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Original Research Article

A prospective cross-sectional observational study to compare the predictive performance of four types of risk malignancy index and computed tomography and magnetic resonance imaging findings in the triage of adnexal masses at a tertiary care centre in Mumbai, India

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ABSTRACT

Background: Accurate pre-operative differentiation between benign and malignant adnexal masses is essential for appropriate referral and management.
Methods: A prospective cross-sectional observational study was conducted from August 2023 to July 2024 in the Department of Obstetrics and Gynaecology, Topiwala National Medical College and BYL Nair Charitable Hospital, Mumbai. Sixty women with adnexal masses were evaluated using clinical parameters, ultrasound, CA-125, and four types of risk of malignancy indices (RMI I-IV). Computed tomography and magnetic resonance imaging (CT/MRI) findings were compared wherever available. Histopathology served as the gold standard.
Results: Mean age 37.4±10.4 years. Of 60 cases, 45 (75%) benign, 15 (25%) malignant. RMI IV had highest diagnostic accuracy area under the curve (AUC=0.892). CT showed 100% sensitivity and 94.4% specificity.
Conclusions: RMI IV is the most reliable index for differentiating benign and malignant adnexal masses. CT provides additional diagnostic accuracy and is recommended for equivocal cases.

Keywords: Risk of malignancy index, CA-125, Adnexal mass, CT, MRI, Ovarian tumour

INTRODUCTION

Ovarian cancer represents one of the most challenging malignancies in gynaecologic oncology due to its asymptomatic onset and late presentation. Globally, it accounts for approximately 3% of all cancers in women, with more than 313,000 new cases and 207,000 deaths reported annually according to the world health organization's global cancer observatory.[1] In India, ovarian cancer ranks as the third most common malignancy among women after breast and cervical cancers, with an age-adjusted incidence rate of 7.2 per 100,000 women and rising trends in urban centres such as Mumbai and Delhi.[2]

Adnexal masses are among the most frequent presentations encountered in gynaecologic practice, encompassing a broad spectrum from benign functional cysts to malignant epithelial tumours. Differentiating benign from malignant masses preoperatively is critical for appropriate surgical planning, optimal referral to oncologic centres, and improved prognosis. Traditional diagnostic modalities such as ultrasonography and serum CA-125 levels have individually shown limitations in sensitivity and specificity, particularly in early-stage disease or premenopausal women where physiological variations in CA-125 can yield false-positive results.[3,7,8]

To overcome these limitations, Jacobs et al introduced the RMI in 1990, integrating ultrasound morphology,

menopausal status, and serum CA-125 levels into a composite score.[3] Subsequent modifications by Tingulstad et al (RMI II and III) and Yamamoto et al (RMI IV) refined weighting factors to enhance diagnostic accuracy.[4-6] These indices have since been widely validated across different populations, showing varying diagnostic thresholds depending on demographic and epidemiologic characteristics.[5,6,8]

Despite its broad utility, the diagnostic performance of RMI can differ considerably between populations, especially in developing countries where late presentation, limited access to imaging, and variation in tumour histotypes can alter predictive accuracy. Studies from India have demonstrated heterogeneity in RMI cut-off values, emphasizing the need for the contextual validation.[12,13]

Cross-sectional imaging modalities such as CT and MRI add complementary information regarding lesion architecture, solid components, and metastatic spread. Kinkel et al and Thomassin-Naggara et al have shown that combining morphological and functional imaging parameters substantially improves diagnostic confidence, particularly in indeterminate ultrasound cases.[10,11]

This prospective study was therefore designed to compare the predictive performance of four RMIs (I-IV) and correlate them with CT/MRI findings for the preoperative triage of adnexal masses at a tertiary-care centre in Mumbai, India. By analysing sensitivity, specificity, and predictive values of each index in both pre- and post-menopausal women, the study aims to identify the most reliable RMI for use in the Indian clinical setting and to assess the incremental value of CT/MRI in improving diagnostic precision.

METHODS

Study design and setting

This was a prospective, cross-sectional observational study conducted in the Department of Obstetrics and Gynaecology at Topiwala National Medical College and BYL Nair Charitable Hospital, Mumbai, India. The study period extended over one year, from August 2023 to July 2024. Ethical clearance was obtained from the institutional ethics committee prior to initiation, and written informed consent was obtained from all participants. The study adhered to the ethical standards of the Helsinki declaration.

Study population and eligibility criteria

A total of 60 women presenting with adnexal masses detected either incidentally on imaging or clinically during routine gynaecologic evaluation were enrolled. Inclusion criteria were: (i) women aged ≥18 years; (ii) adnexal mass identified by pelvic examination or ultrasonography; and (iii) patients scheduled for surgical management. Exclusion criteria included pregnancy, known cases of non-ovarian pelvic pathology (such as tubo-ovarian abscess), previous diagnosis of ovarian malignancy, and refusal to provide consent.

Demographic details including age, parity, menopausal status, presenting symptoms, and duration were recorded. Patients were classified as premenopausal or postmenopausal based on the absence of menstruation for ≥12 months. A detailed clinical examination was performed, including abdominal and bimanual pelvic assessment to document mass size, consistency, mobility, and tenderness.

Laboratory and imaging evaluation

All participants underwent serum CA-125 estimation using a chemiluminescent microparticle immunoassay (Abbott Architect i2000SR system). A value of >35 IU/mL was considered elevated, following established literature cut-offs.[3,7,8]

Transabdominal and transvaginal ultrasonography (USG) was performed using high-frequency probes (5-7.5 MHz) by experienced radiologists blinded to laboratory results. Sonographic parameters included unilocular or multilocular cystic structure, presence of solid areas, papillary projections, septations, bilaterality, and ascites. Each feature was scored as per the ultrasound component of the original Jacobs' RMI model.[3]

RMI I-IV were computed for each case using the following general formula:

RMI=U×M×CA-125

Where U represents the ultrasound score, M denotes menopausal status, and CA-125 is the serum concentration in IU/mL.

RMI I (Jacobs et al)

Ultrasound features (U): Multilocularity, solid areas, bilaterality, ascites, and intra-abdominal metastases.

U=0 (no abnormal feature), 1 (one abnormal feature), 3 (two or more abnormal features). M=1 for premenopausal, 3 for postmenopausal. Cut-off value: 200.[3]

RMI II (Tingulstad et al)

U=1 (one abnormal feature), 4 (two or more abnormal features). M=1 (premenopausal), 4 (postmenopausal), cut-off value: 200.[4]

RMI III (Tingulstad et al)

U and M as defined in RMI I (U=1 or 3; M=1 or 3), cut-off value: 200.[5]

RMI IV (Yamamoto et al)

Builds upon RMI I by incorporating maximum tumour diameter (D) as an additional variable. Formula: RMI IV=U×M×D×CA-125, where D represents maximum tumour size (in cm) measured by ultrasound. Cut-off value: 450.[6]

All four indices were computed for each patient, and diagnostic efficacy was evaluated against histopathological diagnosis as the reference standard. Thresholds of 200 for RMI I-III and 450 for RMI IV were used, as established in previous literature and validated in similar Indian studies.[5,6,8,12,13]

CT and MRI were performed in patients with indeterminate or suspicious ultrasound findings, or where further characterization was clinically indicated. CT scans were acquired on a 128-slice multidetector scanner with intravenous contrast enhancement. MRI studies were conducted using a 1.5 Tesla system, employing T1-weighted, T2-weighted, and diffusion-weighted sequences with gadolinium contrast where appropriate. Radiologic features such as solid components, septal thickness, peritoneal implants, and lymphadenopathy were evaluated. Findings were interpreted according to the criteria described by Kinkel et al and Thomassin-Naggara et al for benign and malignant ovarian lesions.[10,11]

Surgical and histopathological correlation

All patients underwent surgical exploration, and intraoperative findings were documented. Specimens were sent for histopathological examination (HPE), which served as the gold standard for final diagnosis. Tumours were categorized as benign, borderline, or malignant based on the 2020 WHO classification of ovarian neoplasms.

Data management and statistical analysis

All data were entered into Microsoft excel and analysed using IBM SPSS statistics, version 26.0 (IBM Corp., Armonk, NY, USA). Quantitative variables were expressed as mean±SD and compared using the student's t-test. Categorical variables were analysed using the Chi-square test or Fisher's exact test, as appropriate.

Diagnostic performance of each RMI and imaging modality was evaluated by calculating sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall accuracy. Receiver operating characteristic (ROC) curves were plotted, and the AUC was computed to assess discriminative ability.

The RMI version demonstrating the highest AUC and overall accuracy was considered the most reliable for clinical application. Subgroup analyses were performed for pre- and post-menopausal women to evaluate index performance across hormonal categories. A $p<0.05$ was considered statistically significant.

RESULTS

A total of 60 women with adnexal masses were evaluated during 1-year study period. All patients underwent detailed clinical, biochemical, ultrasonographic, and where indicated, cross-sectional imaging assessment, followed by surgical exploration and histopathological confirmation.

Demographic and clinical characteristics

The mean age of the study population was 37.4±10.4 years (range: 19-68 years). The Shapiro-Wilk p=0.125 suggests that the ages are likely normally distributed in this sample.

Table 1: Age distribution of the participants.

Age distribution (in years)		
Mean	**Standard deviation**	**Shapiro-Wilk p**
37.4	10.4	0.125

Among these, 83% (n=50) were premenopausal and 17% (n=10) postmenopausal. Malignant lesions significantly more common in postmenopausal women ($p<0.05$).

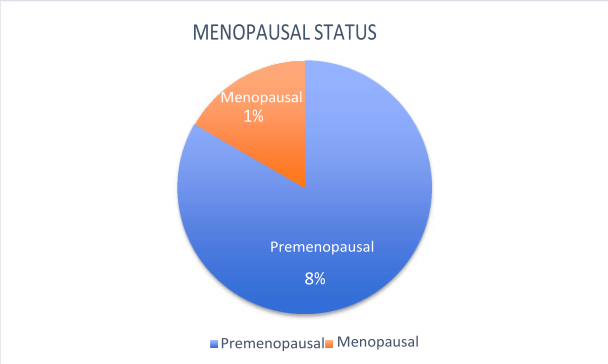

Figure 1: Menopausal status among the study participants.

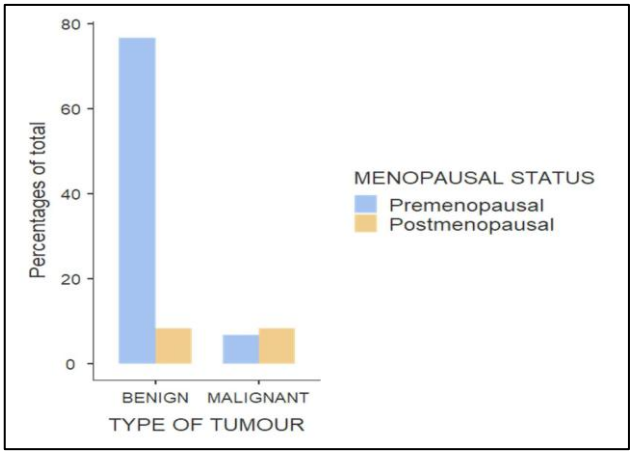

Figure 2: Distribution of study participants between benign and malignant groups based on menopausal status.

The mean age among malignant cases was 49.9±8.1 years, compared with 35.1±9.6 years in benign cases.

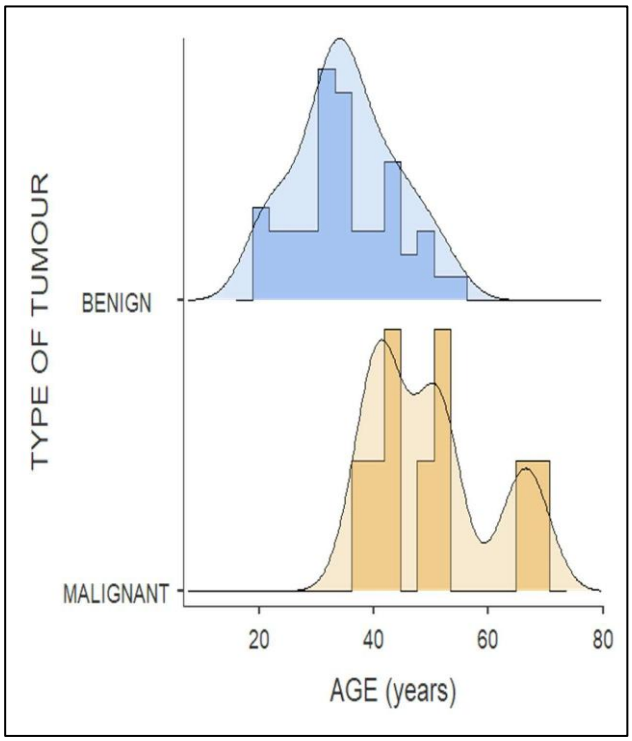

Figure 3: Histogram showing age distribution in benign and malignant groups.

The majority of patients (80%) presented with lower-abdominal pain or lump, while 15% reported menstrual irregularities, and 5% were incidentally detected on imaging.

Parity ranged from nulliparous to grand multiparous, with no significant correlation between parity and malignancy risk (p>0.05).

Mean tumour diameter on ultrasound was 8.2 cm (range: 3-22 cm), with malignant lesions showing greater mean size (11.4 cm) than benign ones (7.5 cm, p<0.05).

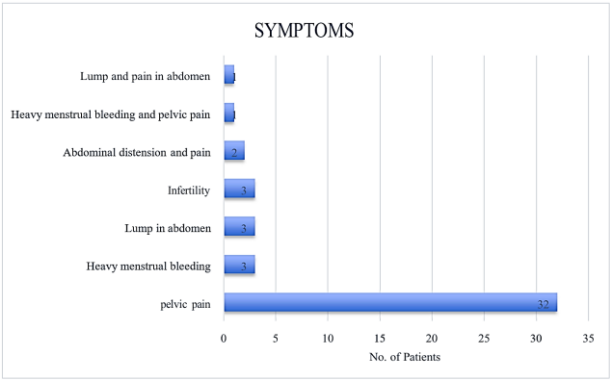

Figure 4: Symptoms among the study participants.

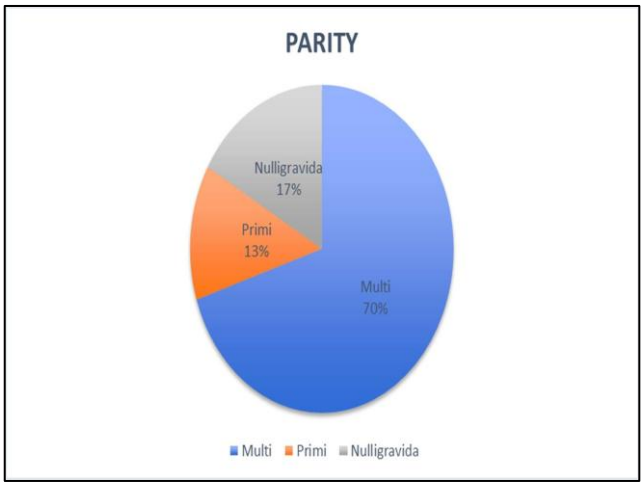

Figure 5: Parity status among the study participants.

Table 2: Association of size of tumour with the type of tumour.

Chi-square association			Type of tumour		
			Benign	Malignant	Total
Size of tumor	<7 cm	Observed	45	5	50
		% row	90.0	10.0	100
		% column	88.2	55.6	83.3
	>7 cm	Observed	6	4	10
		% row	60.0	40.0	100.0
		% column	11.8	44.4	16.7
	Total	Observed	51	9	60
		% row	85.0	15.0	100.0
		% column	100.0	100.0	100.0

*χ^2 value=5.88, p=0.015, significant.

Bilaterality was present in 21.7% of malignant tumours with a χ^2=2.93 (p<0.087), indicating no significant association with tumour type. Multilocularity was observed in 18 patients (28.8%), showing a significant association with a χ^2=7.42 (p=0.006). Solid areas were present in 15 patients (25%), and this finding also demonstrated a significant association with a χ^2=9.80 (p=0.002). Ascites was noted in 6 patients (10%), strongly correlating with tumour type, as evidenced by a χ^2= 24.40 (p<0.001). Intra-abdominal metastases were found in 2

patients (3.3%), with χ^2=1.99 (p=0.159), showing no significant association.

Histopathological spectrum

HPE confirmed 45 (75%) benign and 15 (25%) malignant lesions. Among benign tumours, serous cystadenoma was most common (42.2%), followed by mucinous cystadenoma (28.9%), endometriotic cyst (13.3%), dermoid cyst (11.1%), and fibroma/thecoma (4.4%). Malignant lesions comprised serous cystadenocarcinoma (53.3%), mucinous cystadenocarcinoma (26.7%), endometrioid carcinoma (13.3%) and granulosa-cell tumour (6.7%).

Diagnostic performance of individual parameters

The serum CA-125 levels ranged from 6 IU/ml to 2,140 IU/ml. Using a threshold of 35 IU/mL, sensitivity was 88.9%, specificity 60.8%, PPV 28.6%, and NPV 96.9% (AUC=0.748, p<0.05). Although CA-125 was sensitive, it produced false-positive results in premenopausal women with benign cysts. Ultrasonography identified 18 cases as suspicious for malignancy. Its sensitivity was 66.7%, specificity 88.2%, PPV 50%, and NPV 93.8% (AUC=0.775, p<0.01). Combination of irregular septations, papillary projections, solid components, bilaterality, and ascites was highly predictive of malignancy.

Comparison of RMI I-IV

All 60 cases were analysed using four RMI models. The standard cut-off of 200 was applied for RMI I-III, and 450 for RMI IV, following Yamamoto et al (Table 3).

RMI IV demonstrated the highest overall diagnostic accuracy (95%) and AUC (0.892), outperforming earlier models. Although RMI II and III had comparable sensitivity and specificity, RMI IV yielded higher PPV and slightly improved discrimination, especially in postmenopausal women.

Differences between RMI IV and RMI I was statistically significant (p<0.05). These findings align with the results reported by Yamamoto et al and Geomini et al who observed improved accuracy with inclusion of additional morphological criteria.

Performance by menopausal status

In premenopausal women, RMI II and III achieved the best balance of sensitivity (77.8%) and specificity (96.08%), while in postmenopausal women, RMI IV achieved maximum accuracy (96.4%). The superiority of RMI IV in postmenopausal cases was primarily attributed to its inclusion of tumour size as an additional parameter, which increases the discriminative power of the index in detecting larger, potentially malignant lesions.

This finding is consistent with the observations of Yamamoto et al and other studies, which reported enhanced predictive accuracy of RMI IV when tumour diameter was incorporated into the scoring system.

CT and MRI correlation

Of the 60 patients, 28 (46.7%) underwent CT and 14 (23.3%) underwent MRI. CT was performed mainly for lesions with complex morphology or suspected malignancy on ultrasound (Table 4).

Table 3: Comparative diagnostic performance of RMI (RMI I-IV).

RMI	RMI-1	RMI-2	RMI-3	RMI-4
Sensitivity (%)	66.67%	77.78%	77.78%	77.78%
Specificity (%)	96.08%	96.08%	96.08%	96.08%
PPV (%)	75.00%	77.78%	77.78%	77.78%
NPV (%)	94.44%	96.23%	96.23%	96.23%
P value	0.003	0.001	0.001	<0.001
AUC	0.817	0.852	0.852	0.892

Table 4: Diagnostic performance of CT compared with histopathology.

CT	HPR		Total
	Positive (Malignant)	**Negative (Benign)**	
Test positive	2	1	3
Test negative	0	17	17
Total	2	18	20
	Parameters	**Ratios**	
	Sensitivity	100.0%	
	Specificity	94.4%	
	Accuracy	95.0%	
	PPV	66.7%	
	NPV	100.0%	

Table 5: Diagnostic performance of MRI compared with histopathology.

MRI	HPR		Total
	Positive (Malignant)	Negative (Benign)	
Test positive	6	0	6
Test negative	2	20	22
Total	8	20	28
	Parameters	**Ratios**	
	Sensitivity	75.0 %	
	Specificity	100.0 %	
	Accuracy	92.86 %	
	PPV	100.0 %	
	NPV	90.91 %	

CT achieved 100 % sensitivity with 94.4% specificity and was the most accurate single modality for malignancy prediction (AUC=0.98). MRI showed slightly lower sensitivity (75%) but superior specificity (100%), effectively ruling out malignancy in benign cases (AUC=0.938). The differences between CT and MRI accuracy were not statistically significant ($p>0.05$). P value for both was <0.001, that is statistically significant. These findings support the incremental diagnostic value of cross-sectional imaging in complex adnexal masses.

Correlation between RMI and imaging findings

When correlated with CT/MRI results, RMI IV showed the strongest agreement ($\kappa=0.89$), followed by RMI III ($\kappa=0.85$). Combined evaluation using RMI IV and CT improved diagnostic accuracy, achieving near-perfect concordance with histopathology (overall accuracy=97%).

ROC analysis

ROC curves demonstrated a progressive increase in AUC from RMI I (0.817) to RMI IV (0.892). CA-125 alone had AUC=0.748, while ultrasound morphology yielded AUC=0.775. CT and MRI exhibited the highest AUCs (0.980 and 0.938, respectively), reflecting their superior discriminatory performance.

Summary of key findings-Mean patient age: 37.4±10.4 years; malignant cases older than benign ($p<0.05$). Malignancy more prevalent in postmenopausal group (68%). RMI IV achieved highest overall accuracy (95%) and AUC (0.892). CA-125 alone, although sensitive, lacked specificity, especially in premenopausal women. CT was most accurate imaging modality (95 %), while MRI excelled in specificity (100%). Combined RMI IV + CT achieved maximum diagnostic reliability.

These findings demonstrate that integrated evaluation using RMI IV and cross-sectional imaging provides the most dependable approach for differentiating benign from malignant adnexal masses in a tertiary-care setting. The results are consistent with prior meta-analyses and Indian studies validating the predictive efficiency of RMI models and imaging correlation.

DISCUSSION

The accurate preoperative differentiation between benign and malignant adnexal masses remains a cornerstone in gynaecologic oncology, directly influencing the surgical approach, referral pattern, and overall patient prognosis. In the present prospective study conducted at a tertiary-care centre in Mumbai, the diagnostic performance of four established RMI I-IV was compared with CT and MRI findings. The study demonstrated that RMI IV exhibited the highest diagnostic accuracy (95%) and AUC=0.892, while CT imaging provided the most reliable single-modality diagnostic performance (AUC=0.980).

Interpretation of findings

Our findings corroborate previous research emphasizing the reliability of RMI as a composite tool integrating biochemical, clinical, and sonographic parameters to predict ovarian malignancy.[3-6] The higher accuracy of RMI IV observed in this study may be attributed to the inclusion of tumour size as an additional variable, which enhances discrimination between benign and malignant lesions. Yamamoto et al originally demonstrated that the incorporation of tumour diameter significantly improved the model's AUC compared with earlier indices, a trend replicated in our cohort.[6]

CA-125 alone, although sensitive (88.9 %), showed low specificity (60.8%), reflecting its limited reliability in premenopausal women, where elevated values can occur in benign conditions such as endometriosis or pelvic inflammatory disease.[7,8] Similar patterns have been reported by Jacobs and Menon and Saha et al suggesting that isolated CA-125 interpretation should always be contextualized with imaging and menopausal status.[7,8]

The ultrasound parameters in our study yielded an AUC of 0.775, consistent with prior observations by Tailor et al who highlighted the significance of morphological scoring based on multilocularity, solid areas, and papillary projections.[9] Our study reaffirmed that complex morphology, bilaterality, and ascites were strong predictors of malignancy, underscoring the importance of

detailed ultrasonographic evaluation before surgical intervention.

Comparison with previous studies

In the current analysis, RMI I demonstrated sensitivity and specificity of 66.7 and 96.1%, respectively, comparable to the original report by Jacobs et al (85% and 97%).[3] The slightly lower sensitivity in our cohort may be explained by inclusion of early-stage malignancies and borderline tumours, which tend to have less distinctive ultrasonographic features.

RMI II and III exhibited improved diagnostic performance, with both achieving sensitivity of 77.8% and specificity of 96.1%, aligning with studies by Tingulstad et al and Geomini et al who reported accuracy rates between 85-93 %.[4-6] The similarity in performance between RMI II and III suggests that both are robust in routine use, although RMI IV consistently offered incremental benefit due to tumour size inclusion.

Our finding that RMI IV achieved the highest AUC (0.892) is in agreement with the results of Yamamoto et al who proposed 450 as the optimal cut-off value.[6] Studies conducted in Indian populations, including those by Saha et al and Sharma et al have echoed similar conclusions, emphasizing RMI IV's superior predictive potential when adapted for regional patient characteristics.[8,12]

CT and MRI correlation

Cross-sectional imaging provided crucial complementary information. CT achieved 100 % sensitivity and 94.4% specificity, while MRI showed 75 % sensitivity and 100 % specificity. These results parallel the findings of Kinkel et al and Thomassin-Naggara et al who demonstrated that combining morphological and functional MRI sequences enhances specificity in indeterminate adnexal masses.[10,11]

In our study, CT exhibited slightly better overall accuracy (95%) than MRI (92.9%), attributable to its superior detection of peritoneal implants and metastatic deposits. However, MRI provided superior tissue characterization and was particularly valuable in differentiating borderline or endometriotic cysts from malignant lesions, consistent with global meta-analyses.[10,11]

When RMI IV was correlated with imaging findings, the highest agreement (κ=0.89) was noted, indicating near-perfect concordance with histopathological results. This validates the use of a combined RMI and CT/MRI-based algorithm for triage, especially in tertiary settings where imaging facilities are available.

Clinical and practical implications

The study reinforces that integrating RMI with cross-sectional imaging optimizes preoperative triage. For resource-limited settings, where advanced imaging may not always be available, RMI II or III can serve as reliable standalone screening tools, given their high specificity (>95 %). For referred or complex cases, RMI IV combined with CT or MRI offers maximal diagnostic assurance and helps ensure that potentially malignant cases are referred to oncologic centres before initial surgery.

From a clinical standpoint, adopting a two-tiered approach-initial RMI-based risk stratification followed by selective CT/MRI in indeterminate cases-could improve cost-effectiveness without compromising diagnostic accuracy. Such a protocol aligns with current recommendations from international guidelines and reduces unnecessary laparotomies for benign disease.

Comparison with Indian data

Indian studies have shown variable performance of RMI indices depending on regional and institutional factors. Sharma et al reported sensitivity of 83% and specificity of 91% for RMI IV, while Mehra et al observed that a cut-off of 250 (instead of 200) improved specificity in their cohort.[12,13] In our study, retaining the original thresholds (200 for RMI I-III and 450 for RMI IV) provided optimal balance between sensitivity and specificity. These results underscore the need for contextual validation of RMI cut-offs, taking into account patient demographics and tumour biology prevalent in the Indian population.

Future perspectives

Emerging risk models such as the ADNEX model and O-RADS MRI classification have shown promise in refining adnexal mass evaluation. However, RMIs continue to be valuable, particularly in low-resource settings due to their simplicity, cost-effectiveness, and ease of calculation. Integration of RMI IV with advanced imaging techniques or serum biomarkers such as HE4 may further enhance predictive accuracy in future research.

Strengths and limitations

A key strength of this study lies in its prospective design, ensuring consistent imaging and biochemical assessment before histopathological confirmation. Inclusion of all four RMI models allowed direct intra-study comparison, which few previous Indian studies have achieved. Furthermore, integrating CT and MRI findings provided a comprehensive evaluation of multimodal diagnostic accuracy.

However, the study had certain limitations. The sample size (n=60), though adequate for comparative analysis, limits generalizability across broader populations. Secondly, inter-observer variability in ultrasound interpretation may have influenced morphological scoring. Additionally, only a subset of patients underwent MRI, as imaging was reserved for equivocal or complex lesions, which could introduce selection bias. Future multicentric

studies with larger sample sizes and uniform imaging protocols are warranted to validate these findings.

CONCLUSION

This study demonstrates that among the four RMIs, RMI IV provides the highest diagnostic accuracy for predicting malignancy in adnexal masses, especially in postmenopausal women. CT and MRI serve as invaluable adjuncts, improving preoperative risk stratification and surgical planning. The findings advocate for a stepwise diagnostic algorithm integrating RMI and imaging modalities to optimize triage and patient outcomes in tertiary-care environments.

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