and Data System (O-RADS) and similar standardized reporting systems have greatly enhanced the diagnostic performance and repeatability of ultrasonography **[7]**. To help doctors make better decisions, O-RADS sorts' ovarian lesions into risk categories according to their morphology, from normal to high risk of cancer. When included into the RMI computation, it improves the index's predictive power. The gold standard for ovarian cancer tumor markers is serum CA-125. While elevated levels are often linked to epithelial ovarian cancers, they may also be elevated in benign diseases such menstruation, endometriosis and pelvic inflammatory disease **[8]**. Therefore, CA-125 cannot accurately differentiate between benign and malignant tumors on its own. Adding CA-125 to the RMI enhances its diagnostic capabilities by enhancing the correlation between clinical and imaging results. When calculating the likelihood of cancer, menopausal state is an additional important factor to consider. Compared to pre-menopausal women, post-menopausal women are more likely to carry malignant ovarian tumors **[9]**. To further stratify patients according to their baseline risk, menopausal state is now included in the RMI computation. The most reliable method of diagnosis is still histopathology, even though imaging and tumor markers have come a long way. To confirm its diagnostic precision and therapeutic value, it is crucial to compare preoperative RMI scores with post-operative histopathological results **[10]**. Therefore, it is of interest to determine whether or not the RMI algorithm correlates with histopathological results in tertiary care settings when it comes to classifying ovarian masses.

Materials and Methods:
Study area:
The study was conducted in a tertiary care hospital (IGIMS) in the Department of Pathology.

Study design:
This was a prospective observational study.
Sample size:
155 cases of ovarian masses meeting the inclusion criteria were included over a period of one year after obtaining approval from the Institutional Ethics Committee.

Inclusion criteria:
[1] All cases presenting with ovarian masses on clinical examination were included.
[2] Cases confirmed by imaging techniques such as ultrasonography were included.

Exclusion criteria:
[1] Patients with diagnosed ovarian cancer who had already received chemotherapy were excluded.
[2] Masses originating from sites other than the ovary were excluded.
[3] Pregnancies with complications such as ectopic pregnancy, molar pregnancy and post-abortion conditions were excluded.

Methodology:
Following established histopathological protocols, the Department of Pathology examined and analyzed all ovarian mass specimens received, including those obtained during oophorectomy and biopsy. Hematoxylin and eosin staining allowed for histomorphological examination of tissue slices. According to well-established histological criteria, the final diagnosis was classified as either benign, borderline, or malignant. Medical records were used to gather clinical data of patients, such as their age, presenting symptoms and menopausal status. All patients had their serum CA-125 levels checked before surgery. The O-RADS classification system was used to assess the ultrasound results; this method divided ovarian masses into five categories according to the likelihood of cancer:
[1] O-RADS 1: Normal
[2] O-RADS 2: Almost benign
[3] O-RADS 3: Low risk
[4] O-RADS 4: Intermediate risk
[5] O-RADS 5: High risk

The Risk of Malignancy Index (RMI) was calculated using the formula:

RMI = Ultrasound score × Menopausal score × CA-125 level (U/ml)

Ultrasound score was assigned based on O-RADS findings.
Menopausal score:
1 for pre-menopausal women
2 for post-menopausal women

Ovarian tumors were classified as benign, borderline, or malignant based on a cut-off value of RMI = 250.

Histopathological findings served as the reference standard for evaluating the diagnostic performance of the Risk of Malignancy Index, including its sensitivity, specificity, positive predictive value and negative predictive value for detecting ovarian malignancy. Appropriate statistical tests were used to evaluate the correlation between RMI scores and histopathological results.

Results:
The participants in this prospective observational research were 155 women who had ovarian masses. Histopathology was the gold standard for diagnosis and all patients were evaluated preoperatively using the Risk of Malignancy Index (RMI). Patients' ages varied from eighteen to seventy-five, with almost half of all instances falling between the 31–50 age brackets. There were 94 women who were premenopausal and 39.35% who were post-menopausal. There were 155 instances of tumors, with 65.81% being benign, 22.58% malignant and 11.61% borderline. It is important to note that although the majority of ovarian masses are benign, more than a third are borderline or malignant lesions. This highlights the need for accurate preoperative diagnostic methods like RMI **(Table 1)**. The vast majority of patients (86.36%) with RMI < 250 were benign, with just 4.54% being malignant. There is a clear correlation between higher RMI scores and malignancies, as 66.67% of patients with an RMI of 250 or more were malignant. Among borderline tumors, 44.44% had a high RMI, indicating an intermediate distribution. As a result, RMI successfully divides ovarian tumors into those at low risk and those at high risk **(Table 2).** The RMI excels in accurately detecting both benign and malignant cases, as shown by its high sensitivity (85.71%) and specificity (93.14%). A very strong negative predictive value of 96.36 percent indicates that a low RMI score consistently rules out cancer. The fact that RMI is a very dependable diagnostic tool in clinical practice is confirmed by the statistically substantial association between RMI scores and histological diagnosis, as shown by the p-value < 0.001 **(Table 3)**.

Table 1: Distribution of ovarian masses based on histopathology

Histopathological Diagnosis	Number (n=155)	Percentage (%)
Benign	102	65.81%
Borderline	18	11.61%
Malignant	35	22.58%
Total	155	100%

Table 2: Distribution of Cases According to RMI Score (Cut-off = 250)

RMI Category	Benign	Borderline	Malignant	Total	Percentage (%)
RMI < 250	95	10	5	110	70.97%
RMI ≥ 250	7	8	30	45	29.03%
Total	102	18	35	155	100%

Table 3: Diagnostic Performance of RMI Compared with Histopathology

Parameter	Value (%)
Sensitivity	85.71%
Specificity	93.14%
Positive Predictive Value	77.78%
Negative Predictive Value	96.36%
Accuracy	91.61%

p-value	<0.001

Discussion:

This research compared the results of the Risk of Malignancy Index **(**RMI**)** with those of histological diagnosis to see how well the RMI can distinguish between benign, borderline and malignant ovarian tumors. The findings prove that RMI is an economical, non-invasive and very successful method for risk assessment before surgery. The vast majority of tumors in this research were benign **(**65.61%**)**, with a small percentage of malignant (22.58%) and borderline tumors **(**11.61%**)**. Consistent with other research, this distribution shows that the majority of ovarian tumors are harmless, particularly in women who have not yet reached menopause **[2]**. A reliable diagnostic technique for early diagnosis is crucial, nevertheless, because of the comparatively large percentage of cancerous cases. Histopathological results were highly correlated with the RMI score. In the group with a low risk **(**RMI < 250**)**, 86.36% of the cases were benign, whereas 66.67% of the cases in the group with a high risk (RMI ≥ 250) were malignant. These results are in line with what was found in the study by Andreotti *et al.* and other validation investigations, which showed that higher RMI scores are strongly linked to cancer **[4]**. In line with previous research, this investigation found a sensitivity of 85.71 percent and a specificity of 93.14%. In a small number of studies, RMI was shown to have a sensitivity of 78% to 90% and a specificity of 85% to 95% when it came to diagnosing ovarian cancer **[7]**. Similarly, RMI is still a valid screening tool with good diagnostic accuracy across many groups, according to a multicenter research from 2021 **[6]**. More recently, Krishnan *et al.* reported high diagnostic accuracy for RMI at a cut-off of 100, with 95.0% sensitivity and 92.0% specificity, further supporting its utility as a practical tool for pre-operative differentiation of benign and malignant ovarian tumors **[10].** This study's very substantial negative predictive value (96.36%) implies that patients with low RMI scores may be safely handled conservatively or with less invasive surgical techniques. This study's very substantial negative predictive value **(**96.36%**)** implies that patients with low RMI scores may be safely handled conservatively or with less invasive surgical techniques. This finding has important therapeutic implications. Especially for younger women who want to keep their fertility, this lessens the need for surgery and the risks associated with it **[8]**. A large part of the RMI's precision came from ultrasound assessments conducted using the O-RADS system. With O-RADS, there is a consistent way to describe adnexal masses and classify them according to their potential for cancer. Clinical trials performed after 2018 have shown that using O-RADS increases diagnostic consistency and decreases interobserver variability **[11]**. The current research provides evidence for the incorporation of higher O-RADS categories into RMI computation by showing a robust association with malignant histology. When evaluating RMI, serum CA-125 levels were also very important. Although certain benign illnesses did show moderate increases of CA-125, they were more often seen in malignant situations. This is in line with the results of Dochez *et al.*, who highlighted that CA-125 does not have specificity on its own but greatly improves diagnostic accuracy when imaging and clinical data are included **[12]**. A further significant component impacting RMI was menopausal state. Consistent with earlier research showing an increasing risk of cancer with advancing age, post-menopausal women had a larger percentage of malignant tumors **[13]**. Adding menopausal status to RMI makes it more predictive by taking this demographic risk factor into consideration. There are certain limits to RMI, despite its benefits. It was more challenging to correctly categorize borderline cancers since they had intermediate RMI values. This has been shown in several investigations, which implies that in order to enhance the identification of borderline lesions, further imaging methods or biomarkers would be necessary **[5, 14]**. Research on other models, such as ADNEX and the Risk of Ovarian Malignancy Algorithm (ROMA), has been ongoing between 2020 and 2025. Due to its simplicity, cost and convenience of computation, RMI continues to be frequently employed, even if these models may provide superior sensitivity in some circumstances **[12, 15]**. All things considered, the results of this research confirm that RMI is an excellent diagnostic tool as it combines radiological, biochemical and clinical characteristics into one index. It is a great tool for directing clinical decision-making and referring patients to specialist cancer clinics because to its high diagnostic accuracy and significant connection with histology.

Conclusion:

Risk of Malignancy Index (RMI) is a useful and dependable tool for pre-operative assessment of ovarian masses, showing good diagnostic accuracy linking with histological findings at a cut-off value of 250. Incorporating menopausal status, serum cancer antigen 125 and ultrasound findings enhances its feasibility and cost-effectiveness for routine clinical practice. Borderline tumors remain challenging to classify, highlighting the need for further evaluation and complementary diagnostic approaches.

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