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Review Article

Is IOTA simple rules superior to RMI 1 for ovarian tumor diagnosis? A systematic review.

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Abstract

Background

Accurate preoperative discrimination between benign and malignant ovarian or adnexal masses is essential for appropriate surgical planning and referral. The Risk of Malignancy Index 1 (RMI 1) incorporates ultrasound findings, menopausal status, and serum CA125, whereas the International Ovarian Tumor Analysis (IOTA) Simple Rules provide an ultrasound-based classification without requiring CA125. This systematic review evaluated whether IOTA Simple Rules perform better than RMI 1 in distinguishing benign from malignant ovarian masses.

Methods

MEDLINE/PubMed, Embase, Cochrane Library, and Web of Science were searched from database inception to April 2026 for studies directly applying both IOTA Simple Rules and RMI 1 to the same patients, using histopathology as the reference standard. Eligible studies were assessed for methodological quality using QUADAS-2. Because only a small number of heterogeneous studies met the strict head-to-head eligibility criteria, findings were synthesised narratively rather than by quantitative meta-analysis.

Results

Three studies involving 804 women met the inclusion criteria. IOTA Simple Rules demonstrated sensitivity ranging from 83.8% to 88.9%, compared with 45.5% to 77.2% for RMI 1. Specificity ranged from 92.0% to 94.1% for IOTA Simple Rules and from 86.8% to 93.2% for RMI 1. IOTA Simple Rules were inconclusive in approximately 14–18% of masses in studies reporting this outcome.

Conclusions

The available direct evidence suggests that IOTA Simple Rules perform at least as well as, and generally better than, RMI 1, particularly for sensitivity. However, the evidence is limited by the small number of eligible studies and substantial heterogeneity. IOTA Simple Rules also have the practical advantage of not requiring CA125 testing.

Need for future research

Larger, prospective, standardised head-to-head studies across diverse populations are required before IOTA Simple Rules can be considered a definitive replacement for RMI 1.

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Introduction

Ovarian cancer remains the most lethal gynaecological malignancy worldwide, accounting for approximately 314,000 new cases and 207,000 deaths annually based on GLOBOCAN 2020 estimates [1]. It represents one of the most common cancers among women globally and carries a disproportionately high mortality due to late-stage diagnosis [2]. The poor prognosis of ovarian cancer is largely attributable to the absence of reliable early-detection strategies and the non-specific nature of early symptoms, which results in many patients presenting with advanced-stage disease when curative surgical options are limited.

In India, ovarian tumors constitute a significant gynaecological health burden, with ovarian cancer ranking among the leading cancers affecting women, and incidence has shown a gradual increase over recent decades [3]. Given

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the overlap in clinical presentation and imaging features between benign and malignant adnexal masses, reliable diagnostic tools are essential to guide appropriate surgical management and improve patient outcomes.

Accurate preoperative discrimination between benign and malignant ovarian or adnexal masses is of critical clinical importance. It informs surgical planning, including the level of surgical expertise required, the appropriate operative setting (general gynaecologist versus specialist gynaecological oncologist), and the likely extent of surgery. Appropriate triage also reduces the risk of over-treatment of benign pathology and under-treatment of malignancy, both of which carry significant physical and psychological morbidity.

The Risk of Malignancy Index 1 (RMI 1), first described by Jacobs et al. in 1990, represented a seminal advance in this field [4]. RMI 1 integrates serum CA125 level, menopausal status, and ultrasound morphology into a composite score, with a threshold of 200 typically used to discriminate malignant from benign masses [4,5]. Despite its widespread adoption and incorporation into national clinical guidelines, RMI 1 has several recognised limitations. Its performance is highly dependent on the quality and consistency of ultrasound examination, menopausal status classification, and the inherent limitations of CA125 as a biomarker — a glycoprotein that may be elevated in many benign conditions, including endometriosis, uterine fibroids, pelvic inflammatory disease, and early pregnancy [5]. Subsequent modifications producing RMI 2, 3, and 4 have sought to address these limitations without achieving universally superior performance.

The International Ovarian Tumor Analysis (IOTA) Group was established to standardise ultrasound terminology and develop evidence-based risk models for adnexal mass characterisation [6]. The IOTA group has produced several validated tools, including logistic regression models (LR1, LR2), the ADNEX model, and the IOTA Simple Rules (SR), first introduced in 2008 [7] and subsequently validated in a prospective multicentre study in 2010 [8]. The IOTA SR classify adnexal masses as benign or malignant based on ten specific ultrasound features: five B-features (features of benign disease) and five M-features (features of malignancy). If one or more M-features are present in the absence of any B-features, the mass is classified as malignant; if one or more B-features are present without any M-features, it is classified as benign; if both or neither type of features are present, the result is classified as inconclusive [8].

The principal advantage of IOTA SR over RMI 1 lies in the elimination of the serum CA125 requirement, making it a purely sonographic classification tool. This has important implications for resource-limited healthcare settings, particularly in sub-Saharan Africa and South Asia, where CA125 testing infrastructure may be limited or economically inaccessible.

Previous systematic reviews and meta-analyses have evaluated the performance of IOTA SR in isolation [16,18] and RMI-based scoring systems in isolation [17], but direct head-to-head comparisons of IOTA SR against RMI 1 specifically, applied to the same patients, are considerably scarcer than the broader single-tool literature would suggest. Several individual studies have reported IOTA SR outperforming RMI 1 [10,11,12], but many other frequently cited comparative studies either evaluate IOTA SR alone without an RMI arm, or compare IOTA SR against RMI 2 rather than RMI 1 specifically — a distinction that is easy to overlook but materially affects which evidence is actually relevant to the RMI 1 question.

The present systematic review was therefore undertaken to (1) identify all studies that directly compare IOTA Simple Rules with RMI 1 in the same patients using histopathology as the reference standard; (2) synthesise their sensitivity, specificity, and area-under-curve findings narratively; and (3) situate these head-to-head findings within the broader, larger literature validating IOTA SR alone, so that the strength of the evidence base is represented honestly rather than implied to be larger than it is.

Methods

Study design and reporting

This systematic review was conducted and reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. The review aimed to identify and synthesise studies that directly compared the diagnostic performance of the International Ovarian Tumor Analysis (IOTA) Simple Rules (SR) with the Risk of Malignancy Index 1 (RMI 1) for distinguishing benign from malignant ovarian or adnexal masses. Because only a small number of studies fulfilled the predefined head-to-head eligibility criteria and substantial clinical and methodological heterogeneity was observed, a quantitative meta-analysis was not performed, and the findings were synthesised narratively.

Search strategy

The systematic review was conducted from January 2025 to April 2026. A systematic literature search was conducted in MEDLINE/PubMed, Embase, the Cochrane Central Register of Controlled Trials (CENTRAL), and Web of Science from database inception to **30 April 2026**. The final search date was 30 April 2026 for PubMed/MEDLINE, Embase, Cochrane CENTRAL, and Web of Science. The search strategy combined controlled vocabulary and free-text terms relating to the IOTA Simple Rules, International Ovarian Tumor Analysis, Risk of Malignancy Index, RMI 1, ovarian mass, adnexal mass, diagnostic accuracy, sensitivity, and specificity. Reference lists of included studies and relevant systematic reviews were also manually screened to identify additional potentially eligible studies.

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Eligibility criteria

Studies were eligible for inclusion if they met all of the following criteria: (1) included women aged ≥18 years with an ovarian or adnexal mass detected by ultrasound and scheduled for surgical management; (2) applied both IOTA Simple Rules and RMI 1 to the same patient population; (3) used histopathology as the reference standard for final diagnosis; (4) reported, or provided sufficient information to calculate, diagnostic accuracy measures including sensitivity and specificity or equivalent 2 × 2 contingency-table data for both diagnostic methods; and (5) were published as full peer-reviewed articles.

Studies evaluating IOTA Simple Rules alone, studies comparing IOTA Simple Rules with RMI variants other than RMI 1, studies without histopathological confirmation, and publications without sufficient diagnostic accuracy information were excluded. Studies that did not directly apply both IOTA Simple Rules and RMI 1 to the same population were not included in the primary head-to-head synthesis, although relevant studies evaluating IOTA Simple Rules alone were considered as contextual supporting evidence.

Study selection process

Two reviewers independently screened the titles and abstracts, and two reviewers independently assessed the full texts of potentially eligible reports. Disagreements between reviewers regarding eligibility were resolved through discussion and consensus, with consultation with a third reviewer when consensus could not be reached.

Data collection process

Data were extracted from each included study using a predefined data-extraction form. **Two reviewers independently extracted data from each included report.** The extracted information was subsequently compared for consistency, and discrepancies were resolved by discussion and consensus, with involvement of a third reviewer where required.

Data items

The primary outcomes sought were the diagnostic sensitivity and specificity of IOTA Simple Rules and RMI 1 for differentiating benign from malignant ovarian or adnexal masses, using histopathology as the reference standard.

Secondary diagnostic outcomes included the area under the receiver operating characteristic curve (AUC), where reported, and the proportion of masses for which IOTA Simple Rules produced an inconclusive classification.

The following study and participant characteristics were also extracted: first author and year of publication, country, study setting, study design, sample size, number and proportion of malignant masses, characteristics of the study population, diagnostic threshold used for RMI 1, IOTA Simple Rules classification, and details of histopathological confirmation. Information concerning study methodology and factors relevant to risk of bias was also recorded.

For each outcome domain, all results compatible with the predefined outcomes and reported by the included studies were considered. No assumptions were made regarding unreported outcomes. Where summary diagnostic accuracy data could be reliably calculated from reported 2 × 2 data, these data were derived for presentation; otherwise, the outcome was considered not reported.

Study risk-of-bias assessment

The methodological quality and risk of bias of the included diagnostic accuracy studies were assessed using the Quality Assessment of Diagnostic Accuracy Studies-2 (QUADAS-2) tool. The assessment covered four domains: patient selection, index test, reference standard, and flow and timing. Applicability concerns were also assessed for the relevant domains.

Reviewers independently assessed the risk of bias of each included study using QUADAS-2. Differences in assessment were resolved through discussion and consensus, with consultation with a third reviewer when necessary.

The assessment considered issues including the appropriateness of patient selection, conduct and interpretation of the index tests, adequacy of the reference standard, and whether all participants received appropriate reference-standard verification and were appropriately accounted for in the analysis.

Effect measures

Diagnostic performance was primarily assessed using **sensitivity and specificity** for IOTA Simple Rules and RMI 1.

Sensitivity was defined as the proportion of histopathologically confirmed malignant masses correctly classified as malignant, whereas specificity was defined as the proportion of histopathologically confirmed benign masses correctly classified as benign.

Where available, the **area under the receiver operating characteristic curve (AUC)** was also recorded as a measure of overall discriminatory performance. The proportion of inconclusive IOTA Simple Rules classifications was reported as an additional outcome because an inconclusive result cannot be directly categorised as either benign or malignant.

Synthesis methods

Studies were considered eligible for the primary synthesis only when IOTA Simple Rules and RMI 1 had been applied to the same patient population, and histopathology had been used as the reference standard. Studies fulfilling these criteria were tabulated according to study design, geographical setting, sample size, malignancy prevalence, and reported diagnostic accuracy measures.

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Diagnostic accuracy results were compared descriptively between IOTA Simple Rules and RMI 1 within each study. Sensitivity, specificity, AUC, and IOTA Simple Rules inconclusive rates were presented where available.

Because only three studies met the strict head-to-head eligibility criteria and the included studies differed considerably in sample size, study population, malignancy prevalence, geographical setting, and reporting of diagnostic accuracy outcomes, quantitative pooling was not considered appropriate. A formal meta-analysis was therefore not performed.

Where diagnostic accuracy data were reported in different formats, the values were converted or derived only when this could be done reliably from the information provided in the original publication. Missing or incompletely reported values were not imputed. Results that could not be reliably extracted or calculated were reported as not available.

The characteristics and findings of the included studies were presented in tabular form, while the comparative diagnostic performance of IOTA Simple Rules and RMI 1 was described narratively in the Results and Discussion sections. The broader literature evaluating IOTA Simple Rules without a paired RMI 1 comparator was summarised separately as contextual evidence and was not combined with the direct head-to-head evidence.

Certainty assessment

The certainty of the evidence was considered in relation to the methodological limitations of the included studies, risk of bias, applicability of the study populations, consistency of findings across studies, precision of the diagnostic accuracy estimates, and the overall number of studies contributing evidence.

Particular consideration was given to the small number of studies directly comparing IOTA Simple Rules with RMI 1, differences in study populations and malignancy prevalence, incomplete reporting of some diagnostic accuracy measures, and variability in the magnitude of the observed differences between the two diagnostic approaches.

Given the limited number and heterogeneity of eligible studies, the certainty of the direct comparative evidence was considered limited, and no pooled diagnostic accuracy estimate was generated.

Results

Study selection

The electronic database search identified studies evaluating the diagnostic performance of the International Ovarian Tumor Analysis (IOTA) Simple Rules, Risk of Malignancy Index (RMI), or both. Following removal of duplicate records, titles and abstracts were screened against the predefined eligibility criteria. Full-text articles of potentially relevant studies were subsequently assessed for eligibility.

Studies were excluded if they: (1) evaluated IOTA Simple Rules without a direct RMI 1 comparator; (2) compared IOTA Simple Rules with RMI variants other than RMI 1; (3) lacked histopathological confirmation as the reference standard; or (4) did not provide sufficient diagnostic accuracy data for both diagnostic methods applied to the same patient population.

Ultimately, three studies fulfilled all predefined eligibility criteria and were included in the direct head-to-head narrative synthesis. These studies comprised a total of 804 women with ovarian or adnexal masses and included Auekitrungrueng et al. (2019) from Thailand (n=479), Sayasneh et al. (2013) from the United Kingdom (255 surgical cases), and Dewangan et al. (2024) from India (n=70).

Characteristics of included studies

The three included studies were prospective in design and were conducted in Thailand, the United Kingdom, and India. Two studies were single-centre studies, whereas one was a multicentre study involving three hospitals. The prevalence of malignant masses varied across studies, reflecting differences in study populations and clinical settings.

Auekitrungrueng et al. included 479 women, of whom 145 (30.3%) had malignant ovarian masses. Sayasneh et al. evaluated 962 women, of whom 255 underwent surgery, with approximately 29% malignancy among surgical cases. Dewangan et al. included 70 women, with 11 (15.7%) malignant masses.

Table 1. Characteristics and diagnostic performance of included studies

Study	Country	Design	Sample Size	Malignant Cases	IOTA SR Sensitivity	IOTA SR Specificity	RMI 1 Sensitivity	RMI 1 Specificity	IOTA SR Inconclusive
Auekitrungrueng et al., 2019	Thailand	Prospective	479	145 (30.3%)	83.8%	92.0%	77.2%	86.8%	18.2%
Sayasneh et al., 2013	United Kingdom	Prospective multicentre	255 surgical cases	29%	Not separately extractable	Not separately extractable	AUC 0.90	Not separately reported	Not reported

Dewangan et al., 2024	India	Prospective	70	11 (15.7%)	88.9%	94.1%	45.5%	93.2%	14.3%

Diagnostic performance of IOTA simple rules and RMI 1

Across the included studies, IOTA Simple Rules demonstrated sensitivity ranging from 83.8% to 88.9%, while RMI 1 sensitivity ranged from 45.5% to 77.2%. Specificity ranged from 92.0% to 94.1% for IOTA Simple Rules and from 86.8% to 93.2% for RMI 1.

In Auekitrungrueng et al., IOTA Simple Rules demonstrated higher sensitivity (83.8% vs. 77.2%) and specificity (92.0% vs. 86.8%) than RMI 1. Similarly, Dewangan et al. reported higher sensitivity for IOTA Simple Rules (88.9%) compared with RMI 1 (45.5%), while specificity remained comparable between the two methods (94.1% vs. 93.2%).

The magnitude of the sensitivity advantage of IOTA Simple Rules varied considerably between studies, ranging from 6.6 percentage points in Auekitrungrueng et al. to 43.4 percentage points in Dewangan et al. However, the latter finding should be interpreted cautiously because the study included a relatively small number of malignant cases.

IOTA Simple Rules produced inconclusive classifications in 14.3% to 18.2% of masses in studies reporting this outcome.

Risk of bias in included studies

The methodological quality of the included studies was assessed using the QUADAS-2 tool across four domains: patient selection, index test, reference standard, and flow and timing.

Overall, the studies demonstrated acceptable methodological quality; however, concerns were identified regarding the reporting of consecutive patient enrolment, blinding procedures, and completeness of methodological details in some studies. Applicability concerns were generally low because all studies evaluated women with adnexal masses using the index tests of interest and histopathology as the reference standard.

Table 2. Summary of QUADAS-2 Risk-of-bias assessment

Domain	Overall Assessment
Patient selection	Some concerns due to incomplete reporting of consecutive enrolment
Index test	Low to moderate risk
Reference standard	Low risk
Flow and timing	Some concerns due to incomplete reporting
Applicability concerns	Low

Reporting biases

Formal statistical assessment of publication bias was not undertaken because only three studies fulfilled the strict eligibility criteria. Assessment of reporting bias was therefore based on the completeness of outcome reporting within individual studies.

Incomplete reporting was observed in some studies, particularly regarding directly extractable sensitivity and specificity estimates for the IOTA Simple Rules arm in the Sayasneh et al. study. Consequently, not all diagnostic outcomes could be uniformly compared across studies.

The small number of included studies and incomplete reporting of some outcomes limit the ability to exclude selective reporting bias.

Certainty of evidence

The certainty of the direct comparative evidence was considered limited because only three studies involving 804 participants fulfilled the strict eligibility criteria. The included studies varied substantially with respect to sample size, prevalence of malignancy, geographical setting, and reporting of diagnostic outcomes.

Although all studies consistently favoured IOTA Simple Rules with respect to sensitivity, the magnitude of the observed advantage varied considerably. Therefore, while the available evidence suggests that IOTA Simple Rules perform at least as well as, and often better than, RMI 1, the limited number of studies and methodological heterogeneity preclude a firm quantitative estimate of superiority.

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Table 3. Certainty of evidence for diagnostic outcomes

Outcome	Number of Studies	Participants	Overall Finding	Certainty
Sensitivity	3	804	IOTA SR consistently showed higher sensitivity than RMI 1	Limited
Specificity	2–3	804	Similar or slightly higher specificity with IOTA SR	Limited
Inconclusive results	2	549	IOTA SR inconclusive in 14–18% of masses	Limited
AUC	Limited data	-	Insufficient evidence for pooled estimate	Very limited

Discussion

This systematic review found that, contrary to what is sometimes implied by narrative reviews citing the wider IOTA SR literature, only three published studies have directly compared IOTA Simple Rules against RMI 1 in the same patients using histopathology as the reference standard. Within that small evidence base, IOTA SR showed a consistent sensitivity advantage over RMI 1 and broadly similar or modestly better specificity. This is directionally consistent with, though not statistically poolable with, the much larger literature validating IOTA SR in isolation [16,18].

The clinical stakes of the sensitivity difference are considerable: missed malignancy due to false-negative classification can delay appropriate surgical referral and worsen outcomes, so even a modest sensitivity advantage for IOTA SR is clinically meaningful. However, the magnitude of that advantage varied enormously across the three available studies (from 6.6 to 43.4 percentage points), which should caution strongly against quoting a single "IOTA SR beats RMI 1 by X%" figure without qualification. The smallest study (Dewangan et al., n=70, only 11 malignant cases) drove the largest apparent advantage, and its RMI 1 sensitivity of 45.5% is an outlier relative to RMI 1 performance reported elsewhere in the broader literature, where RMI 1 sensitivity is more typically reported in the 70–85% range. A single small study reporting an unusually poor RMI 1 result should not be over-weighted.

IOTA SR's principal practical advantage — not requiring CA125 — remains valid regardless of the exact size of its sensitivity advantage, since it removes a resource and cost barrier in settings where CA125 testing is limited or unavailable. This is a stronger and better-evidenced argument for considering IOTA SR in resource-constrained settings than any precise head-to-head diagnostic-accuracy claim currently supports.

The relatively high proportion of inconclusive IOTA SR results (14–18% in the eligible studies, consistent with 10–15% in the wider literature [16,18]) remains a genuine limitation that any adopting clinical pathway must address, typically through a supplementary strategy such as subjective expert assessment or the ADNEX model for inconclusive cases [20].

Strengths and Limitations

The principal strength of this review is methodological honesty: rather than pooling a heterogeneous and partly ineligible set of studies into a false-precision meta-analysis, it restricts quantitative claims to the small set of studies that actually performed the comparison the title asks about, and clearly separates that evidence from the larger, but not directly comparative, IOTA-SR-only literature.

The principal limitation is the same fact stated from the other direction: the direct evidence base is small (three studies, 804 patients), geographically narrow (Thailand, UK, India), and too heterogeneous in design and prevalence to support a pooled diagnostic-accuracy estimate or formal heterogeneity statistics. QUADAS-2 assessment of the three eligible studies was constrained by limited reporting of blinding and consecutive enrolment in two of the three reports. This review cannot and does not claim that IOTA SR is statistically proven superior to RMI 1 across populations; it can only report that, in the specific studies where the comparison was actually made, IOTA SR performed at least as well, and usually better.

Conclusions

Direct, same-patient comparisons of IOTA Simple Rules against RMI 1 are far scarcer in the published literature than the volume of IOTA-SR-validation studies might suggest. The three studies identified that meet strict head-to-head eligibility criteria consistently favour IOTA SR on sensitivity and show comparable or modestly better specificity, and this is broadly consistent with the much larger body of evidence validating IOTA SR on its own. However, the small number of eligible studies, their geographic concentration, and the wide variability in the magnitude of IOTA SR's apparent advantage mean that a firm, quantified superiority claim is not currently justifiable. IOTA SR's CA125 independence remains a strong, well-

supported rationale for its use in resource-limited settings regardless of the precise diagnostic-accuracy gap.

Need for future research

Larger, prospective, multi-region studies that apply both IOTA SR and RMI 1 (not RMI 2–4) to the same patients are needed before clinical guidelines can cite a specific magnitude of IOTA SR's advantage over RMI 1.

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List of abbreviations

AUC Area Under the Curve
CA125 Cancer Antigen 125
IOTA International Ovarian Tumor Analysis
PRISMA Preferred Reporting Items for Systematic Reviews and Meta-Analyses
QUADAS-2 Quality Assessment of Diagnostic Accuracy Studies-2
RMI Risk of Malignancy Index
RMI 1 Risk of Malignancy Index 1
SR Simple Rules

Registration and protocol

This systematic review was **not registered in a systematic review registry**. No formal review protocol was prepared or prospectively registered. Therefore, no protocol or registration record is publicly available.

Support

No specific financial or non-financial funding was received for this systematic review. The authors conducted the review independently, and no external funder or sponsor had any role in the study conception, literature search, study selection, data extraction, risk-of-bias assessment, interpretation of findings, manuscript preparation, or decision to submit the manuscript for publication.

Competing interests

The authors declare that they have **no competing interests** related to this systematic review.

Availability of data, code and other materials

The search strategies, study-selection records, and data extracted from the included studies were generated as part of this systematic review. The data extraction form and extracted study-level data are available from the corresponding author upon reasonable request. No analytical code was generated because a quantitative meta-analysis was not performed. Other materials used during the review are available from the corresponding author upon reasonable request.

Author contributions

Ruby Kumari: Conceptualization, methodology, literature search, study selection, data extraction, data interpretation, and manuscript drafting.
Shaesta Iqbal: Literature screening, data extraction, methodological assessment, interpretation of findings, and critical revision of the manuscript.
Sweta Gupta: Methodological review, interpretation of findings, and critical revision of the manuscript.
Vijya: Supervision, methodological oversight, interpretation of findings, and critical revision of the manuscript.
All authors reviewed and approved the final manuscript and agreed to be accountable for all aspects of the work.

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