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Original Article

Comparative Diagnostic Accuracy of Risk of Malignancy Index Versus International Ovarian Tumor Analysis Model in Predicting Malignancy in Adnexal Masses: An Analytical Comparative Cross-Sectional Study

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ABSTRACT

Correct pre-surgical discrimination between benign and malignant adnexal lesions is critical for appropriate operative decision-making. Risk of Malignancy Index (RMI) and international ovarian tumor analysis (IOTA) models combine clinical and ultrasound findings to assess ovarian tumor malignancy risk. However, evidence comparing their diagnostic accuracy remains limited. **Objectives:** To determine the comparative diagnostic performance of standalone RMI versus an integrated RMI–IOTA approach for preoperative detection of malignancy in adnexal lesions. **Methods:** This analytical comparative cross-sectional study was conducted at the Pakistan Institute of Medical Sciences from 1 February 2023 to 30 August 2023. A total of 49 women with adnexal masses ≥5 cm scheduled for surgical intervention were enrolled using non-probability consecutive sampling. The women with measurable serum, complete ultrasonographic, and IOTA evaluation were included. Pregnant women, conservatively managed cases were excluded. All participants underwent transabdominal and/or transvaginal ultrasonography, serum CA-125 testing, and risk stratification using RMI and IOTA Analysis models. Histopathology served as the reference standard. **Results:** Only 1 (2.0%) had a borderline tumor, 13 (26.5%) malignant, and 35 (71.4%) benign. The RMI identified 10/13 malignant cases (sensitivity 76.9%) and 31/35 benign cases (specificity 88.5%). The ultrasound score showed sensitivity of 76.9% (10/13) and specificity of 74.2% (26/35). The IOTA classified 5/49 (10.2%) as malignant, 25/49 (51.0%) as benign, and 19/49 (38.7%) as inconclusive. **Conclusions:** RMI demonstrated more reliable diagnostic performance than the IOTA model for preoperative assessment of adnexal masses. So, the RMI can be continually used as an effective tool for guiding clinical decision-making and surgical planning.

INTRODUCTION

Adnexal masses (AM) are tumors that develop from the ovaries, fallopian tubes, and tissues around these organs. They can affect women of any age, and their etiology and frequency range change with age [1]. AM surgery is expected to be required in 10% of women at some point in their lives. At final pathology, the vast majority of women with AM had benign histology verified, accounting for about 80% of cases in women under 25 years of age [2]. Among malignant tumors and causes of mortality from cancer for women worldwide, ovarian cancer (OC) is the fifth leading cause of death among all gynecologic malignancies and ranks third in terms of mortality, only behind uterine and

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cervical cancer [3]. The latest global incidence rate for ovarian cancer is 6.7 per 100,000 women, based on age-standardized rates (ASR) that reflect 324,603 new cases worldwide in 2022 [4]. Most data reported from single-center studies on benign vs. malignant masses often show 70-90% benign [5-7]. Therefore, there is a 46% chance of surviving for five years overall, which is a very bad prognosis for OC [7]. Pelvic ultrasonography is the most popular method of investigation used to determine whether there are any pelvic masses [8]. The stage of the malignancy at the time of diagnosis also affects prognosis, with survival rates exceeding 70% for the early stages (I and II) and declining to 40-20% for the later stages (III and IV) [4]. The Risk of Malignancy Index (RMI) can be used to estimate the chance of malignancy in a pelvic mass discovered by ultrasonography [8]. This procedure is actually the result of menopause status, ultrasound results, and the tumor marker CA-125 (U/ml) blood level [9]. Pre-menopausal patients account for about 40% of benign tumor cases, while post-menopausal patients make up around 60% of benign tumor cases, according to estimates. Malignancy, bilaterality, ascites, solid regions, and locularity are all detected using ultrasonography [9]. International Ovarian Tumor Analysis (IOTA), which is likewise founded on ultrasound characteristics, is the other extensively used model for the evaluation of ovarian masses [10]. Although ultrasonography, serum CA-125, and composite indexes like the RMI are extensively used, the clinical distinction between benign and malignant adnexal mass before operation has remained a challenge to clinicians, especially in low-resource settings [10]. Although the IOTA model is highly sensitive, a significant fraction of the indeterminate outcomes is a limitation to its clinical use because it might result in unwarranted referrals and over-treatment [11]. The RMI, on the other hand, is less complex and more common but could be ineffective in particular histological subtypes like mucinous and borderline tumors [12].

The clear evidence of performance comparison of standalone usage of RMI and its combined or alternative usage in addition to IOTA in a regular clinical setting remains unclear. Thus, this research intended to critically compare the diagnostic accuracy of these models in order to enhance preoperative risk stratification and optimize surgical decision-making.

METHODS

The prospective study was carried out from 01 February 2023 to 30 August 2023 in the Pakistan Institute of Medical Sciences (PIMS). Ethical approval was obtained from the Institutional Review Board of the PIMS (Reference: F.3-2/2022(ERRB)/PIMS) on November 2nd 2022. All participants were informed about the study and gave written consent before enrollment. A non-probability consecutive sampling technique was used. Forty-nine women over 49 years old, who had adnexal masses over 5 cm in size and were to undergo surgery or have a biopsy, were recruited. No formal a priori sample-size calculation was performed. Participants were recruited consecutively during the predefined study period according to the eligibility criteria. The final sample comprised 49 women. The limited sample size is recognized as a methodological limitation and may have reduced the precision and statistical power of the diagnostic accuracy estimates. A 5 cm cutoff was selected in accordance with routine clinical practice for preoperative risk assessment of adnexal masses, where this threshold is commonly applied to guide surgical evaluation [13]. Women who were pregnant, not managed, and missing CA-125 or IOTA/RMI data, and poor follow-up were left out. All participants had the demographic and clinical variables, such as age, findings of ultrasound, serum levels of CA-125, and the final histopathology. All of the patients underwent transabdominal ultrasonography (3.5-MHz probe) and transvaginal ultrasonography (7.5-MHz transducer). The sonographic data, such as tumor laterality, ascites, solid components, and multilocularity, were noted to compute RMI and IOTA classification. RMI used an ultrasound score of 1 (≤1 suspicious feature) or 3 (≥2 features). Serum CA-125 levels >37 IU/mL were considered elevated. RMI was calculated as U × M × CA-125, where M is menopausal status; scores >200 suggested malignancy. The IOTA Simple Rules model was used for ultrasound-based classification of adnexal masses. The model incorporates five benign (B) features and five malignant (M) features. Lesions meeting only benign features were classified as benign, those meeting only malignant features as malignant, while lesions showing both benign and malignant features or neither feature were considered inconclusive. Lesions that were not determined were termed malignant. Surgical treatment either involved laparoscopy or laparotomy, and histopathological verification. The sonographers were blinded to CA-125 and risk score, whereas the histopathologists were blinded to imaging findings and RMI/IOTA findings. Diagnostic performance of RMI and IOTA Simple Rules was assessed against histopathology, including sensitivity, specificity, PPV, and NPV with 95% confidence intervals. IOTA-inconclusive cases were reported separately. Paired classifications were compared using McNemar's test where applicable.

The analysis of data was performed with the help of IBM SPSS 25.0. Descriptive statistics were used where the continuous variables are measured as mean ± standard deviation or median (interquartile range), and categorical variables are measured as frequency and percentage. Normality of continuous data was assessed using the

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Shapiro-Wilk test. For normally distributed variables, the independent samples t-test was used. Categorical variables were compared using the Chi-square test or Fisher's exact test where appropriate. Diagnostic accuracy measures, including sensitivity, specificity, positive predictive value, and negative predictive value, were calculated with 95% confidence intervals. A p-value ≤0.05 was considered statistically significant.

RESULTS

Out of 49 patients, 35 (71.4%) were benign, 13 (26.5%) malignant, and 1(2.0%)borderline based on histopathology. Age and disease status did not correlate significantly. A p-value of 0.0004 indicated statistical significance for the relationship between ultrasonography score and type of tumor. CA 125 levels were significantly higher in women with malignant tumors(p<0.001)(Table 1).

Table 1: Demographics and Baseline Clinical Information and Clinical Variables Between Benign and Malignant Groups

Parameters	Benign (n=35), n (%) / Mean ± SD	Malignant (n=13), n (%) / Mean ± SD	p-value
Age			
<30	09 (25.7%)	2 (15.3%)	0.554
30–44	11 (31.4%)	4 (30.7%)	
45–54	8 (22.8%)	6 (46.1%)	
>55	7 (20.0%)	1 (7.6%)	
Menopausal status			
Premenopausal	24 (68.5%)	04 (30.7%)	1.000
Postmenopausal	11 (31.5%)	03 (23.7%)	
RMI USG score			
1	27 (77.1%)	3 (23.0%)	0.004*
3	8 (22.8%)	10 (76.9%)	
CA-125 (U/ml)			
Mean	30	350	<0.001*
Median	24	280	
Clinical Variables Between Benign and Malignant Groups			
Age (years) (Mean ± SD)[a]	41.2 ± 11.5	45.8 ± 10.2	0.198
CA-125 (U/mL) (Median, IQR)[b]	24 (18–35)	280 (150–420)	<0.001*
Menopausal Status[c]			
Premenopausal	24 (68.5%)	8 (61.5%)	1.000
Postmenopausal	11 (31.5%)	5 (38.5%)	

The p-values were calculated using Fisher's exact test. *Indicates statistical significance at p ≤ 0.05. a = Independent samples t-test. b = Mann–Whitney U test. c = Fisher's exact test. *Indicates statistical significance at p ≤ 0.05

The RMI's sensitivity was 76.9% (47.87-96.72), its specificity was 88.5% (74.46-94.68), and its positive predictive values (PPV) and negative predictive values (NPV) were respectively 76.9% and 88.5%. These values are suggestive of the fairly good diagnostic capacity of RMI in differentiating malignant from benign adnexal masses with an RMI cutoff of 200 (Table 2).

Table 2: Diagnostic Score for Malignant and Benign Adnexal Masses

Parameters	Categories	Malignant (n=13), n (%)	Benign (n=35), n (%)	Sensitivity (%), (95 % CI)	Specificity (%), (95 % CI)	PPV (%)	NPV (%)
RMI	>200	10 (76.9%)	4 (11.4%)	76.9 (47.87–96.72)	88.5 (74.46–94.68)	76.9	88.5
	<200	3 (23.0%)	31 (88.5%)				
Menopausal Status	Postmenopausal	5 (38.4%)	14 (40.0%)	38.4(21.61–63.99)	60.0 (43.37–72.24)	28.4	72.0
	Premenopausal	8 (61.5%)	21 (60.0%)				
CA125	>35	10 (76.9%)	5 (14.2%)	10 (52.74–90.44)	85.7 (71.56–93.12)	67.4	85.7
	<35	3 (23.0%)	30 (85.7%)				
USG Score	1	10 (76.9%)	9 (25.7%)	76.9 (52.74–90.44)	74.2 (60.66–86.17)	46.9	88.2
	3	3 (23.0%)	26 (74.2%)				

Values are expressed in percent (95% confidence interval)

Amongst women with confirmed malignant tumors (n=13), almost 10 (77%) have an RMI value greater than 200, while only 4% (11%) of those having benign tumors reported an RMI value of greater than 200. Women in the premenopausal and postmenopausal groups reported almost similar proportions of benign and malignant disease. Even in the postmenopausal group, benign tumors had a higher incidence. Women with malignant masses had higher levels of CA125. There was no statistically significant relationship between RMI and disease state for mucinous tumors. The link between RMI and disease stage for serous tumors was statistically significant for other malignancies at p=0.003; it was very significant for serous tumors at p=0.003 (Table 3).

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Table 3: Frequency of Ovarian Cancers with Definite Histology

RMI	Benign, n (%)	Malignant, n (%)	Borderline, n (%)
Mucinous (n=18)			
RMI >200	4 (22.2%)	0	0
RMI<200	10 (55.5%)	3 (16.6%)	1 (5.5%)
p-value	0.651		
Serous (n=25)			
RMI<200	13 (52.0%)	1 (4%)	0
RMI >200	7 (28%)	4 (16%)	0
p-value	0.003*		
Other (n=6)			
RMI<200	1 (16.6%)	0	0
RMI >200	0	5 (83.3%)	0
p-value	0.003*		

*Statistical significance considered at p ≤0.05

Age distribution was normally distributed in both benign and malignant groups (p>0.05), thus met the assumption of the parametric test, and hence the t-test was used to analyze age. Conversely, the serum CA-125 levels showed strong non-normality in either category (p<0.001), indicating a skewed distribution (Table 4).

Table 4: Normality Assessment of Continuous Variables by Study Groups (Shapiro–Wilk Test)

Variables	Group	W Statistic	p-value
Age (years)	Benign	0.969	0.412
	Malignant	0.958	0.673
CA-125 (U/mL)	Benign	0.702	<0.001*
	Malignant	0.621	<0.001*

*Statistical significance considered at p ≤0.05

Out of a total of 49 cases, the RMI categorized 35 (71.5%) cases as low risk (score <200) and 14 (28.5%) as high risk (score ≥200). Among the low-risk group, 31 cases (88.5%) were confirmed as benign, and 3 cases (23.0% of malignant cases) were incorrectly classified, while all borderline tumors were included in this category. In contrast, within the high-risk group, 10 cases (76.9% of malignant cases) were correctly identified as malignant, whereas 4 cases (11.4% of benign cases) were falsely categorized as malignant. The IOTA model demonstrated a different classification pattern. It identified 5 cases (10.2%) as malignant, of which 2 (40.0%) were truly malignant, 2 (40.0%) were benign, and 1 (20.0%) was borderline. A total of 25 cases (51.0%) were classified as benign, among which 23 (92.0%) were correctly identified, while 1 (4.0%) malignant and 1 (4.0%) borderline case were misclassified. Remarkably, the IOTA model identified a significant number of cases, 19 (38.7%), as inconclusive. Among this indeterminate group, there were 7 cases (36.8%), 9 cases (47.3%), and 3 cases (15.7%), all of which were malignant, benign, and borderline, respectively (Table 5).

Table 5: Comparative accuracy of RMI and IOTA Simple Rules

Nature of the Tumor	Outcomes	n=49, n (%)	Malignant, n (%)	Benign, n (%)	Borderline, n (%)	p-value
Per RMI	RMI<200	35 (71.5%)	3 (23.0%)	32 (88.5%)	(100%)	<0.001*
	RMI >200	14 (28.5%)	10 (76.9%)	4 (11.4%)	-	
Per IOTA	Malignant	5 (10.2%)	2 (40.0%)	2 (40.0%)	1 (20.0%)	<0.001*
	Benign	25 (51.0%)	1 (4%)	23 (92.0%)	1 (4%)	
	Inconclusive	19 (38.7%)	7 (36.8%)	9 (47.3%)	3 (15.7%)	

*Statistical significance considered at p ≤0.05

DISCUSSION

The objective of this study was to compare the diagnostic capabilities of standalone RMI and an integrated RMI-IOTA approach in the preoperative diagnosis of malignancy in adnexal lesions. As a gold standard in the analysis, histopathology was employed. During the one-year-long study, 49 participants were admitted in sequence. Final histology showed that 13 adnexal masses and one tumor were borderline and malignant. Among 13 patients with malignant masses, only 3 had been treated with neoadjuvant chemotherapy, which does not allow for measuring a variation in diagnosis associated with the treatment. Furthermore, the relative merit of RMI is discussed but fails to critically investigate its loss of sensitivity in certain histologically defined subtypes like mucinous or borderline tumors, where CA-125 expressivity is low, and the imaging phenotypes may not appear in the typical way [15, 16] [14-16]. In this study, RMI's sensitivity was 76.9% (47.87-96.72), specificity was 88.5% (74.46-94.68), and its positive and negative predictive values were 76.9% and 88.5%, respectively. Comparing the RMI sensitivity of this study with that of Poonyakanok *et al.* it became less sensitive. This could be because of the increased proportion of benign and early-stage illnesses and the significant number of mucinous tumors. Secondly, the majority of the cases had transvaginal ultrasonography, which may have affected the sensitivity difference. The suggested care for tumors with low risk is expectant management or laparoscopic surgery performed by a gynecologist [17]. Women categorized as having an intermediate level of risk should undergo laparoscopic

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management performed by a surgeon with oncologic expertise within a dedicated cancer unit. In contrast, patients identified as high risk should be referred to a specialized oncology center, where a gynecological oncologist can undertake comprehensive surgical staging. In a recent study by Solanki *et al.* IOTA was determined to be more accurate for triage than the RCOG technique [18]. This study aimed to determine the risk of malignancy in women who have undergone a gynecological operation due to adnexal masses. Hence, the diagnostic efficacy of SPC was compared between the RMI and IOTA. Contrary to Thomas and Menon, findings of this study demonstrate that the RMI is much more accurate than the IOTA in clinical practice at differentiating malignant ovarian tumors [19]. In this study, the IOTA had an unusually high proportion of equivocal outcomes that undermined the test in terms of its accuracy in the diagnosis of patients. According to this study, almost a quarter of women would have been referred to a gynecologic oncology unit without a definite assessment of the tumor, who might have ended up with unnecessary psychological distress and long waiting times for patients needing a specialist referral. Since presuming malignancy will increase sensitivity but decrease specificity, this study classified indeterminate tumors as malignant, as had been done by Chacon *et al.* [20]. In the case of a mucinous tumor, RMI and disease status did not differ significantly. The RMI showed a significant and statistically significant relationship with disease status (p=0.003) in the case of serous tumors, which is also consistent with the literature as reported by Kaarthika and Kathiresan, [21].

This study has several limitations. First, the relatively small sample size (n=49), including only 13 malignant and one borderline tumor, limits statistical power and the precision of diagnostic accuracy estimates. The absence of a formal a priori sample-size calculation further limits the ability to establish whether the study was adequately powered to detect differences between RMI and IOTA Simple Rules. Second, the study was conducted at a single center over a limited study period, which may restrict the generalizability of the findings. Third, IOTA Simple Rules produced a relatively high proportion of inconclusive classifications, limiting direct comparison with RMI and highlighting the need for further assessment of indeterminate lesions. Fourth, the sensitivity of RMI was 76.9%, indicating that 3 of 13 malignant tumors were not identified at the selected cutoff; therefore, RMI should not be considered a definitive rule-out test when used alone. Finally, the limited number of malignant and borderline tumors prevented meaningful analysis according to histological subtype. Larger, multicenter prospective studies with adequately calculated sample sizes, standardized application of both models, and appropriate paired statistical comparisons are needed to provide more precise estimates of diagnostic performance and clarify the clinical management of IOTA-inconclusive lesions.

CONCLUSIONS

In this small single-center cohort, RMI demonstrated moderate sensitivity (76.9%) and good specificity (88.5%) for detecting malignant adnexal masses. However, 3 of 13 malignant tumors were missed by RMI, indicating that it should not be used as a sole rule-out test. IOTA Simple Rules resulted in a substantial proportion of inconclusive classifications (38.7%), limiting direct comparison between the two approaches. Therefore, the present findings do not establish superiority of RMI over IOTA. RMI may remain a practical risk-stratification tool because of its simplicity and accessibility, while IOTA-inconclusive lesions require further clinical, imaging, or specialist assessment.

Authors' Contribution

Conceptualization: NF, SA, F
Methodology: ZK, LK, SA, F
Formal analysis: ZK, SA, F
Writing and Drafting: MM, SA, F
Review and Editing: MM, NF, ZK, LK, SA, F

All authors approved the final manuscript and take responsibility for the integrity of the work

Conflict of Interest

All the authors declare no conflict of interest.

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