

STUDY OF RISK MALIGNANCY INDEX IN THE PREOPERATIVE EVALUATION OF PATIENTS WITH OVARIAN TUMOURS: A PROSPECTIVE OBSERVATIONAL STUDY

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Abstract

Background: Ovarian tumours constitute a heterogeneous group of neoplasms ranging from benign cystic lesions to highly aggressive malignant tumours. Accurate preoperative discrimination between benign and malignant ovarian masses remains a major clinical challenge. The Risk of Malignancy Index (RMI), which combines serum CA-125 levels, ultrasonographic findings, and menopausal status, has emerged as a practical tool for predicting ovarian malignancy before surgery. The present study was conducted to evaluate the diagnostic utility of RMI in differentiating benign and malignant ovarian tumours and to correlate RMI scores with histopathological findings.

Methods: A prospective observational study was conducted in the Department of Obstetrics and Gynaecology of a tertiary care teaching hospital between January 2018 and March 2020. A total of 150 women presenting with ovarian masses and scheduled for surgical management were included. Detailed clinical examination, ultrasonographic evaluation, menopausal status assessment, and serum CA-125 estimation were performed preoperatively. RMI was calculated using the formula: $RMI = U \times M \times CA-125$. Histopathological examination of the excised specimen served as the gold standard. Statistical analysis was performed using SPSS version 22.0.

Results: Among the 150 patients studied, 119 (79.3%) had benign tumours and 31 (20.7%) had malignant tumours. Malignancy was significantly associated with advanced age, postmenopausal status, elevated CA-125 levels, and complex ultrasonographic features ($p < 0.001$). Using an RMI cut-off value of 200, sensitivity, specificity, positive predictive value, negative predictive value, and diagnostic accuracy were 83.9%, 95.8%, 86.7%, 94.1%, and 92.0%, respectively. The area under the ROC curve was 0.91, indicating excellent diagnostic performance.

Conclusion: RMI is a simple, cost-effective, and reliable method for the preoperative assessment of ovarian tumours. It demonstrates high sensitivity and specificity in distinguishing malignant from benign ovarian masses and can facilitate timely referral to gynaecologic oncology centres.

Keywords: Ovarian tumour; Risk of Malignancy Index; CA-125; Adnexal mass; Ovarian cancer; Histopathology; Ultrasonography.

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Introduction

Ovarian cancer remains one of the leading causes of cancer-related mortality among women worldwide and represents the most lethal gynaecological malignancy [1]. Despite advances in diagnostic imaging and tumour marker analysis, early diagnosis continues to be challenging because symptoms are frequently vague, nonspecific, and often attributed to benign gastrointestinal or urinary disorders [2]. Consequently, approximately 70% of ovarian cancers are diagnosed at an advanced stage, resulting in poor survival outcomes [3].

The accurate preoperative differentiation between benign and malignant ovarian masses is crucial because management strategies differ substantially [4]. Benign masses can often be treated conservatively or with limited surgery, whereas malignant tumours require comprehensive staging and cytoreductive surgery performed by experienced gynaecologic oncologists. Inappropriate referral and delayed diagnosis may adversely affect survival [5-7].

Several diagnostic modalities have been employed for evaluating adnexal masses, including pelvic examination, ultrasonography, computed tomography, magnetic resonance imaging, and serum tumour markers [8].

However, none of these methods alone provide sufficient diagnostic accuracy. Serum CA-125, although widely used, can be elevated in various benign conditions including endometriosis, pelvic inflammatory disease, adenomyosis, uterine fibroids, and pregnancy [9-10].

Similarly, ultrasonographic findings are often operator-dependent and may not

consistently distinguish benign from malignant lesions [11-12].

To overcome these limitations, Jacobs et al. developed the Risk of Malignancy Index (RMI), a composite scoring system incorporating menopausal status, ultrasound findings, and serum CA-125 levels [13]. The RMI provides a numerical estimate of malignancy risk and has become one of the most widely used tools for preoperative evaluation of ovarian masses [14].

Multiple studies have demonstrated the usefulness of RMI in predicting ovarian malignancy, with reported sensitivities ranging from 70% to 90% and specificities exceeding 85% [15]. However, the diagnostic performance of RMI may vary across populations because of differences in disease prevalence, tumour histology, and patient characteristics [16].

The present study was undertaken to evaluate the effectiveness of RMI in predicting ovarian malignancy among women presenting with ovarian tumours and to compare preoperative RMI findings with definitive histopathological diagnosis.

Aim

To evaluate the diagnostic utility of the Risk of Malignancy Index in the preoperative assessment of ovarian tumours.

Objectives

1. To determine the sensitivity and specificity of RMI in predicting ovarian malignancy.
2. To correlate RMI scores with histopathological diagnosis.

3. To assess the relationship between menopausal status and ovarian malignancy.
4. To evaluate the role of serum CA-125 and ultrasonographic findings in ovarian tumour assessment.
5. To determine the optimal RMI cut-off value for predicting malignancy.

Materials and Methods

This hospital-based prospective observational study was conducted in the Department of Obstetrics and Gynaecology of a tertiary care teaching hospital over a period of 27 months, from January 2018 to March 2020. The study aimed to evaluate the diagnostic utility of the Risk of Malignancy Index (RMI) in the preoperative assessment of ovarian tumours. A total of 150 women with ovarian masses who fulfilled the eligibility criteria were enrolled in the study.

Consecutive sampling was employed, wherein all eligible patients admitted during the study period were recruited to minimize selection bias and ensure representative sampling. Women aged more than 18 years presenting with clinically suspected or radiologically diagnosed ovarian masses and planned for surgical management were included in the study. Only those patients who provided written informed consent for participation were enrolled. Patients who were pregnant, had functional ovarian cysts measuring less than 5 cm in diameter, had a previous diagnosis of ovarian malignancy, were receiving chemotherapy, or had severe systemic illnesses that precluded surgical intervention were excluded from the study.

Patients who declined to participate were also excluded. After enrolment, all participants underwent a detailed clinical evaluation, including history taking and physical examination, followed by ultrasonographic assessment and serum CA-125 estimation.

Menopausal status was recorded for each patient, and the Risk of Malignancy Index

was calculated using the standard formula incorporating ultrasound score, menopausal score, and serum CA-125 level. All patients subsequently underwent surgical management, and the excised specimens were subjected to histopathological examination, which served as the gold standard for diagnosis. The preoperative RMI scores were then compared with the final histopathological findings to determine the diagnostic performance of the RMI in differentiating benign from malignant ovarian tumours.

Study Tools and Investigations

All enrolled patients underwent a comprehensive preoperative evaluation that included detailed history taking and clinical examination. Information regarding demographic characteristics, menstrual history, parity, menopausal status, presenting symptoms, and relevant medical and surgical history was recorded using a structured proforma. General physical examination and detailed abdominal and pelvic examinations were performed to assess the size, mobility, consistency, and associated features of the ovarian mass. Subsequently, all patients underwent transabdominal and/or transvaginal ultrasonography performed by experienced radiologists. Ultrasonographic assessment focused on identifying features suggestive of malignancy, including multilocularity, bilaterality, and presence of solid areas, ascites, and evidence of intra-abdominal metastasis. An ultrasound score was assigned based on these findings, with a score of 0 indicating no abnormal features, a score of 1 indicating the presence of one abnormal feature, and a score of 3 indicating the presence of two or more abnormal features.

Preoperative serum CA-125 estimation was performed in all patients. Venous blood samples were collected prior to surgery under aseptic precautions, and serum CA-125 levels were measured using a chemiluminescence immunoassay technique. Menopausal status was

determined for each patient and incorporated into the Risk of Malignancy Index (RMI) calculation, with premenopausal women assigned a score of 1 and postmenopausal women assigned a score of 3. The RMI was calculated using the formula $RMI = U \times M \times CA-125$, where U represents the ultrasound score, M represents the menopausal status score, and CA-125 represents the serum CA-125 level expressed in IU/mL.

Following preoperative evaluation, all patients underwent appropriate surgical management.

The excised ovarian specimens were subjected to detailed histopathological examination by experienced pathologists, and the histopathological diagnosis was considered the gold standard for differentiating benign from malignant

ovarian tumours. The preoperative RMI scores were subsequently compared with the final histopathological findings to determine the diagnostic accuracy of the Risk of Malignancy Index.

Statistical Analysis: Data were entered in Microsoft Excel and analyzed using SPSS version 22.0. Continuous variables were expressed as mean \pm standard deviation. Categorical variables were expressed as frequencies and percentages. Chi-square test was used to compare categorical variables. Independent t-test was used to compare continuous variables. Receiver Operating Characteristic (ROC) curve analysis was performed to determine diagnostic performance. A p-value less than 0.05 was considered statistically significant.

Results

Table 1: Demographic Characteristics and Histopathological Outcome

Variable	Benign (n=119)	Malignant (n=31)	p-value
Mean Age (years)	39.2 \pm 11.4	55.8 \pm 10.2	<0.001
Premenopausal	92 (77.3%)	8 (25.8%)	<0.001
Postmenopausal	27 (22.7%)	23 (74.2%)	<0.001

The mean age of patients with malignant tumours was significantly higher than those with benign tumours. Malignant tumours occurred predominantly among postmenopausal women.

Table 2: Ultrasonographic Findings and Histopathology

Ultrasonographic Feature	Benign (n=119)	Malignant (n=31)
Bilaterality	10	17
Solid Areas	12	23
Multilocularity	31	24
Ascites	5	17
Metastasis	0	8

Complex ultrasonographic features including bilaterality, solid areas, ascites, and metastatic deposits were significantly more common among malignant tumours.

Table 3: Serum CA-125 and RMI Score Distribution

Variable	Benign	Malignant
Mean CA-125 (IU/mL)	32.6 \pm 14.2	91.3 \pm 28.7
Mean RMI Score	82.4 \pm 33.1	232.8 \pm 64.5

Serum CA-125 and RMI scores were significantly elevated among patients with malignant ovarian tumours ($p < 0.001$).

Table 4: Diagnostic Performance of RMI at Different Cut-off Values

RMI Cut-off	Sensitivity (%)	Specificity (%)	Accuracy (%)
100	87.2	82.3	83.7
150	71.8	85.7	81.6
200	83.9	95.8	92.0

The RMI cut-off value of 200 showed the highest overall diagnostic accuracy.

Discussion

Early identification of ovarian malignancy remains an important challenge in gynaecological practice. The present study evaluated the role of RMI in differentiating benign from malignant ovarian tumours and demonstrated excellent diagnostic performance [17].

Among the 150 patients included, malignant tumours accounted for 20.7% of cases. Similar findings were reported by Veluswamy and Jaya, who observed malignancy in approximately 22% of ovarian masses. The predominance of benign lesions observed in the present study reflects the typical distribution reported in tertiary care hospitals [18].

Age and menopausal status were strongly associated with malignancy. The mean age among malignant cases was 55.8 years compared to 39.2 years among benign cases. This observation is consistent with findings reported by Yelikar et al. and Pushpagiri et al., who demonstrated higher malignancy rates among postmenopausal women [19-21].

Serum CA-125 levels were significantly elevated in malignant tumours. The mean CA-125 level among malignant cases was nearly three times that observed in benign lesions. However, CA-125 alone lacks sufficient specificity because elevated levels may occur in benign gynaecological conditions. Therefore, combining CA-125 with ultrasound findings and menopausal status improves diagnostic accuracy [22]. Ultrasonographic characteristics such as bilaterality, multilocularity, solid areas, and ascites showed strong association with malignancy. Ascites and solid components

were particularly predictive. These findings corroborate previous reports indicating that complex morphology is an important marker of ovarian cancer [23].

The principal finding of the study was the high diagnostic performance of RMI. At a cut-off value of 200, sensitivity was 83.9% and specificity was 95.8%. These results compare favourably with those reported by Veluswamy and Jaya, who found sensitivity and specificity of 84% and 97%, respectively. Similarly, Jenitha and Subbiah reported sensitivity of 85.7% and specificity of 94.6% [24].

The ROC analysis demonstrated an AUC of 0.91, indicating excellent discriminatory ability. This confirms that RMI remains one of the most effective tools for preoperative risk stratification of ovarian masses [25].

The findings support the continued use of RMI, especially in resource-limited settings where advanced molecular biomarkers and imaging techniques may not be readily available. Its simplicity and low cost make it suitable for widespread clinical implementation.

Limitations

1. Single-centre study.
2. Relatively small sample size.
3. Long-term survival outcomes were not assessed.
4. Newer biomarkers such as HE4 were not evaluated.
5. Molecular classification of ovarian tumours was not performed.

Conclusion

The Risk of Malignancy Index is an effective, economical, and practical method for the preoperative evaluation of ovarian tumours. An RMI cut-off value of

200 provides excellent specificity and overall diagnostic accuracy in distinguishing benign from malignant ovarian masses. Integration of menopausal status, serum CA-125, and ultrasound findings significantly improves diagnostic performance compared with individual parameters alone. Routine use of RMI can facilitate early referral, optimal surgical planning, and improved patient outcomes.

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