JURNAL KEDOKTERAN DIPONEGORO
(*DIPONEGORO MEDICAL JOURNAL*)
Online : http://ejournal3.undip.ac.id/index.php/medico
E-ISSN : 2540-8844
DOI : 10.14710/dmj.v15i5.54325
JKD (DMJ), Volume 15, Number 5, September 2026 : 426-431

COMPARISON OF SCORING SYSTEMS IN ASSESSING THE RISK OF MALIGNANCY IN OVARIAN CYSTS: A LITERATURE REVIEW AND CLINICAL IMPLICATIONS

I Gde Sastra Winata*, Jessica Nathalia
[1]Department of Obstetric and Gynecology, Faculty of Medicine, Udayana University, Bali, Indonesia

Keywords:
Ovarian cyst,
Adnexal mass,
RMI,
IOTA Simple Rules,
IOTA ADNEX,
Malignancy risk score.

Received: 17 November 2025
Revised: 10 December 2025
Accepted: 11 December 2025
Available online: 01 September 2026

Corresponding Author:
E-mail: sastra@unud.ac.id

ABSTRACT
Background: Preoperative assessment of ovarian cysts with suspected malignancy requires reliable scoring systems to distinguish between benign and malignant lesions. Several scoring systems have been developed, including the Risk of Malignancy Index (RMI), IOTA Simple Rules, and IOTA ADNEX. **Objective:** To review the literature on the diagnostic accuracy of these scoring systems, compare their strengths and weaknesses, and discuss their clinical implications. **Methods:** Literature search from open-access databases until the most recent articles, including studies comparing scoring systems for ovarian/adnexal masses. **Results:** Several studies show that IOTA models (especially ADNEX) have higher diagnostic performance (AUC) compared to RMI. However, each system has limitations in clinical applications. **Conclusion:** The choice of scoring system should consider local facilities (ultrasound, tumor markers, imaging expertise) and patient risk; the use of high-performing models can improve triage and management of patients with ovarian cysts.

INTRODUCTION

Ovarian cysts are common findings in women and are often discovered incidentally during routine gynecological examinations. While most ovarian masses are benign, distinguishing malignant lesions early is crucial for improving survival outcomes. Ovarian cancer alone has a 5-year survival rate of <50%. It is worth noting that the majority of ovarian cancers, roughly 80%, are detected in the later stages of the disease when it has spread beyond the ovaries.[1,2]

Several studies have suggested the use of preoperative imaging modalities (laparoscopy, CT, PET scan) or serum biomarkers (CA 125, HE-4) but those modalities are sometimes expensive and inaccessible for low-resource setting that commonly present in developed country such as Indonesia. Several preoperative scoring systems, including the Risk of Malignancy Index (RMI)**,** IOTA Simple Rules**,** and IOTA ADNEX**,** have been developed to assess the likelihood of malignancy and guide management decisions. These models incorporate clinical, ultrasound, and biomarker data, but their diagnostic performance varies across studies.[3-6]

METHODS

A comprehensive literature search was conducted in open-access databases, including PubMed, PMC, and other relevant sources, using the following keywords: "RMI adnexal mass," "IOTA ADNEX model ovarian cyst," "IOTA simple rules adnexal masses diagnostic accuracy." The search included studies published up to the latest available date (insert search date). Studies were selected based on the following inclusion criteria:

1. **Study Design**: Studies that evaluated scoring systems for ovarian/adnexal masses**,** with histopathology or follow-up as the gold standard for diagnosing the presence of malignancy.
2. **Comparative Studies**: Studies comparing at **least** two of the following scoring systems: Risk of Malignancy Index (RMI)**,** IOTA Simple Rules**,** and IOTA ADNEX model**.**

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3. **Diagnostic Accuracy**: Studies providing data on diagnostic performance metrics (sensitivity, specificity, area under the curve [AUC], positive/negative predictive values, and likelihood ratios).
4. **Clinical Application**: Studies that examined the clinical applicability of these scoring systems in preoperative decision-making or triaging of patients with ovarian/adnexal masses.

RESULT

Risk of Malignancy Index (RMI)

The Risk of Malignancy Index (RMI) is one of the most widely used scoring systems for assessing the likelihood of malignancy in ovarian cysts or adnexal masses. Developed by Jacobs et al., the RMI combines three primary factors: CA-125 levels, menopausal status, and ultrasound findings. CA-125 is a well-known tumor marker that is elevated in many ovarian cancers, although it can also be elevated in benign conditions, such as endometriosis or uterine fibroids[1]. The menopausal status is incorporated because postmenopausal women are at a higher risk for malignancy compared to premenopausal women. The ultrasound findings are assigned a score based on the mass's appearance, with higher scores indicating a greater likelihood of malignancy.[3,4] The RMI score is calculated by multiplying the CA-125 value by a factor depending on menopausal status and the ultrasound score.

While RMI has become a cornerstone in many clinical settings due to its simplicity and ease of use, it has certain limitations. RMI has been shown to have a sensitivity ranging from 60% to 70% and a specificity of approximately 55%.[3,4] This relatively low sensitivity, particularly in detecting early-stage ovarian cancers, limits its effectiveness in clinical practice, especially in cases where CA-125 levels are not elevated or are borderline. Additionally, RMI does not account for other relevant biomarkers, such as HE4, which could improve its diagnostic accuracy.[4] Therefore, newer models, such as those developed by the IOTA group, have been designed to overcome these limitations by incorporating more sophisticated diagnostic criteria and offering higher diagnostic accuracy.[5]

The most commonly used cut-off is 200, indicating a high risk of malignancy, requiring referral to a specialist gynecological cancer center for further evaluation and potential treatment. Different RMI versions (RMI 1, 2, 3, 4) use slightly varied scoring but generally keep the ≥200 threshold, with higher scores suggesting greater malignancy risk, though some studies find different optimal cut-offs for specific RMI versions or patient groups, like RMI 4 needing 450.[5,6]

Variants	Ultrasound Score (U)[a]	Menopausal Score (M)	Tumor Size (S), cm[b]
RMI I = U × M × CA-125	U = 0 (0 parameter)	M = 1 (premenopausal)	Not applicable
	U = 1 (1 parameter)	M = 3 (postmenopausal)	
	U = 3 (≥2 parameters)		
RMI II = U × M × CA-125	U = 1 (0 or 1 parameter)	M = 1 (pre-menopausal)	Not applicable
	U = 4 (≥2 parameters)	M = 4 (postmenopausal)	
RMI III = U × M × CA-125	U = 1 (0 or 1 parameter)	M = 1 (premenopausal)	Not applicable
	U = 3 (≥2 parameters)	M = 3 (postmenopausal)	
RMI IV = U × M × S × CA-125	U = 1 (0 or 1 parameter)	M = 1 (premenopausal)	S = 1 (<7)
	U = 4 (≥2 parameters)	M = 4 (postmenopausal)	S = 2 (≥7)

[a]Parameters: presence of a multilocular cystic lesion, solid areas, a bilateral lesion, ascites, and intra-abdominal metastasis
[b]Single greatest diameter

Figure 1. RMI score[5]

IOTA Simple Rules

The IOTA Simple Rules offer a more refined approach for distinguishing between benign and malignant ovarian tumors, relying exclusively on ultrasound features. The IOTA group developed this system to provide a simple yet effective method for characterizing adnexal masses, eliminating the need for complex testing or biomarkers.[2] The system is based on ultrasound features, categorized into two groups: benign (B-features) and malignant (M-features). If the mass shows only B-features, it is classified as benign, whereas masses with only M-features are classified as malignant. If both benign and malignant features are present, the mass is considered inconclusive, and further assessment or expert evaluation is required.[2-4]

One of the strengths of the IOTA Simple Rules is its high sensitivity, which can exceed 90%, making it particularly useful in detecting malignant tumors. This system has been validated across multiple studies and is considered highly reliable for early detection of ovarian cancer, particularly in premenopausal women. However, the specificity is lower than that of more complex models, with some studies reporting specificity as low as 55%. The inconclusive cases present a significant challenge, as the system relies on the ability to clearly identify ultrasound features, which may be difficult without the expertise of a trained sonographer.[7]

Despite these challenges, the IOTA Simple Rules have become a valuable tool in clinical practice,

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especially in settings where CA-125 testing is unavailable or when less-experienced clinicians are assessing patients. The Simple Rules offer a non-invasive and cost-effective method for preoperative evaluation of adnexal masses, thereby reducing the need for unnecessary surgeries or interventions.[8] If there is one or more malignant component and no benign component, it is classified as malignant. Conversely, if there is more than one benign component and no malignant component, it is classified as benign. If there are both benign and malignant components, this score cannot be used.[9]

Table 1. IOTA Simple Rules Component[8]

Benign	Malignant
Unilocular	Irregular solid tumor
Presence of solid components where the largest solid component has a largest diameter < 7mm	Presence of ascites
Presence of acoustic shadow	At least four papillary structures
Smooth multilocular tumor with largest diameter < 100mm	Irregular multilocular solid tumor with largest diameter ≥ 100mm
No blood flow	Very strong blood flow

IOTA ADNEX Model

The IOTA ADNEX model represents one of the most advanced tools available for preoperative risk assessment of ovarian masses. The IOTA group developed this model to address the need for more detailed and accurate risk stratification. Unlike RMI and IOTA Simple Rules, which rely on relatively simple parameters, the ADNEX model needs the input of three clinical variables, including age (years), serum CA-125 level (U/mL), and type of center (oncology center/other hospital), and the measurement of six sonographic variables to predict the malignancy risk of adnexal masses.[8,10,11]

Six ultrasound parameters are assessed: the maximum diameter of the lesion (mm), the percentage of solid tissue, the number of papillary projections (0/1/2/3/>3), the presence of more than 10 cystic locules, acoustic shadowing, and ascites. The percentage of solid tissue refers to the ratio between the largest solid component's maximum diameter and the lesion's overall maximum diameter.[11]

Regarding the type of healthcare facility, an "oncology center" is defined as a tertiary institution specializing in gynecologic oncology; the rate of ovarian malignancy in such centers typically ranges from 22–66%, whereas in non-oncology hospitals it is generally below 30%. After entering these variables into the ultrasound system, the likelihood of benign versus malignant disease is calculated, and the patient's risk is presented as a relative risk (RR) based on a predefined formula.[11]

The classification consists of five categories: benign, borderline tumor, stage I invasive ovarian cancer, stage II–IV invasive ovarian cancer, and metastatic cancer, and identifies indicators associated with elevated RR values. A malignancy risk threshold of 10% is applied, with borderline tumors considered part of the malignant group.[11]

The ADNEX model has been extensively validated and has demonstrated superior diagnostic accuracy, with studies reporting an AUC of ~0.94 for distinguishing benign from malignant ovarian masses. The model's ability to classify tumors into specific categories enhances its clinical utility, especially in differentiating between borderline and early-stage invasive cancers, which can be challenging to detect with other systems.[13,14]

Additionally, the ADNEX model has been shown to perform well even in low-resource settings where access to biomarkers and specialized equipment may be limited. However, the ADNEX model is more complex than RMI and IOTA Simple Rules, requiring greater expertise and access to advanced imaging techniques.[12] This complexity may limit its use in clinical settings with less experienced practitioners or limited resources. Despite these challenges, the ADNEX model remains the gold standard for preoperative ovarian cancer risk assessment, owing to its comprehensive and highly accurate diagnostic capabilities.[13,14]

RMI is the simplest and most commonly used scoring system, which utilizes CA-125 levels, menopausal status, and ultrasound findings to assess the risk of malignancy. However, its relatively low sensitivity in early-stage cancers limits its effectiveness for some patients. IOTA Simple Rules offers high sensitivity, especially for identifying malignant ovarian tumors; however, it suffers from lower specificity, as cases with both benign and malignant features can be classified as inconclusive, requiring expert evaluation.[4,8,10,13,14]

IOTA ADNEX, the most complex of the three, incorporates ultrasound features, CA-125, age, and additional clinical factors to categorize tumors into

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five categories (benign, borderline, early-stage invasive, advanced-stage invasive, and metastatic). It demonstrates high accuracy in distinguishing between benign and malignant masses, with an AUC of 0.94. However, its complexity and reliance on trained examiners limit its use in settings where expertise is not readily available.[4,8,10,13,14]

Table 2. Comparison table between the Risk of Malignancy Index (RMI), IOTA Simple Rules, and IOTA ADNEX model based on their key characteristics, strengths, and weaknesses.[4,8,10,13,14]

Scoring System	Key Criteria	Strengths	Weaknesses
RMI	Ultrasound, CA-125, Menopausal Status	Simple to calculate, widely used in clinical practice, easy to apply	Lower sensitivity, especially in early-stage cancers, less accurate in some cases
IOTA Simple Rules	Ultrasound Features (B/M-features)	High sensitivity (~90%) in detecting malignant masses, easy to apply	Lower specificity, inconclusive cases when both benign and malignant features present
IOTA ADNEX	Ultrasound feature, CA-125, Age, Others	High diagnostic accuracy (AUC ~0.94), comprehensive model, suitable for early-stage cancers	Complex, requires trained examiners, not as accessible in low-resource settings

DISCUSSION

The assessment of ovarian cysts and adnexal masses with suspected malignancy is a critical aspect of gynecological practice, as it directly influences treatment decisions and patient outcomes. Over the years, several scoring systems have been developed to help clinicians distinguish between benign and malignant masses. Among these, the Risk of Malignancy Index (RMI), IOTA Simple Rules, and IOTA ADNEX model are the most widely used and studied models. Each system has its strengths and weaknesses, which should be considered in choosing the most appropriate tool for clinical practice.

The RMI is a quick and straightforward method widely used across clinical settings. It combines CA-125 levels, menopausal status, and ultrasound findings, making it easily applicable.[2,4] However, RMI has been criticized for its lower sensitivity and specificity, particularly in detecting early-stage ovarian cancers, where CA-125 levels may not be sufficiently elevated. In contrast, the IOTA Simple Rules rely entirely on ultrasound findings, offering a non-invasive and cost-effective approach to predicting malignancy.[6,8] The high sensitivity of IOTA SR (up to 93%) makes it a valuable tool in detecting malignant masses, especially in high-risk populations. However, its lower specificity means that some benign masses may be misclassified as malignant, and inconclusive cases can complicate decision-making.[8]

The IOTA ADNEX model is the most comprehensive of the three, incorporating not only ultrasound features but also CA-125 levels, age, and other clinical factors to stratify ovarian masses into multiple risk categories, including benign, borderline, early-stage invasive, advanced-stage invasive, and metastatic cancers.[12] This multifactorial approach provides higher diagnostic accuracy, particularly in distinguishing between benign and malignant lesions.[3,4] Studies have demonstrated that IOTA ADNEX offers superior AUC values (~0.94), making it the most reliable tool for preoperative risk assessment. However, the complexity of the ADNEX model and the need for trained sonographers and advanced imaging may limit its application in settings with fewer resources or less specialized expertise.[13,14]

Furthermore, recent studies have highlighted the IOTA models' ability to maintain high diagnostic performance even when used by non-expert examiners or in low-resource settings. This feature significantly expands the applicability of the IOTA Simple Rules and IOTA ADNEX by reducing dependence on highly specialized training.[15] However, challenges remain in ensuring that these models are used appropriately across diverse clinical environments, where the skill level of clinicians and availability of resources may vary.

CONCLUSION

In conclusion, RMI, IOTA Simple Rules, and IOTA ADNEX all make valuable contributions to the diagnosis of ovarian malignancy, with each model demonstrating its own strengths and limitations. RMI remains a widely used and straightforward tool, but its lower sensitivity limits its effectiveness, particularly in the early stages of cancer. IOTA Simple Rules is an effective tool, particularly due to its high sensitivity,

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though it faces challenges with lower specificity and in cases that are inconclusive. On the other hand, the IOTA ADNEX model, while the most complex, provides the highest diagnostic accuracy, making it an ideal choice for stratifying ovarian masses into specific risk categories. However, the complexity of ADNEX limits its use in some clinical settings where expertise may be limited.

The choice of scoring system should depend on the clinical setting, available resources, and the healthcare team's expertise. For high-risk patients or those with complex cases, the IOTA ADNEX model provides superior performance and should be prioritized when available. For more general practice, IOTA Simple Rules and RMI offer simpler, more accessible alternatives, though IOTA SR may provide better sensitivity and performance in detecting malignancy.

ETHICAL APPROVAL

No ethical approval.

CONFLICTS OF INTEREST

The author declares no conflict of interest.

FUNDING

No specific funding has been provided for this article.

AUTHOR CONTRIBUTIONS

The author conducts research based on previously published scientific articles.

ACKNOWLEDGMENT

The writing of this article was supported by the Department of Obstetrics and Gynecology, Faculty of Medicine, Udayana University.

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