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Diagnostic accuracy of pre-operative prediction of ovarian malignancy

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Abstract

Introduction: Pre-operative differentiation of ovarian neoplasm is essential to guide optimal management of women with ovarian masses. This study was done to evaluate the diagnostic accuracy of clinical examination, Risk of Malignancy Index (RMI-3), Sassone score, International Ovarian Tumor Analysis (IOTA) simple rules, and Ovarian-Adnexal Reporting and Data System (O-RADS) in differentiating benign and malignant ovarian tumors.

Method: A prospective cross-sectional descriptive study was conducted among 213 women at a tertiary care hospital in Nepal over two years (10th May 2023 – 23rd May 2025) after the ethical approval. Women with ovarian masses who were scheduled for surgery with complete preoperative CA-125 and ultrasound assessments were included in the study. Chi-square test was used to determine the statistical significance of diagnostic performance and $p < 0.05$ was considered significant.

Result: All of the pre-operative tools evaluated achieved significant diagnostic agreement in discriminating the benign from malignant lesions. ORADS demonstrated the highest diagnostic accuracy (97.8%) with excellent specificity (99.4%) and moderate sensitivity (72.7%) while IOTA simple rules showed consistently high sensitivity (96.5%) and negative predictive value (97.1%).

Conclusion: Among the various pre-operative assessment methods, IOTA simple rules and O-RADS showed the highest concordance with histopathologic findings compared to the clinical evaluation, RMI 3 and Sassone's score.

Keywords: Diagnosis; Ovarian Neoplasm; Tumor Markers



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Introduction

The global cancer burden continues to rise, with an estimated 19.3 million new cases diagnosed annually.¹ Ovarian cancer represents a significant public health challenge, ranking as the seventh most common malignancy among women and one of the top ten leading causes of cancer-related mortality worldwide.^{2,3} Its incidence is increasing, particularly across Asia—including Nepal, where it is among the top five cancers affecting women.³ Early-stage ovarian cancer often manifests with vague, non-specific symptoms, complicating timely diagnosis and contributing to the high rate of detection at advanced stages. Consequently, prognosis tends to be poor and treatment options more limited.⁴ Despite incremental improvements in survival over the years, ovarian cancer remains the most lethal of all female reproductive tract cancers, largely due to the absence of effective population-level screening strategies and the predominance of late-stage presentation.⁵

Accurate preoperative differentiation between benign and malignant ovarian masses is critical for informed clinical decision-making, including the selection between conservative and radical surgical interventions.⁶ To enhance diagnostic accuracy, various tools have been developed that combine clinical assessment, imaging characteristics, and biochemical markers. Among the most widely adopted diagnostic tools are Risk of Malignancy Index (RMI-3), Sassone scoring system, International Ovarian Tumor Analysis (IOTA) simple rules, and Ovarian-Adnexal Reporting and Data System (O-RADS).⁷ The primary aim of this study was to evaluate the diagnostic performance of various pre-operative diagnostic modalities as clinical examination, RMI and sonographic scoring systems- Sassone Score, IOTA simple rules and O-RADS in differentiating benign lesions from malignant ovarian tumors.

Method

This prospective cross-sectional descriptive study was conducted at the Department of Obstetrics and Gynecology, Patan Academy of Health Sciences, Lalitpur, Nepal, involving 213 women with ovarian masses over two years (10th May 2023 – 23rd May 2025). Approval was obtained from the Institutional Review Committee of the hospital prior to its initiation. Informed written consent was taken from all participating patients. To ensure confidentiality and protect patient's privacy, personal identifiers such as names were not collected; only hospital registration numbers were recorded for data tracking and analysis purposes.

After detail clinical examination, 213 consecutive women with symptomatic or incidentally detected

ovarian masses, scheduled for surgery, and with complete preoperative assessments as tumor marker (CA-125) and ultrasound assessments were included in the study age ranging from 11 to 81 years. Cases lacking imaging reports or biochemical data and those with intra-operative findings of non-ovarian origin were excluded. The diagnostic tools applied included clinical assessment based on features such as laterality, consistency, mobility, and presence of ascites. Ovarian lesions which were unilateral, cystic, mobile, and well-circumscribed without ascites were classified as clinically benign. In contrast, ovarian lesions which were bilateral, firm, and ill-defined, often presenting with ascites were clinically malignant. RMI-3 was calculated by multiplying the menopausal score, ultrasound score, and serum CA-125 level with the cut-off of 200 as malignant.⁸ Sassone scoring system was based on sonographic morphology, wall structure, septations, echogenicity, and papillary projections and total score of >9 indicated malignancy.⁹ IOTA simple rules were applied to assess morphological characteristics, with outcomes classified as benign, malignant or inconclusive.¹⁰ O-RADS was applied based on standardized sonographic descriptors and risk stratification with O-RADS four as intermediate risk with 10-50% risk of malignancy while O-RADS five as high risk with >50% risk of malignancy.¹¹ All data were collected in the predesigned proforma and entered into the MS-Excel spreadsheet.

Surgical management (either laparoscopic or open) was tailored according to patient age, tumor characteristics, and fertility considerations. In cases of ovarian malignancy, staging laparotomy was done as recommended by the International Federation of Gynecology and Obstetrics.¹² Clinician and the radiologists performing the assessments were not aware of the histopathology reports. Final histopathology of each ovarian mass was collected and entered into the proforma. Histopathological analysis served as the reference standard, and diagnostic accuracy measures (sensitivity, specificity, PPV, NPV) were calculated for each modality using SPSS 20. Chi-square testing determined the statistical significance of diagnostic performance and $p < 0.05$ was considered significant.

Result

Among the 213 women, 115(62.77%) benign lesions were seen in women ≤ 40 years while 16(66.66%) malignant lesions were found in women > 40 years and 6(66.66%) borderline lesions among 31-50 years women. Among 173(81.22%) premenopausal women, 13(7.51%) had malignant ovarian tumor while among 39(18.3%) postmenopausal women, 11(28.20%) had malignant ovarian tumor, Table 1.

Table 1. Demographic and clinical profile of women with ovarian masses

Demographic and clinical profile		Benign (by HPE)	Borderline (by HPE)	Malignant (by HPE)	Total
Age (years)	≤ 20	10	1	2	13
	21- 30	49	1	3	53
	31 - 40	56	4	3	63
	41- 50	33	2	7	42
	51- 60	19	0	4	23
	≥ 61	13	1	5	19
Gravidity / Parity	G1	4	0	1	6
	G2	1	0	0	1
	P0	51	2	2	57
	P1	40	4	2	45
	P2	51	1	9	61
	P3	21	0	4	25
	≥ P4	12	2	6	19
Menstrual Status	Pre-menarchal	1	0	0	1
	Pre-menopausal	153	7	13	173
	Post-menopausal	26	2	11	39

Table 2. Ovarian masses histopathology and menstrual status

Histopathology of ovarian masses		Pre-menopausal	Post menopausal	Total
Non-neoplastic / Benign	Endometrioma	38+6*	0	38+6*
	Corpus luteal cyst	24+1*	0	24+1*
	Others	11	0	11
	Mature cystic teratoma	51+9*	3	54+9*
	Struma ovarii	1	0	1
	Serous cystadenoma	20+2*	9	29+2*
	Mucinous cystadenomas	10	5	15
	Seromucinous cystadenoma	3	0	3
	Fibroma	1	2	3
	Brenners	0	1	1
Borderline	Serous	2+1	0	2+1
	Mucinous	6	0	6
	Sero-mucinous	1+1*	0	1+1*
Malignant	Serous carcinoma	2	6	8
	Mucinous cystadenocarcinoma	2	2	4
	Granulosa cell tumor	4	2	6
	Immature teratoma	4	0	4
	SCC [#] with tubo-ovarian mass	0	1	1
	SCC [#] with MCT [§]	1	0	1

Note: *Bilateral lesions, [#]Squamous Cell Carcinoma, [§]Mature Cystic Teratoma

In this study, benign ovarian tumors had a wide range of CA-125 (0.70-399.00 U/mL) with the mean of 38.90 U/mL. Borderline tumors presented with intermediate levels (13.00 to 619.00 U/mL), with a mean of 72.80 U/mL, while malignant tumors showed both the highest range (5.50 to 1000.00 U/mL) and the highest mean value of 121.90 U/mL. Among the benign ovarian tumors, mature teratomas (60), endometriomas (44), and corpus luteal cysts (25) were the commonest while mucinous variety (6) was most prevalent among the borderline ones. Bilaterality was observed in both benign and borderline cases, particularly among

teratomas and endometriomas. Among 'Other' benign lesions, seven were of ovarian inflammatory / suppurative masses and one case each of hydatid cyst of ovary, simple cyst, hemorrhagic cyst with extensive necrosis, and organized tubo-ovarian ectopic mass. Among malignant ovarian tumors, high-grade serous carcinoma (eight) and granulosa cell tumor (six) were the common histological types, Table 2.

Clinical evaluation, RMI-3 and Sassone's score identified majority of the cases as benign lesions (87.79-91.54%) while malignant lesions ranged from 8.45 to 12.20%. Similarly, IOTA simple rules and

O-RADS also classified majority of the lesions as benign (80.22- 81.22%) with 5.16 to 12% of the lesions malignant. Histopathological examination revealed 180(84.50%) benign, nine (4.22%) borderline, and 24(11.26%) malignant ovarian tumors, Table 3.

Clinical evaluation and RMI-3 both showed strong concordance correctly identifying most benign and malignant tumors with some misclassification (clinical-five benign and 15 malignant; RMI-3-eight benign and 10 malignant). Sassone's score, though statistically significant ($p=0.0126$) had weaker alignment, misclassifying 11 malignant cases. The IOTA simple rules model demonstrated high accuracy ($p < 0.001$) with 16 malignancies correctly identified and 16 inconclusive cases (three malignant by HPE). O-RADS also performed

Table 3. Comparison of pre-operative methods and histopathology of ovarian tumors

Pre-operative diagnostic methods		n (%)
Clinical	Benign ovarian tumor	191(89.67%)
	Malignant ovarian tumor	22(10.32%)
RMI-3	Benign ovarian tumor	187(87.79%)
	Malignant ovarian tumor	26(12.20%)
Sassone	Benign ovarian tumor	195(91.54%)
	Malignant ovarian tumor	18(8.45%)
IOTA simple rules	Inconclusive	16(7.51%)
	Benign ovarian tumor	171(80.28%)
	Malignant ovarian tumor	26(12.20%)
O-RADS	Benign ovarian tumor	173(81.22%)
	Malignant ovarian tumor	11(5.16%)
	Intermediate Risk	28(13.14%)
Histopathology	Benign ovarian tumor	180(84.50%)
	Borderline ovarian tumor	9(4.22%)
	Malignant ovarian tumor	24(11.26%)

Table 4. Comparison of the pre-operative diagnostic methods with histopathology

Pre-operative diagnostic methods		Benign (by HPE)	Borderline (by HPE)	Malignant (by HPE)	Total	p value
Clinical	Benign	175	7	9	191	<0.001 [#]
	Malignant	5	2	15	22	
	Total	180	9	24	213	
RMI-3	Benign	172	5	10	187	<0.001 [#]
	Malignant	8	4	14	26	
	Total	180	9	24	213	
Sassone's score	Benign	169	8	18	195	0.0126 [#]
	Malignant	11	1	6	18	
	Total	180	9	24	213	
IOTA simple rules	Benign	165	1	5	171	<0.001 [#]
	Malignant	6	4	16	26	
	Inconclusive	9	4	3	16	
	Total	180	9	24	213	
O-RADS	Benign	168	2	3	173	<0.001 [#]
	Malignant	1	3	8	12	
	Indeterminate	11	4	13	28	
	Total	180	9	24	213	

Note: [#]Chi Square Test

Table 5. Performance characteristics of pre-operative diagnostic methods

Pre-operative diagnostic methods		Sensitivity	Specificity	PPV	NPV	DA
Clinical		62.5	97.2	75	95	89
RMI-3		58.3	95.6	63.6	94.5	87.3
Sassone's score		25	93.9	35	90.4	82.2
IOTA simple rules	Including Inconclusive case	76	96.5	72	97.1	94
	Excluding Inconclusive cases	71	91.3	57	95.5	88.7
O-RADS	Including Indeterminate case	72.7	99.4	88.9	98.2	97.8
	Excluding Indeterminate cases	75	93.5	93.6	96.1	90.6
Combined Model*		85	97	89.5	96.5	93

Note: *Clinical + RMI-3 + Sassone's score + IOTA + O-RADS

well accurately classifying 8 malignancies but marking 28 cases (13 malignant by HPE) as indeterminate. All methods achieved significant diagnostic agreement, with IOTA simple rules and O-RADS offering added value through risk stratification of uncertain cases, Table 4.

Among the evaluated pre-operative methods, O-RADS—including indeterminate cases—achieved the highest diagnostic accuracy (97.8%), with sensitivity of 72%, specificity of 99%, PPV of 88.9%, and NPV of 98.2%, reflecting its strong ability to correctly classify adnexal masses while minimizing diagnostic errors. In contrast, Sassone's score showed

the lowest sensitivity (25%), limiting its reliability in detecting malignancies. The IOTA simple rules model demonstrated balanced performance across scenarios, with consistently high sensitivity and NPV, making it a dependable option in ambiguous clinical contexts. A combined diagnostic model, integrating clinical, RMI-3 and imaging data, yielded the highest sensitivity (85%) with excellent specificity (97%), Table 5.

Discussion

An estimated 19.3 million new cancer cases and nearly 10 million deaths are reported globally, with a significant burden attributed to female-specific cancers, including ovarian cancer. Due to its asymptomatic nature and delayed diagnosis, ovarian cancer continues to carry a high mortality-to-incidence ratio.¹ Similar to global findings, increased number of ovarian malignancy was seen in women >40 years in this study as well.^{13,14} Borderline tumors predominantly affected women aged 31–50 years, suggesting a hormonal influence during this biologically active period.¹⁵ Multiparity was observed in over 60% of malignant cases, potentially modulated by reproductive history, hormonal exposure, and genetic factors.¹⁴⁻¹⁶ Malignancy prevalence was higher in postmenopausal women compared to premenopausal women (28.20%, 7.51%), supporting the need for clinical vigilance for adnexal masses after menopause.¹⁷ The findings of this study showed surface epithelial tumors being most frequent, with serous cystadenoma being the commonest (29) is comparable to the findings reported by Kayastha et al (38).¹⁴ Similarly, among germ cell tumors, mature cystic teratoma predominated (60 vs. 24), primarily affecting women under 40. High-grade serous carcinoma as the most common malignant subtype, primarily in postmenopausal patients (six of eight cases) reflect findings by Chen et al.¹⁸ Consistent with previous literature, borderline tumors were exclusive to premenopausal women.¹⁹ Benign ovarian tumors are usually unilateral, cystic, mobile, and well-circumscribed without ascites. In contrast, malignant tumors are frequently bilateral, firm, and ill-defined, often presenting with ascites. However, clinical diagnosis remains challenging due to patient factors like obesity, deep pelvic anatomy, and examiner variability.^{20,21} Similar to this study, Priya et al. noted misclassification of 25 malignancies by clinical examination, underlining the limitations of clinical examination alone.²⁰ This accentuates the value of adjunctive modalities such as ultrasonography, tumor markers (e.g., CA-125), and emerging tools like liquid biopsies.²² Ultrasonography has sensitivities of 75–88% and specificities of 80–88.8% in various studies.^{20,23}

The RMI, proposed by Jacobs et al., integrates menopausal status, ultrasonographic features, and CA-125 levels with score above 200 indicating higher risk of malignancy.⁸ Among its variants (1-5), RMI-3 showed enhanced performance at a cut-off of 300, with a diagnostic accuracy of 93%, specificity of 93%, PPV of 56%, and NPV of 99%.²⁴⁻²⁶ Similar to the finding in this research, another study reported specificity of RMI-3 of 96.4% and NPV of 95.8%.²⁷ However, recent comparisons suggest that RMI is being outperformed by newer models such as IOTA and O-RADS as seen in this study.^{28,29}

The IOTA simple rules evaluate morphology, vascularity, bilaterality, and solid components. It categorizes lesions into benign/malignant, and cases with overlapping/absent features are deemed inconclusive warranting further evaluation.¹⁰ In this study, IOTA exhibited slightly lower sensitivity (76%) and higher specificity (96 %) compared to Singh et al.³⁰ and a meta-analysis which reported pooled sensitivity and specificity of 92% when applied by expert sonographers.³¹⁻³³ This could be due to the expert sonographers had more refined skills in applying IOTA criteria, leading to improved detection of malignancies. These findings highlight the importance of standardized training, local calibration of diagnostic tools, and the potential need for adjunctive decision-support systems to optimize performance across diverse clinical settings.

O-RADS categorizes adnexal masses using a standardized scoring system that incorporates tumor size, vascular architecture, septation, and morphological features.¹¹ When comparing diagnostic models, O-RADS outperformed IOTA simple rules in this study in terms of overall accuracy (97.8% vs 87%), although with slightly lower sensitivity (72.7% vs 76%) but substantially higher specificity (99.4% vs 96%). While IOTA's performance may have been influenced by operator experience and population factors, O-RADS maintained robust accuracy, likely owing to its more structured and standardized scoring criteria. This observation is supported by study by Ahmed et al. who found O-RADS achieved balanced predictive values with high sensitivity (94.1%) and overall accuracy (86%).³⁴ The consistent performance of O-RADS across studies, including non-specialist settings, underscores its adaptability and clinical utility in stratifying adnexal masses.^{35,36} These findings suggest that while both systems offer value, O-RADS may provide greater diagnostic consistency, especially in contexts with varying operator expertise as in this study.

The Sassone scoring system uses wall thickness, internal septations, echogenicity, and mural nodules to evaluate malignancy risk, with a score >9 suggesting possible malignancy.⁹ In this study, it had specificity

of 93.9% and negative predictive value of 90.4%. Although morphologically informative and simple to use, it demonstrated the slightly lower diagnostic performance (82%) compared to other modalities. Similar findings have been seen in other studies which could be due to its use of grey scale ultrasound features only and addition of clinical as well as tumor marker could be more useful in categorizing various types of ovarian tumors.^{37,38}

The superior diagnostic performance of the combined model suggests a range of valuable clinical applications. Foremost, this approach facilitates earlier and more accurate identification of high-risk cases, particularly in the evaluation of adnexal masses, enabling timely referral and intervention. The model's high specificity also minimizes unnecessary procedures, contributing to improved surgical planning and patient outcomes. The integration of this model into clinical decision support systems, could standardize diagnostic workflows and assist less-experienced practitioners in managing complex presentations. Future studies should focus on refining and validating such integrated models across broader populations and incorporating digital decision-support tools to ensure consistent application.

Conclusion

Among the various pre-operative diagnostic methods to separate the benign ovarian masses from the malignant ones, IOTA simple rules and O-RADS showed the highest concordance with histopathology compared to the clinical evaluation alone, RMI-3 and Sassone's score. A multidisciplinary approach combining clinical, biochemical, and structured imaging assessments remains vital in preoperative discrimination on the ovarian masses.

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Conflict of Interest

None

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Author Contribution

Concept; data collection, analysis and manuscript writing: RJ.

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