Section: Obstetrics and Gynecology

Systematic Review

ACCURACY OF RISK OF MALIGNANCY INDEX IN OVARIAN MALIGNANCIES IN PERI MENOPAUSAL AND POSTMENOPAUSAL WOMEN - A SYSTEMATIC REVIEW

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Abstract

An accurate diagnosis of ovarian malignancies is crucial for effective clinical management and surgical planning, particularly in perimenopausal and postmenopausal women. This study aimed to evaluate the diagnostic accuracy of the Risk of Malignancy Index for distinguishing ovarian malignancies in perimenopausal and postmenopausal women. A comprehensive search was conducted across major scientific databases, including PubMed, Scopus, and the Web of Science, covering studies published until May 2024. The inclusion criteria were studies involving peri-menopausal and postmenopausal women with adnexal masses and reporting original data on RMI's accuracy of RMI. The synthesis of findings from 15 selected studies revealed that RMI exhibits high sensitivity and specificity for diagnosing ovarian malignancies. Key studies have demonstrated RMI's effectiveness of RMI, with sensitivity ranging from 66.7% to 96% and specificity from 77.24% to 94.74%. The findings highlight the reliability of RMI across diverse populations, although limitations exist in borderline and early-stage ovarian tumours. The Risk of Malignancy Index showed high accuracy in diagnosing ovarian malignancies in perimenopausal and postmenopausal women, making it a reliable diagnostic tool. Standardising RMI cutoff values and combining them with other diagnostic indices, such as ROMA, could enhance its precision. This review highlights the importance of collaborative efforts to improve the management of ovarian malignancies in this population.

INTRODUCTION

The diagnosis of ovarian malignancies plays a critical role in clinical management and surgical planning. Establishing a standardized preoperative methodology for the identification of potentially malignant masses is pivotal in ensuring optimized initial treatment for women diagnosed with ovarian cancer.[1] Referral of patients harbouring malignant tumours to a gynaecological oncologist is imperative, given the significance of cytoreductive surgery quality and surgical staging/lymph node dissection as key prognostic determinants in the context of ovarian cancer. Research has indicated that prompt referral to a gynaecological oncologist can positively impact survival rates among ovarian cancer patients.[2]

Ovarian malignancies are often characterised as "silent killers" due to their asymptomatic nature and slow progression within the body.[3] Epithelial ovarian cancer, which is prevalent among postmenopausal women, especially those aged 65 years and older, poses a substantial clinical challenge.[4] Accurate preoperative identification of suspected ovarian masses (OMs) is crucial for devising appropriate therapeutic interventions. Despite the availability of various diagnostic tools such as pelvic assessments, tumour markers, and radiological investigations, none of these methods exhibit adequate sensitivity or specificity for the detection of malignancies.[5]

The risk of malignancy (RMI) index has emerged as a valuable composite parameter for the assessment of ovarian masses, incorporating factors such as menopausal status, ultrasonographic findings, and serum CA-125 levels. CA-125 is a tumour marker commonly used for ovarian cancer screening. CA-125 is usually secreted from the ovarian epithelial and peritoneal lining cells as well as cells of the

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gastrointestinal tract (GIT), pancreas, and lungs. Elevated CA-125 levels are commonly found in epithelial ovarian tumours, as well as breast, lung, pancreatic, and endometrial cancers, pelvic inflammatory disease (PID), endometriosis, adenomyosis, inflammatory bowel disease, and liver diseases.[6]

The primary objective of this systematic review was to assess the diagnostic accuracy of the Risk of Malignancy Index in distinguishing between ovarian masses in perimenopausal and postmenopausal women.

MATERIALS AND METHODS

Literature Search Strategy.

A systematic and exhaustive search will be conducted across major scientific databases, including PubMed, Scopus, and Web of Science, to identify relevant studies on the accuracy of the Risk of Malignancy Index (RMI) in diagnosing ovarian malignancies in perimenopausal and postmenopausal women. The search covered studies published until May 2024. The search strategy will include variations of keywords such as "Risk of Malignancy Index", "RMI", "ovarian cancer", "ovarian malignancies", "peri-menopausal women", "postmenopausal women", and other related terms. Boolean operators (AND, OR) will be used to refine the search and capture the intersection of these terms.

Inclusion and Exclusion Criteria

Studies were included if they met the following criteria.

- Studies involving perimenopausal and postmenopausal women diagnosed with adnexal masses or ovarian malignancies.
- Peer-reviewed articles published in English until May 2024.
- Randomised controlled trials, cohort studies, case-control studies, and observational studies reported original data on the accuracy of the Risk of Malignancy Index.
- Studies specifically report the use of RMI in the preoperative assessment of ovarian masses.

Studies were excluded if they were as follows

- Studies published in languages other than English.
- Case reports, reviews, conference abstracts, dissertations, and theses.
- Studies involving populations other than peri-menopausal and postmenopausal women.
- Studies that do not provide sufficient data on the RMI or its components.

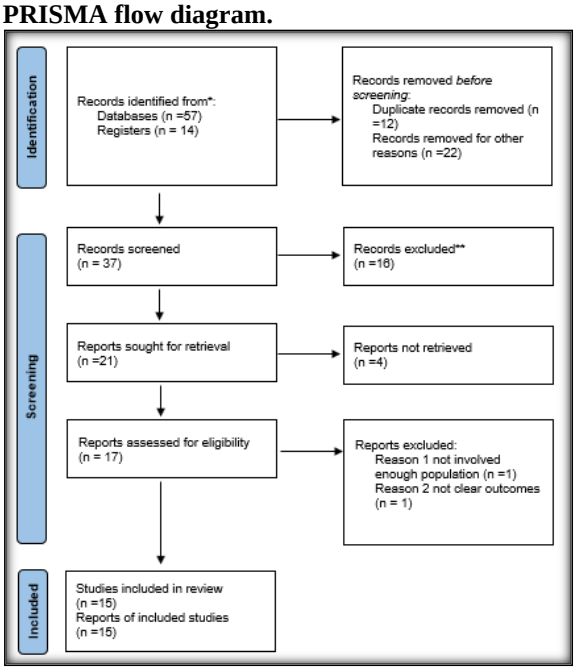
Synthesis of Findings

Data synthesis will involve a narrative review of key study characteristics, methodologies used, and major findings related to the accuracy of RMI in diagnosing ovarian malignancies in perimenopausal and postmenopausal women. Owing to the anticipated variety in study designs and methodologies, a qualitative approach will be used to emphasise each study's unique contributions to our comprehensive understanding of RMI's diagnostic accuracy.

Ethical Considerations:

As this review was based on an analysis of previously published studies, ethical approval was not applicable. All the included studies adhered to ethical standards, as outlined in their respective publications.

PRISMA flow diagram.



RESULTS

The risk of malignancy (RMI) index is an important tool for assessing ovarian masses, especially in menopausal women, where an accurate diagnosis is crucial. Several studies have investigated the effectiveness of RMI in different patient groups, providing valuable information regarding its ability to differentiate between benign and malignant ovarian masses with high accuracy. These studies collectively enhance our understanding of how RMI performs in clinical practice by providing insights into its sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV).

Radwan et al. demonstrated that RMI-I is effective for diagnosing ovarian malignancy in menopausal women. Using a cutoff of 200, the RMI-I showed 75.8% sensitivity and 91.8% specificity among 82 participants with suspected ovarian masses. A cut-off greater than 241.5 resulted in 96% sensitivity and 94.74% specificity. These findings suggest that RMI-I can be a valuable tool for diagnosing ovarian malignancy in menopausal women, particularly when a higher cutoff is used.[6] The study by Terzic et al. aimed to evaluate the effectiveness of the Risk of Malignancy Index (RMI) in distinguishing between benign and malignant tumours in premenopausal and postmenopausal patients with adnexal masses. Among 540 women, RMI accurately identified benign and malignant tumours in 84.6% of the cases,

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with a sensitivity of 83.81% and a specificity of 77.24%. The positive and negative predictive values (PPV) were 47.06% and the negative predictive value (NPV) was 95.18%. The study found that RMI performed similarly well in both premenopausal and postmenopausal groups, indicating its effectiveness in diagnosing adnexal masses across different menopausal statuses.[7]

In a study conducted by Terzic et al., 81 patients with adnexal masses underwent ultrasounds. The RMI was calculated based on menopausal status and CA-125 levels. Patients were divided into three RMI groups: <25, 25-200, and >200. Histopathological analysis confirmed that 62.96% of the cases had benign lesions, whereas 37.04% had malignant masses. This study revealed a strong positive correlation between RMI values and malignancy. An RMI cut-off of 200 showed a sensitivity of 83.33%, specificity of 94.12%, positive predictive value of 89.29%, and negative predictive value of 90.57%. These findings demonstrate the reliability of RMI in clinical practice for accurately distinguishing between benign and malignant adnexal masses.[8]

Dotlic et al. focused on identifying preoperative predictors of ovarian tumour malignancy, with a specific focus on RM) among other factors. The authors examined 81 patients with adnexal masses. Histopathological findings revealed that there were significantly more benign tumours (n=51) than malignant tumours (n=30). They found that patients with malignant tumours were older, menopausal, and had higher BMI values. The study also demonstrated a positive correlation between high-risk RMI categories and malignant histopathological findings.[9] In a prospective cohort study conducted by Rao et al., 100 patients were examined RMI demonstrated 66.7% sensitivity in premenopausal women and 83.3% in postmenopausal women, with specificities of 96.3% and 81.8% respectively. The PPV was 40% and 71.4%, and the NPV was 98.7% and 90%, respectively. The diagnostic accuracy was 95.2% and 82.4% for premenopausal and postmenopausal women, respectively. These results indicate that RMI plays a crucial role in identifying patients who may require Staging Laparotomy.[10]

In addition, Andersen et al. The RMI incorporates menopausal status, ultrasonographic findings, and serum CA 125 levels, with a cutoff of 200 for centralised primary surgery. The study reported a sensitivity, specificity, PPV, and NPV of 70.6%, 89.3%, 66.1%, and 91.1%, respectively. Notably, for patients undergoing surgery, the sensitivity was 70.6%, specificity was 87.7%, PPV was 66.1%, and NPV was 89.8%. When considering stage I disease as "benign", the sensitivity increased to 95.5%, with a specificity of 87.9%, PPV of 57.8%, and NPV of 99.1%. Despite its simplicity and applicability, RMI has limitations in borderline ovarian tumours, stage I invasive cancers, and nonepithelial tumours, suggesting the need for alternative diagnostic approaches in these cases.[11]

Mohammed et al. compared the diagnostic accuracies of RMI-3 and RMI-4 in predicting ovarian malignancy. involving 172 patients who had undergone surgery for adnexal masses. The study found 76.2% benign, 8.7% borderline, and 15.1% malignant tumours. For malignant masses, RMI-3 showed a sensitivity, specificity, PPV, NPV, and diagnostic accuracy of 80.7%, 93.1%, 70%, 96%, and 91%, respectively. RMI-4 demonstrated a similar performance. In borderline masses, RMI-3 and RMI-4 had lower sensitivity, but comparable specificity. Both indices were more accurate at predicting malignant masses. The study concludes that RMI is a simple and reliable method for evaluating ovarian masses, with RMI-3 and RMI-4 showing comparable performance.[12]

Enakpene et al. assessed the effectiveness of RMI in predicting malignancy and guiding the treatment of adnexal masses in 302 women. RMI, which considers menopausal status, ultrasound morphology, and CA-125 levels, demonstrated a sensitivity of 88.2%, specificity of 74.3%, PPV of 71.3%, and NPV of 90% with a cut-off of 250. This suggests that RMI can effectively differentiate between benign and malignant masses, helping in the selection of the most appropriate treatment and prioritizing patient care.[13]

Manjunath et al. involving 152 women explored the performance of three different RMIs (RMI 1, RMI 2, and RMI 3) incorporating menopausal status, serum CA 125 levels, and ultrasound features. Our findings indicate that RMI outperforms individual factors in diagnosing malignancy, with no significant differences observed among the three RMI variations. The RMI emerges as a simple yet efficient tool for identifying pelvic masses, facilitating appropriate therapy and referral decisions in less specialized gynaecology centres.[14]

Obeidat et al. conducted a study aimed to evaluate the efficacy of RMI in discriminating between benign and malignant pelvic masses. A total of 100 women who underwent laparotomy were retrospectively analysed. RMI, incorporating CA 125 levels, ultrasound findings, and menopausal status, outperformed the individual criteria. With a cutoff of 200, the RMI demonstrated a sensitivity of 90%, specificity of 89%, PPV of 96%, and NPV of 78%. RMI proved effective in distinguishing between benign and malignant masses, facilitating optimal patient selection for primary surgery.[15]

Yamamoto et al. compared four RMIs (RMI 1, RMI 2, RMI 3, and RMI 4) and found RMI-4 to have the highest reliability, with a sensitivity of 91% and specificity of 85% at a cut-off value of 200. The superior performance of RMI-4 indicates its preference in clinical settings for evaluating ovarian masses, providing clinicians with a dependable diagnostic tool.[16]

The study by McDonald et al. aimed to evaluate the predictive accuracy of preoperative ultrasonography, serum CA 125 levels, and patient demographics in assessing the risk of malignancy among women with ultrasonographically confirmed adnexal masses.

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Analysis of data from 395 patients undergoing surgery revealed that those with solid or complex ovarian tumours and elevated serum CA 125 levels (>35 units/mL) were at high risk of ovarian malignancy. This definition demonstrated a positive predictive value of 84.7% and a negative predictive value of 92.4%, effectively identifying the majority of ovarian cancer cases across different stages.[17]

Ma et al. conducted a study a data from 140 women were analysed. RMI outperformed the individual criteria in diagnosing cancer, exhibiting a sensitivity of 87.3%, specificity of 84.4%, and positive predictive value of 82.1% at a cutoff level of 200. The findings suggest RMI's utility in accurately discerning malignant from benign pelvic masses, offering a valuable tool for patient selection in primary surgery.[18]

Priyanka et al. performed a prospective study to validate the various RMIs. involving 191 patients, our findings indicate that RMI 4 is a superior initial assessment tool, with a sensitivity of 80.6%, specificity of 96.2%, and an area under the curve value of 0.939 at a cutoff of 334. RMI 4 emerges as a valuable method for diagnosing pelvic masses with high malignancy risk, offering potential benefits in low-resource settings.[19]

Moore et al. Moore et al. compared RMI and ROMA for predicting epithelial ovarian cancer (EOC) in 457 women with pelvic masses. They found that ROMA had a higher sensitivity (93%) than RMI (86%) for predicting EOC. HE4 and CA 125, achieved 94.3% sensitivity at 75% specificity, outperforming RMI's 84.6% sensitivity (p=0.0029). ROMA also showed higher sensitivity in stage I and II disease (85.3% vs. 64.7% for RMI, p<0.0001), suggesting ROMA's superiority in identifying EOC.[20]

The 15 studies underscored the importance of using the RMI to evaluate ovarian masses in postmenopausal and perimenopausal women. The consistent sensitivity and specificity values across different studies confirmed that RMI plays a vital role in accurately diagnosing, assessing risk, and making treatment decisions in clinical practice.

Table 1: Characteristics and Key Findings of Included Studies.

Study Authors	Study Design	Participants (n)	Key findings
Radwan et al.	Prospective cohort	82	RMI-I at a cutoff of 200 showed 75.8% sensitivity and 91.8% specificity; at >241.5, 96% sensitivity and 94.74% specificity in diagnosing ovarian malignancy in menopausal women.[6]
Terzic et al.	Retrospective cohort	540	RMI accurately differentiated benign from malignant tumours in 84.6% of cases, with a sensitivity of 83.81%, specificity of 77.24%, PPV of 47.06%, and NPV of 95.18%. Comparable performance in premenopausal and postmenopausal women.[7]
Terzic et al.	Prospective cohort	81	RMI at a cut-off of 200 showed 83.33% sensitivity, 94.12% specificity, PPV 89.29%, and NPV 90.57%. Significant positive correlation between RMI values and malignancy.[8]
Dotlic et al.	Retrospective cohort	81	High-risk RMI categories positively correlated with malignant histopathological findings.[9]
Rao et al.	Prospective cohort	100	RMI sensitivity in premenopausal women 66.7%, postmenopausal women 83.3%; specificity 96.3% and 81.8%; PPV 40% and 71.4%; NPV 98.7% and 90%.[10]
Andersen et al.	Retrospective cohort	102	RMI sensitivity, 70.6%; specificity, 89.3%; PPV, 66.1%; NPV, 91.1%. For stage I disease as "benign," sensitivity 95.5%, specificity 87.9%, PPV 57.8%, NPV 99.1%.[11]
Mohammed et al.	Prospective cohort	172	RMI-3 and RMI-4 showed similar performance with RMI-3 sensitivity 80.7%, specificity 93.1%, PPV 70%, NPV 96%, diagnostic accuracy 91%.[12]
Enakpene et al.	Retrospective cohort	302	RMI at a cutoff of 250 showed 88.2% sensitivity, 74.3% specificity, PPV 71.3%, NPV 90%.[13]
Manjunath et al.	Retrospective cohort	152	RMI outperformed individual factors in diagnosing malignancy with no significant difference among RMI 1, RMI 2, and RMI 3.[14]
Obeidat et al.	Retrospective cohort	100	RMI at a cutoff of 200 demonstrated 90% sensitivity, 89% specificity, PPV 96%, NPV 78%.[15]
Yamamoto et al.	Retrospective cohort	253	RMI-4 showed highest reliability with 91% sensitivity and 85% specificity at a cutoff of 200.[16]
McDonald et al.	Retrospective cohort	395	Solid or complex tumours and elevated CA 125 levels had a positive predictive value of 84.7% and a negative predictive value of 92.4%.[17]
Ma et al.	Retrospective cohort	140	RMI sensitivity 87.3%, specificity 84.4%, PPV 82.1% at a cutoff of 200.[18]
Priyanka et al.	Prospective cohort	191	RMI 4 showed 80.6% sensitivity, 96.2% specificity, AUC 0.939 at a cutoff of 334.[19]
Moore et al.	Prospective multicenter trial	457	ROMA had a higher sensitivity (94.3%) than RMI (84.6%) in predicting EOC. In stage I and II disease, ROMA achieved 85.3% sensitivity compared with 64.7% for RMI, suggesting ROMA's superiority in identifying EOC.[20]

DISCUSSION

This systematic review aimed to elucidate the accuracy of the Malignancy Index (RMI) in diagnosing ovarian malignancies in perimenopausal and postmenopausal women. Our analysis of multiple studies provides a comprehensive understanding of the effectiveness of RMI and highlights its strengths and limitations in clinical practice.

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Several studies, including those by Radwan et al., Terzic et al., and Mohammed et al., have demonstrated that RMI is a robust tool for distinguishing between benign and malignant ovarian masses in menopausal women.[6,7,12] Radwan et al. reported that using an RMI-I cutoff of 200 yielded a sensitivity of 75.8% and a specificity of 91.8% among 82 participants, with improved sensitivity (96%) and specificity (94.74%) at a higher cutoff of 241.5. Similarly, Terzic et al. found that RMI accurately identified tumours in 84.6% of cases, with notable sensitivity (83.81%) and specificity (77.24%). A study by Mohammed et al. comparing RMI-3 and RMI-4 indicated that both indices showed comparable performance, further validating RMI's reliability of RMI in clinical settings.[6-8,12] The findings of Dotlic et al. and Rao et al. further corroborate RMI's utility of RMI. Dotlic et al. noted a significant correlation between high-risk RMI categories and malignant histopathological findings, emphasising their predictive power in menopausal women. Rao et al. reported RMI's diagnostic accuracy of 95.2% in premenopausal women and 82.4% in postmenopausal women, underscoring its pivotal role in identifying patients for staging laparotomy.[9,10]

However, some studies, such as Andersen et al., have highlighted limitations in RMI's applicability of RMI. Meray et al. pointed out reduced sensitivity and specificity in borderline ovarian tumours, stage I invasive cancers, and nonepithelial tumours, suggesting a need for alternative diagnostic approaches in these cases.[11,21] A study by Yamamoto et al. suggests that RMI-4 has better performance and should be used in clinical practice, a view supported by Zhang et al.[16,22]

The diversity in research, sample sizes, and cutoff values create challenges in reaching firm conclusions. However, despite these obstacles, the consistently high sensitivity and specificity of RMI confirms its value in diagnosing ovarian malignancies. The RMI approach, which incorporates menopausal status, ultrasound results, and CA-125 levels, offers a comprehensive method for evaluating patients.

Future research should aim to standardise RMI cutoff values and further investigate their performance in various subgroups, such as those with borderline and early stage ovarian tumours. Additionally, exploring the combination of RMI with other diagnostic indices, such as ROMA, could enhance the diagnostic accuracy and patient outcomes. By addressing these gaps, we can refine RMI's application of RMI and ensure more precise and effective management of ovarian masses in perimenopausal and postmenopausal women.

CONCLUSION

The Risk of Malignancy Index shows high accuracy rates in diagnosing ovarian malignancies, especially for perimenopausal and postmenopausal women. This review confirms RMI's sensitivity and specificity of RMI, making it a reliable diagnostic tool with a strong correlation to malignant outcomes. RMI effectively distinguishes between benign and malignant tumours across different populations, despite limitations, such as reduced efficacy in certain cases. Standardising RMI cutoff values and combining them with other indices such as ROMA will be crucial for future research and enhancing diagnostic precision, offering valuable insights for clinicians and researchers. This emphasises the importance of collaborative efforts to manage ovarian malignancies in perimenopausal and postmenopausal women.

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