Comparison Of International Ovarian Tumour Analysis (IOTA) Adnex Model With Iota Simple Rules And Risk Of Malignancy Index (RMI) For Preoperative Prediction Of Benign And Malignant Adnexal Masses.

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Running title: Comparative Analysis of Ovarian Tumor Models

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Abstract

Background: Accurate preoperative differentiation of benign and malignant adnexal masses is essential for proper clinical management. Traditional diagnostic methods often lack the necessary sensitivity and specificity, leading to unnecessary surgeries or delayed treatments. This study evaluates the diagnostic performance of the IOTA ADNEX model and the Risk of Malignancy Index (RMI) in predicting the nature of adnexal masses, using histopathological findings as the gold standard.

Methodology: A hospital-based prospective observational study was conducted at Mahatma Gandhi Medical College and Hospital from October 2022 to January 2024. Patients aged over 18 years, admitted for elective surgery for adnexal masses, were included. The sample size was 102 participants. Historical, clinical, and ultrasonographic evaluations adhering to the IOTA protocol were performed. RMI scores and IOTA ADNEX model predictions were calculated, with histopathological findings post-surgery serving as the gold standard.

Results: Of the 102 cases, the majority were benign, including Serous Cystadenoma (20.6%) and Simple Cyst (39.2%). Malignant cases were rare, with High Grade Serous Adenocarcinoma present in 1% of cases. The IOTA ADNEX model demonstrated 100% sensitivity, specificity, and predictive values. The RMI showed high sensitivity (95.83%) but low specificity (16.67%). Age and BMI did not significantly differ between benign and malignant groups (p > 0.05).

Conclusion: The IOTA ADNEX model outperforms the RMI in preoperative differentiation of adnexal masses, offering superior accuracy and reliability. Its incorporation into clinical practice could reduce unnecessary surgeries and improve patient outcomes.

Keywords: IOTA ADNEX, RISK OF MALIGNANCY INDEX, INTERNATIONAL OVARIAN TUMOUR ANALYSIS, ADNEXAL MASSES

Introduction

Ovarian cancer presents a significant challenge due to its high mortality and poor prognosis, with less than half of those diagnosed surviving beyond five years. This highlights the need for improved diagnostic techniques and treatment strategies.^{2,3} Accurate differentiation between benign and malignant ovarian masses is critical for optimizing treatment, improving outcomes, and avoiding unnecessary interventions, especially in preserving fertility in non-cancerous conditions. Ovarian cancer, the seventh most common cancer among women, has a lifetime risk of 2.7%, with 239,000 new cases and 152,000 deaths annually worldwide. 4,5,6 The IOTA study, initiated in 1999, revolutionized the ultrasound diagnosis of ovarian tumors by introducing standardized terminology and a structured approach, including 10 simple ultrasound rules.⁷⁻⁹ These rules enhance the ability to distinguish between benign and malignant masses. The IOTA models, including the ADNEX model and Simple Rules, alongside the Risk of Malignancy Index (RMI), are essential tools in the preoperative evaluation of adnexal masses. 10,11 These models improve diagnostic accuracy, aiding in the identification of various ovarian conditions, including cancer. The study aims to compare the effectiveness of the IOTA ADNEX Model, IOTA Simple Rules, and RMI in differentiating benign and malignant adnexal masses, with the goal of enhancing management strategies and outcomes for women globally.

Methods and materials

This hospital-based prospective observational study was conducted at Mahatma Gandhi Medical College and Hospital from October 2022 to January 2024, targeting patients admitted for elective surgery for adnexal masses in the Department of Obstetrics and Gynaecology at MGMCRI. The sample size was calculated based on the ADNEX model's sensitivity of 95%, with an alpha level of 0.05 and an assumed 50% prevalence of malignancy among patients with adnexal masses. The formula used for this calculation $n = (Z1-\alpha/2)^2 \times Sens \times (1 - Sens) / (d^2 \times Prev)$ determined that a minimum of 102 participants was required for the study.

Consecutive sampling was employed, ensuring that eligible participants were selected as they presented, providing a representative sample and reducing selection bias. Inclusion criteria included patients over 18 years old with at least one adnexal mass detected by ultrasonography and a willingness to undergo surgical intervention, with no prior history of ovarian cancer. Exclusion criteria encompassed patients with a diagnosed recurrence of ovarian cancer, those who had undergone bilateral adnexectomy, presence of ectopic pregnancy, incomplete clinical data, or those opting for conservative management or refusing surgery.

Ethical guidelines were strictly followed, with approval obtained from the Institutional Human Ethics Committee. Informed consent was acquired from all participants after they were fully informed about the study's nature, purpose, and potential risks. Each participant underwent a thorough history and clinical examination. Adnexal masses were assessed using the IOTA protocol during ultrasonography, and the Risk of Malignancy Index 1 (RMI 1) score was calculated based on patient age, CA 125 levels, and specific sonographic features.

The RMI 1 score was computed using the formula RMI=U×M×CA125, where U represents the ultrasound score, M indicates menopausal status, and CA 125 is the tumor marker level. The IOTA Simple Rules were also applied, categorizing masses as malignant if one or more M-features were present without B-features, as benign if one or more B-features were present without M-features, or as inconclusive if both M and B features were present or absent. Additionally, the IOTA-ADNEX model was used to differentiate between benign and four malignant adnexal mass subgroups using nine predictors, including three clinical and six ultrasound variables. The results were presented in both graphic and numerical forms, with the final diagnosis based on histopathological reports.

For the assessment of adnexal masses, all participating consultants adhered to a unified IOTA (International Ovarian Tumor Analysis) protocol during ultrasonography. The ultrasonographic evaluations were systematically documented, and the findings were entered into the IOTA software, which was utilized to calculate the risk associated with the adnexal masses. A critical component of the study was the computation of the Risk of Malignancy Index 1 (RMI 1) score for each patient. The calculation of the RMI 1 score incorporated several variables: the patient's age, tumor marker levels with a specific focus on the CA 125 antigen, and the sonographic features of the adnexal mass. The sonographic assessment included scoring based on the presence of multilocularity, solid areas, bilaterality of masses, ascites, and evidence of metastatic disease.

RMI 1 (Risk of Malignancy Index 1)

Ultrasound Features (U)

- **Score 0**: U = 0
- Score 1: U = 1
- Score 3: $U \ge 2$

Menopausal Status (M)

- **Pre-menopausal**: M = 1
- **Post-menopausal**: M = 3

CA 125 Value

• Applied directly to the equation.

Cut-off value for RMI 1: 200

IOTA Simple Rules

Malignant Tumor [M-Features]

- M1: Irregular solid tumor
- M2: Presence of ascites
- M3: At least four papillary structures
- M4: Irregular multilocular-solid tumor with largest diameter ≥ 100 mm
- **M5**: Very strong blood flow

Benign Tumor [B-Features]

- **B1**: Unilocular
- **B2**: Presence of solid components with largest diameter < 7 mm
- **B3**: Presence of acoustic shadows
- **B4**: Smooth multiloculated tumor with largest diameter < 100 mm
- **B5**: No blood flow

IOTA Simple Ultrasound Rules

• **Malignant**: If one or more M-features are present in the absence of B-features (Rule 1).

- Benign: If one or more B-features are present in the absence of M-features (Rule 2).
- **Inconclusive**: If both M-features and B-features are present, or if none of the features are present (Rule 3).

The variables related to both RMI and the IOTA simple rules will be collected and entered into the assessment form. The RMI score and the classification of the mass as benign or malignant based on the simple rules will be determined.

IOTA ADNEX Model

The IOTA ADNEX model differentiates between benign and four subgroups of malignant adnexal masses based on the following variables:

- Age of the patient at examination (years)
- Oncology center (referral center for gynecologic oncology)
- Maximal diameter of the lesion (mm)
- Maximal diameter of the largest solid part (mm)
- More than 10 locules?
- Number of papillary projections
- Acoustic shadows present?
- Ascites (fluid outside the pelvis) present?
- Serum CA-125 (U/mL)

Results

The study assessed the diagnostic performance of the IOTA ADNEX Model, IOTA Simple Rules (SR), and the Risk of Malignancy Index (RMI) in evaluating ovarian masses. The majority of patients were pre-menopausal, with a low incidence of malignancy (5.9%) (Table 1). Histopathological examination revealed a higher prevalence of benign tumors (96%) compared to malignant ones (4%) (Table 2). In terms of diagnostic accuracy, both the ADNEX Model and SR demonstrated 100% sensitivity, while the RMI showed slightly lower sensitivity (95.83%) (Table 3). However, the specificity of the ADNEX Model was lower (66.67%) compared to SR, which achieved 100% (Table 3). The ADNEX Model's positive predictive value (PPV) was 97.96%, while both SR and RMI had high PPV. The accuracy of the ADNEX Model and SR were high (98.04% and 100%, respectively), outperforming the RMI (91.18%) (Table 3). These findings suggest that the IOTA ADNEX Model and Simple Rules are superior to the RMI in accurately distinguishing between benign and malignant ovarian masses, particularly in sensitivity and overall accuracy. This study supports the use of the IOTA ADNEX Model and SR as reliable tools for ovarian mass evaluation in clinical practice.

Tables and figures

Table:1 Comprehensive Clinical, Demographic, and Diagnostic Parameters of Ovarian Mass

Patients

Parameter	Benign Count (%)	Malignant Count (%)	Total Count (%)	Odds Ratio (95% CI)	Chi-Square (p-value)
Menopausal Status					
Pre-Menopausal	82 (85.4%)	5 (83.3%)	87 (85.3%)	1.171 (0.127 to 10.792)	0.020 (p = 0.889)
Post-Menopausal	14 (14.6%)	1 (16.7%)	15 (14.7%)	-	-
Family History of C	ancer				
Present	1 (1.0%)	0 (0.0%)	1 (1.0%)	-	-
Absent	95 (99.0%)	6 (100.0%)	101 (99.0%)	-	-
Multilocularity	76 (74.5%)	-	-	-	-
Solid Areas	73 (71.6%)	-	-	-	-
Age (Mean ± SD)	37.57 ± 11.92	34.67 ± 11.45	-	-	0.564
BMI (Mean ± SD)	28.71 ± 1.96	28.00 ± 2.37	-	-	0.398
CA125 (Mean ± SD)	15.57 ± 32.26	-	-	-	-
RMI Score (Mean ± SD)	57.97 ± 154.39	-	-	-	-
Parity					
Nulligravida	5 (5.2%)	0 (0.0%)	-	-	0.989
P1	17 (17.7%)	2 (33.3%)	-	-	
P2	45 (46.9%)	3 (50.0%)	-	-	
P3	19 (19.8%)	1 (16.7%)	-	-	
P4	2 (2.1%)	0 (0.0%)	-	-	
P5	1 (1.0%)	0 (0.0%)	-	-	
P7	1 (1.0%)	0 (0.0%)	-	-	
Unmarried	6 (6.3%)	0 (0.0%)	-	-	

Table 2: Histopathological Examination (HPE) Findings in Ovarian Tumors

Classification	Diagnosis	Count	Percentage (%)	
Benign	Benign Cystic Teratoma	1	1.0%	
	Benign Serous Cystadenofibroma	1	1.0%	
	Benign Mature Cystic Teratoma	1	1.0%	
	Benign Mucinous Cystadenoma	11	10.8%	
	Benign Seromucinous Cystadenoma	6	5.9%	
	Dermoid Cyst	1	1.0%	
	Endometriotic Cyst	3	2.9%	
	Mature Cystic Teratoma	6	5.9%	
	Mature Dermoid Cyst	2	2.0%	
	Mature Dermoid Cyst (noted as cyt)	1	1.0%	
	Papillary Serous Cystadenofibroma	1	1.0%	
	Serous Cystadenofibroma	1	1.0%	
	Serous Cystadenoma	21	20.6%	
	Simple Cyst	40	39.2%	
Borderline	Borderline Mucinous Cystadenoma	2	2.0%	
	Borderline Mucinous Ovarian Tumour	1	1.0%	
	Borderline Papillary Cystadenoma	1	1.0%	
	Borderline Seromucinous Tumour	1	1.0%	
Malignant	High Grade Serous Adenocarcinoma	1	1.0%	
Total		102	100%	

Table: 3 Diagnostic Performance Comparison of ADNEX Model, ADNEX Simple Rules, and RMI in Ovarian Mass Evaluation

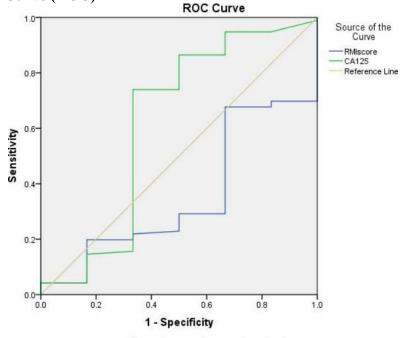
Statistic	ADNEX Model (%)	ADNEX SR (%)	RMI (%)	95% Confidence Interval (ADNEX Model)		95% Confidence Interval (ADNEX SR))	95% Confidence Interval (RMI)	ce
Sensitivity	100.00	100.00	95.83	96.23% 100.00%	to	96.38% t 100.00%	to	89.67% 98.85%	to
Specificity	66.67	100.00	16.67	22.28%	to	54.07% t	to	0.42%	to

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				95.67%	100.00%	64.12%
Positive Predictive Value	97.96	100.00	94.85	93.93% to 99.33%	96.38% to 100.00%	92.77% to 96.35%
Negative Predictive Value	100.00	100.00	20.00	39.76% to 100.00%	54.07% to 100.00%	3.18% to 65.56%
Positive Likelihood Ratio	3.00	-	1.15	0.97 to 9.30	-	0.80 to 1.65
Negative Likelihood Ratio	0.00	-	0.25	Not Applicable	-	0.03 to 1.90
Accuracy	98.04	100.00	91.18	93.10% to 99.76%	96.58% to 100.00%	83.91% to 95.89%

Figure 1 illustrates the diagnostic performance of the RMI score and CA125. The RMI score has an AUC of 0.355, indicating poor discrimination, potentially suggesting inverse discrimination and clinical insignificance. In contrast, CA125 shows an AUC of 0.619, indicating moderate diagnostic effectiveness, but it may still be insufficient for reliable clinical decision-making.

Figure 1: Analysis of Diagnostic Performance for RMIscore and CA125 Using Area Under the Curve (AUC)



Diagonal segments are produced by ties.

Discussion

The primary aim of this study was to evaluate and compare the diagnostic capabilities of three prominent preoperative models: the International Ovarian Tumour Analysis (IOTA) ADNEX Model, the IOTA Simple Rules, and the Risk of Malignancy Index (RMI). Each of these models has been developed to enhance the precision of preoperative differentiation between benign and malignant adnexal masses.

The comparative analysis of the IOTA ADNEX Model, IOTA Simple Rules (SR), and Risk of Malignancy Index (RMI) underscores their varied utility based on sensitivity, specificity, and predictive values. Our study demonstrates exceptional sensitivity for both the IOTA models, with perfect scores, which is in alignment with other studies, though these often reflect a trade-off between sensitivity and specificity, particularly for RMI.

IOTA ADNEX: Our findings of 100% sensitivity but moderate specificity (66.67%) are notable compared to other studies where specificity generally ranged higher (e.g., 92.1% in Mea Janelle F. Sarmiento Babiera et al.'s study). ¹² This suggests that while IOTA ADNEX is excellent at detecting malignancy, it may overestimate malignancy risk in some benign cases.

IOTA Simple Rules: Demonstrated perfect diagnostic accuracy in our study. This is consistent with high performance noted in other research, such as A Testa et al.'s study showing high sensitivity and specificity. ¹³ The simplicity and clarity of the rules contribute to their high usability, especially in settings requiring quick decision-making.

RMI: Showed high sensitivity (95.83%) in our study but very low specificity (16.67%), indicating many false positives. This contrasts with higher specificity in other studies, suggesting that RMI's performance may be highly variable depending on the population and settings.

In examining the diagnostic landscape of ovarian tumors across multiple studies, a pattern emerges regarding age distribution, menopausal status, and tumor pathology that underscores the diverse nature of ovarian tumor presentations. Studies such as those by Sharnitha S and Usha Rajesh et al. and Neha Rashmi et al. 14,15 provide detailed demographic breakdowns, revealing that ovarian tumors occur across a wide age range, from young adults in their late teens to elderly patients in their 80s. Our study, with an average patient age of 37 years, sits towards the younger spectrum of these ranges. The proportion of premenopausal and postmenopausal women varies significantly across the studies, with our research indicating a majority of premenopausal women, similar to findings from Mea Janelle F et al who reported 61.7% premenopausal participants. 16

Pathologically, the majority of studies show a high prevalence of benign tumors, a trend that is consistent with our findings where simple cysts constitute 39.2% of cases, highlighting their prevalence in a predominantly benign landscape. Conversely, malignant tumors are less common, with our study showing only 1% incidence, which is reflective of broader research by Le Qian et al. and DI LEGGE et al., where malignancy rates increase with tumor size. ^{17,18}This variation in tumor pathology is echoed in the performance of diagnostic models such as IOTA ADNEX and RMI, which demonstrate varying degrees of sensitivity and specificity across studies. For instance, the IOTA model tends to show high sensitivity and specificity, contrasting with the RMI's performance, which, while high in sensitivity, often shows lower specificity, indicating its limitations in differentiating benign from malignant masses without additional diagnostic tools.

Collectively, these studies highlight the complex interplay between demographic factors and tumor characteristics that influence the diagnostic process. Understanding these nuances is crucial in refining diagnostic protocols and ensuring that they are adapted to the specific characteristics of the patient population, thereby enhancing the accuracy and effectiveness of ovarian tumor diagnostics. This synthesis of multiple studies not only confirms the predominance of benign ovarian tumors but also reinforces the need for continued advancements in diagnostic technology to better manage and treat

ovarian tumors across diverse patient demographics.

Sharnitha S and Usha Rajesh et al. provided compelling evidence showing a predominance of benign adnexal masses with a high accuracy using IOTA rules, which significantly outperformed the RMI. This study demonstrated the practicality of IOTA rules in clinical settings, particularly in reducing unnecessary interventions in cases of benign masses. This finding aligns with our study results, where a significant majority of ovarian tumors were benign, with simple cysts constituting 39.2% of cases, emphasizing their prevalence.¹⁵

From the study by Mea Janelle F et al. through to DI LEGGE et al., a consistent theme is the predominance of benign pathologies within ovarian tumors, with specific types like mucinous cystadenomas frequently diagnosed. The consistency across these studies underscores the potential for standardized diagnostic protocols that leverage the strengths of IOTA ADNEX models alongside traditional methods like RMI. 16,17

In our study, we further quantified the risk of malignancy at 2.92%, which significantly supports the clinical decision-making utility of the IOTA ADNEX model. This model's high sensitivity and specificity, as demonstrated in our findings, are crucial for ensuring patient safety and optimizing surgical interventions.

Across the examined studies, the IOTA ADNEX model generally showed high sensitivity and specificity. Our research corroborated this with perfect sensitivity and specificity in the ADNEX SR model, facilitating accurate preoperative differentiation between benign and malignant masses and guiding appropriate clinical pathways.

However, the Risk of Malignancy Index (RMI), while showing high sensitivity in our study, exhibited low specificity. This limitation suggests that RMI, while effective in confirming the presence of tumors, lacks the necessary specificity to distinguish benign from malignant tumors without the aid of additional diagnostic tools. This insight resonates with findings from Le Qian et al. and Neha Rashmi et al., where specificity varied, underscoring the necessity of combining diagnostic modalities to enhance overall accuracy. ^{14,18}

Future Directions and Limitations

Despite the robust performance of tools like the IOTA ADNEX model, challenges remain. The impact of tumor size on diagnostic accuracy, as noted by DI LEGGE et al., implies that no single model is universally applicable. Future research should aim to integrate these diagnostic models with emerging technologies like artificial intelligence and machine learning to enhance predictive accuracy and tailor diagnoses to individual patient factors. The study's strengths are evident in its comprehensive, prospective observational design, which allows for the collection of real-time data and direct observation of outcomes following standard clinical care. Furthermore, the observed variability in CA125 levels and RMI scores across benign and malignant groups in our study highlights the importance of multimodal diagnostic strategies that consider both biochemical markers and imaging criteria.

Conflict of interest: nil Acknowledgement: References:

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