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Evaluation of IOTA simple rules for preoperative assessment of ovarian masses in a secondary healthcare centre

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Abstract
With the exponential rise in ovarian cancer cases, the need of the hour is timely diagnosis and treatment for better outcomes. Secondary health care centers have quick access to ultra sound equipments as compared to invasive procedures such as biopsies. Keeping this in regard, implementation of International Ovarian Tumor Analysis (IOTA) simple rules becomes an important methodology.
In the present study, 2000 women were screened over a period of 2 years for ovarian cancer, out of which 52 women were included in the study. The tumor prediction rules were divided into malignant (M-features) and benign (B-features).
The study found that the IOTA Simple Rules classified ovarian masses with high accuracy, showing 84.6% sensitivity and 89.7% specificity compared to histopathology. Most benign masses had low vascularity, while malignant masses commonly exhibited strong blood flow. The rules reliably differentiated benign from malignant tumors in a secondary care setting.
The IOTA simple rules were as effective as biopsy in diagnosing malignant and benign tumors. Thus, this method can help in accurate diagnosis particularly in low resource setting, although unclassified or ambiguous cases may still require further expert assessment or advanced imaging for definitive diagnosis.

Keywords: Ovarian cancer, IOTA simple rules, ultrasound, diagnosis, secondary care

Introduction
The incidences of cancer are on a steep rise due to various factors like sedentary lifestyle, food consumption habits and increasing pollution [1]. In India, the prevalence of cancer is estimated to be 100.4/100,000 in the year 2022, which implies 1 out of 9 people is likely to develop cancer in India [22]. Countries like China, India and the US reported higher frequencies of ovarian cancer cases in 2022 (World Cancer Research Fund).
Ovarian tumors are a diverse group of growths that vary in type, symptoms, and prognosis, and are classified as benign, borderline, or malignant, with epithelial tumors being the most common in adult women. Epithelial ovarian cancer is the deadliest gynecologic malignancy and ranks fifth among cancers in U.S. women, largely due to late-stage diagnosis and poor prognosis. Early detection is difficult because symptoms like abdominal pain or masses are nonspecific and many tumors remain asymptomatic until advanced stages [3].
Accurate preoperative evaluation of ovarian masses is crucial for ensuring patients receive timely and appropriate care. While various diagnostic methods such as serum biomarkers, imaging techniques, and clinical evaluations are used to assess ovarian tumors, they often lack the precision to clearly differentiate between benign and malignant masses. This can result in unnecessary surgeries or delayed cancer diagnoses.
In secondary health care hospitals, the implementation of the “IOTA Simple Rules” could significantly enhance the accuracy of ovarian mass assessments, which will ultimately reduce the number of unnecessary pr, and improve overall patient outcomes. These rules offer a standardized approach that is easy to apply in routine clinical practice and has been shown to be reliable even in the hands of less experienced practitioners [4].
To address this issue, the International Ovarian Tumor Analysis (IOTA) group developed the "Simple Rules," a set of standardized ultrasound criteria designed to improve diagnostic accuracy. These rules identify features indicative of malignancy and benignity, allowing straightforward classification when only one type of feature is present.

Validated in multiple studies, the IOTA Simple Rules have demonstrated high sensitivity and specificity, particularly benefiting secondary healthcare settings with limited access to advanced imaging and specialized expertise. However, some cases remain inconclusive, requiring additional assessment. The current study aims to evaluate the effectiveness of these rules in a secondary care hospital by comparing ultrasound predictions with histopathological findings, thereby supporting their utility in early and accurate ovarian cancer diagnosis, especially in resource-constrained environments.

Description of the simple rules

The IOTA Simple Rules consist of specific ultrasound features categorized into two groups: those suggestive of malignancy (M-features) and those suggestive of benignity (B-features). These rules are applied during transvaginal ultrasonography, the preferred method for evaluating ovarian masses (Fig. 1 and 2).

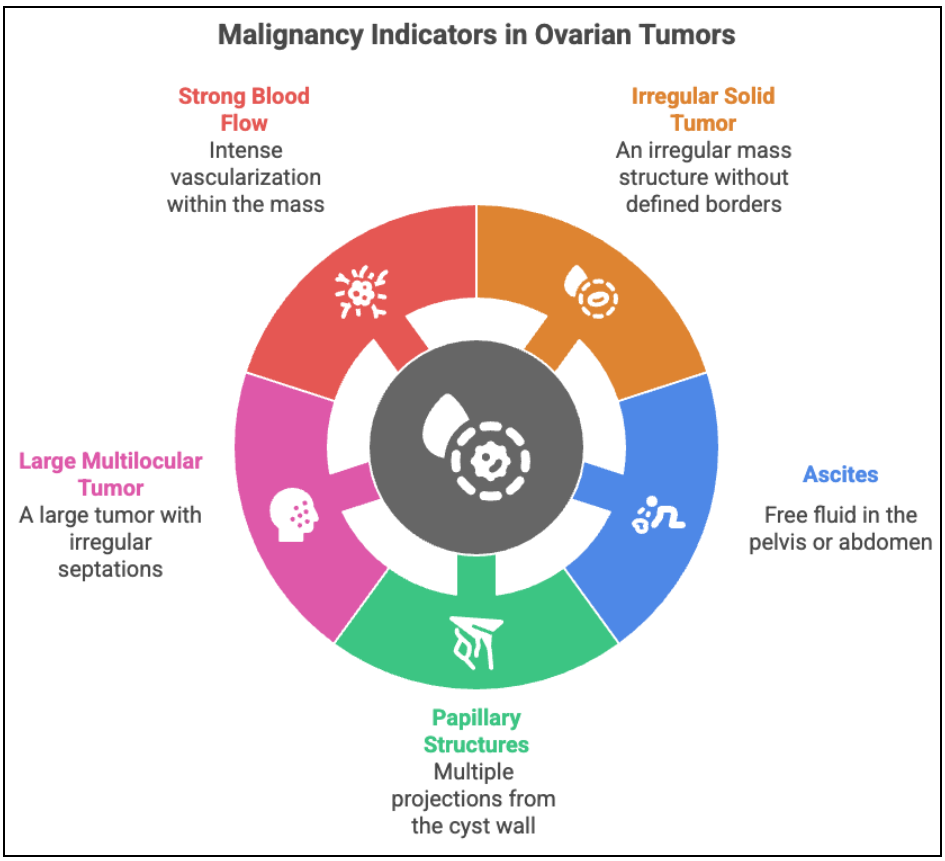

Fig 1: Malignancy indicators in ovarian tumours.

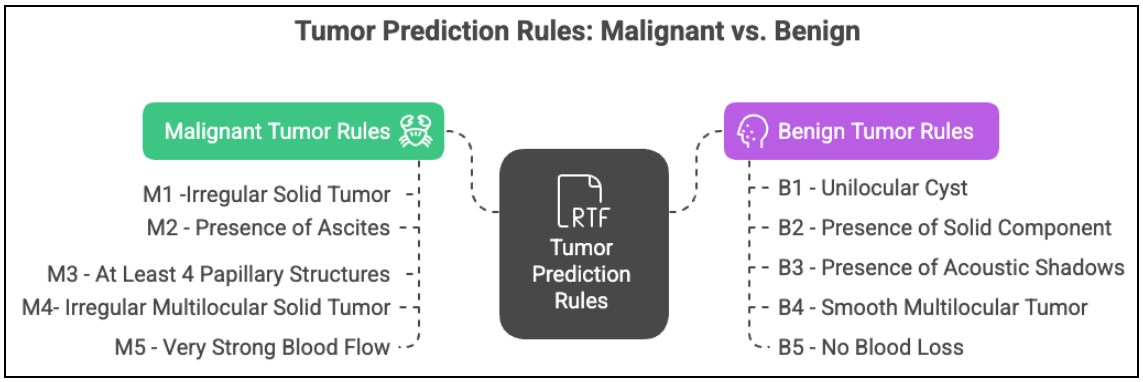

Fig 2: Tumor prediction rules: Malignant vs Benign

Material and Methods

This was a Prospective and Observational study conducted in the Department of Obstetrics and Gynecology Tata Motors Hospital, Jamshedpur between 2023 and 2025. The study population consisted of women with ovarian masses who were referred from various centres within the state as well as neighboring states. These included patients attending both the outpatient and inpatient departments of Obstetrics and Gynecology at Tata Motors Hospital, Jamshedpur. Out of 2000 women screened, 52 met the eligibility criteria and were included in the study. The inclusion criteria covered all patients with ovarian masses presenting to the gynaecology department, whether as outpatients or inpatients. The exclusion criteria were refusal to provide consent, loss to follow-up, declining surgical intervention, or having a mass other than an ovarian mass.

Results

In the present study, the majority (40.38%) belonged to the 26-

40 years age group, representing the reproductive age population, followed by 23.08% in the 11-25 years group. Participants aged 41-55 years constituted 17.31%, while those aged 56-70 years and 71-85 years represented 11.54%and 7.69%, respectively. Thus, age as a baseline character had non significant p value (0.121) which can be further used for evaluation (Fig. 3).

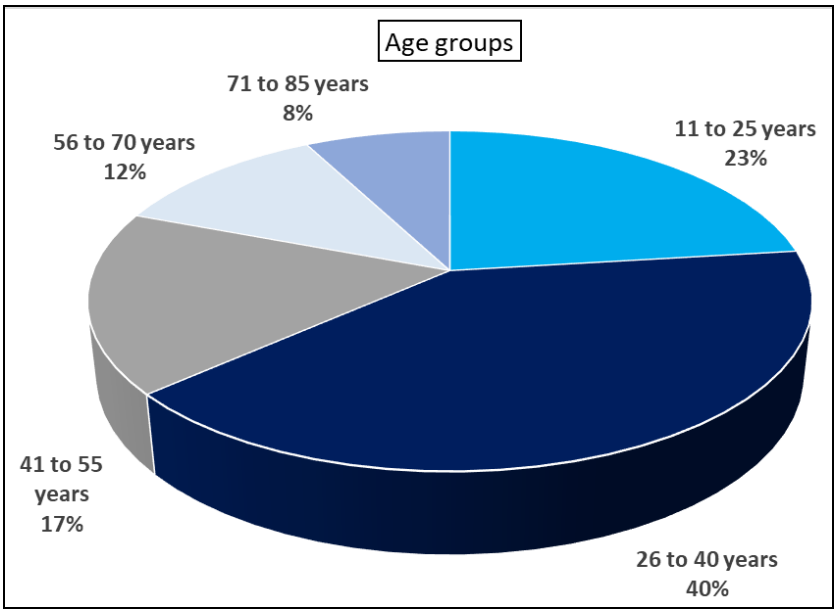

Fig 3: Pie chart representing age groups distribution
(n = 52, data is represented by percentage)

Table 1 compares the histopathological (gold standard) classification of tumors with IOTA simple rules categorization. The p value between the two methods was non significant implying that IOTA simple rules were able to differentiate between malignant and benign tumors.

Table 1: Frequency of nature of tumors based on histopathological and IOTA simple rules report.

Nature of Tumor	Frequency	Frequency (IOTA)	p value
Benign	39 (75%)	32 (61.5%)	0.4
Malignant	13 (25%)	15 (28.80%)	0.7
Unclassified	0 (0%)	5 (9.6%)	N/A
Total	52	52	

Table 2: Combined Analysis: IOTA Score, Color Doppler Score, and Malignant Features

Category	Frequency	Percentage
IOTA Score Classification		
Benign	32	61.50%
Malignant	15	28.80%
Unclassified	5	9.60%
Color Doppler Score		
Score 1 (Lowest Vascularity)	36	69.20%
Score 2	4	7.70%
Score 3	4	7.70%
Score 4 (Highest Vascularity)	8	15.40%
Malignant Features (IOTA M)		
M1 (Irregular solid tumor)	1	9.1% of malignant cases
M2 (Ascites)	1	9.10%
M3 (≥4 papillary structures)	2	18.20%
M4 (Irregular multilocular solid tumor ≥100mm)	1	9.10%
M5 (Very strong blood flow)	6	54.50%

Table 2 displays a combined analysis of categorization of cases among IOTA classifications, their color doppler vascularity assessment and the presence of malignant features within the study population.

Around 38% patients underwent laparoscopy while 62% had laparotomy (Fig. 4).

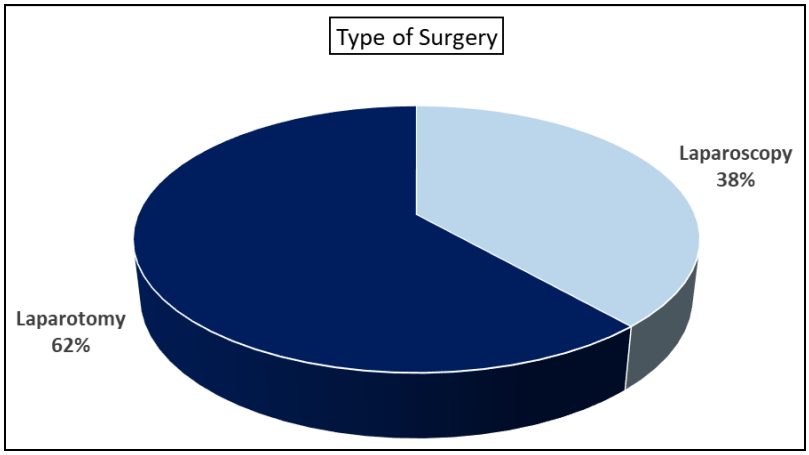

Fig 4: Pie chart representing type of surgery (n = 52, data is represented by percentage)

	Histology Benign (n=39)	Histology Malignant (n=13)	Sensitivity	Specificity	PPV	NPV
IOTA Benign	35	2	84.60%	89.70%	73.30%	94.50%
IOTA Malignant	4	11				

Table 11 presents the diagnostic accuracy of the IOTA Simple Rules in predicting the nature of adnexal masses compared to histopathological findings. Among the 39 benign cases confirmed by histology, the IOTA score correctly identified 35 as benign, yielding a sensitivity of 84.6%. Similarly, of the 13 malignant cases, the IOTA score accurately classified 11 as malignant, resulting in a specificity of 89.7%. The positive predictive value (PPV) was 73.3%, indicating that 73.3% of cases classified as malignant by the IOTA score were truly malignant. The negative predictive value (NPV) was 94.5%, signifying that 94.5% of cases identified as benign were truly benign. These findings demonstrate that the IOTA Simple Rules exhibit high specificity and NPV, making them a reliable tool for ruling out malignancy in a non-oncological setting.

It highlights the interplay between these diagnostic tools, showing that most masses classified as benign also had low vascularity on Doppler, while features such as high Doppler scores and the presence of M5 (very strong blood flow) were more commonly associated with malignant cases.

Discussion

The present study underscores the importance and efficiency of the International Ovarian Tumor Analysis (IOTA) Simple Rules for preoperative classification of masses detected in ovaries. To compare the effectiveness, histopathological biopsy was considered as the gold standard.

The present study revealed that out of the 52 patients assessed, 75% tumours were diagnosed as benign through histopathological findings while the rest 25% were malignant. When the IOTA simple rules were applied, the ultrasound evaluation classified 61.5% of masses as benign, 28.8% as malignant, while 9.6% did not categorise as either of them. The classification by both the methods exhibited high similarity implying that the IOTA methodology was equally effective. Owing to this hypothesis, the diagnostic efficiency Diagnostic accuracy analysis showed the IOTA scoring system had a sensitivity of 84.6%, specificity of 89.7%, positive predictive value of 73.3%, and negative predictive value of 94.5%.

These results affirm the substantial usefulness of IOTA Simple Rules in real-world, resource-limited environments. Most notably, the high specificity and negative predictive value mean that a benign result from IOTA Simple Rules can reliably exclude malignancy vital for reducing unnecessary radical surgery and hospital burden. The study aligns with prior validation work by Timmerman *et al*. [5] and K. P. D. Prabhu *et al*. [6] which also reported high sensitivity and specificity using IOTA criteria.

An important observation is the presence of an “unclassified” category (9.6% of cases), consistent with previous reports that Simple Rules cannot conclusively characterize all masses, especially when features overlap or are ambiguous. This finding underscores the need for further assessment of inconclusive cases via expert sonologist review, advanced imaging, or intraoperative frozen section as appropriate.

The analysis of Color Doppler scoring within the study demonstrates that the majority (69.2%) exhibited low vascularity (Score 1) characteristic of benign pathology while higher scores (Score 4, 15.4%) correlated more with malignancy, as expected. Additionally, among malignant sonographic features (M-rules), the presence of very strong blood flow (M5) was most frequently encountered (54.5%), corroborating the established association between tumor angiogenesis and malignancy.

Despite these strengths, the study also highlighted limitations of the Simple Rules. The criteria do not integrate patient history, tumor markers, or CT/MRI findings, which can be particularly relevant in complex or borderline cases. Furthermore, distinguishing borderline tumors or tumors with both benign and malignant features remains a challenge, occasionally leading to misclassification or delays in definitive care.

Demographic analysis revealed that the majority of patients fell within the reproductive age group (26-40 years), in line with patterns observed in previous Indian and international studies. Most participants had no prior exposure to hormonal contraception, and a preponderance were married, factors that may reflect regional sociocultural or healthcare-access variables rather than independent risk factors for malignancy.

Reference	Study design	Sample size	Remarks
Garg *et al*., 2017 [7]	Prospective hospital based case control	50	IOTA rules applied in 90%; Sensitivity 91.7%, specificity 84.8%, accuracy 86.7%. High agreement with histopathology.
Tongsong *et al*., 2016 [8]	Prospective comparison	150	IOTA rules and subjective assessment had similar diagnostic performance (Sensitivity 82.9%, Specificity 94.0%). IOTA ruled inconclusive in ~20% cases.
Tian *et al*., 2025	Prospective diagnostic study	179	IOTA sensitivity 86.8%, specificity 95.6%. Combined with CEUS, sensitivity reached 92.7%.
Nunes *et al*., 2014 [9]	Meta analysis	303	Sensitivity 96.2%, specificity 88.6%; rules applicable in 78% of tumors.
Patel-Lippman *et al*., 2020 [10]	Prospective comparative	79	Sensitivity 90%, specificity 96.5%, accuracy 96.4%. Compared IOTA Simple Rules and expert impression.
Rashmi *et al*., 2023 [11]	Prospective	77	Sensitivity 66.6% for IOTA, 80% for ADNEX+CA-125. IOTA showed lower sensitivity in this cohort.
Gareeballah *et al*., 2024 [12]	Meta analysis	7,841 masses (27 studies)	Pooled sensitivity & specificity 92%. High effectiveness in presurgical differential diagnosis.

Key takeaways

- Most of the studies reported high sensitivity and specificity for IOTA rules often comparable to other diagnostic models.
- Meta analysis has also proven that large studies with larger cohorts also report similar findings.

Conclusion

In summary, the study strengthens the case for incorporating IOTA Simple Rules into the routine evaluation of ovarian masses in secondary healthcare. It demonstrates that, when applied by trained radiologists even outside oncology specialty centers, these rules offer high diagnostic accuracy and can standardize decision-making, particularly where subspecialty expertise is not readily available. However, the observed limitations point to the need for a multimodal approach and expert oversight in ambiguous cases. Future research should investigate integration with clinical and biochemical parameters and focus on refining classification algorithms for borderline and complex lesions.

Conflict of Interest

Not available

Financial Support

Not available

References

1. Sharman R, Harris Z, Ernst B, Mussallem D, Larsen A, Gowin K. Lifestyle Factors and Cancer: A Narrative Review. Mayo Clinic Proceedings: Innovations, Quality & Outcomes. 2024;8(2):166-183.
2. Sathishkumar K, Chaturvedi M, Das P, Stephen S, Mathur P. Cancer incidence estimates for 2022 & projection for 2025: Result from National Cancer Registry Programme, India. Indian Journal of Medical Research. 2022;156(4 & 5):598-607.
3. Savale AS, Chawla AA, Jadhav PN, Sahu S. Histopathological insights into ovarian tumors: A case series perspective. IJOGR. 2024;11(3):496-503.
4. Sahu SA, Shrivastava D. A Comprehensive Review of Screening Methods for Ovarian Masses: Towards Earlier Detection. Cureus. 2023;15(11):e48545.
5. Timmerman D, Van Calster B, Testa A, Savelli L, Fischerova D, Froyman W, *et al*. Predicting the risk of malignancy in adnexal masses based on the Simple Rules from the International Ovarian Tumor Analysis group. American Journal of Obstetrics and Gynecology. 2016;214(4):424-437.
6. KPD, Prabhu S, BS SP. Validity of international ovarian tumour analysis simple rules in characterization of ovarian mass. Int J Reprod Contracept Obstet Gynecol. 2023;12(7):2128-2132.
7. Garg S. Evaluation of IOTA Simple Ultrasound Rules to Distinguish Benign and Malignant Ovarian Tumours. JCDR. 2017;11(8):TC06-TC09.
8. Tongsong T, Tinnangwattana D, Vichak-Ururote L, Tontivuthikul P, Charoenratana C, Lerthiranwong T. Comparison of Effectiveness in Differentiating Benign from Malignant Ovarian Masses between IOTA Simple Rules and Subjective Sonographic Assessment. Asian Pac J Cancer Prev. 2016;17(9):4377-4380.
9. Nunes N, Ambler G, Foo X, Naftalin J, Widschwendter M, Jurkovic D. Use of IOTA simple rules for diagnosis of ovarian cancer: meta-analysis. Ultrasound in Obstet & Gyne. 2014;44(5):503-514.
10. Patel-Lippmann KK, Sadowski EA, Robbins JB, Paroder V, Barroilhet L, Maddox E, *et al*. Comparison of International Ovarian Tumor Analysis Simple Rules to Society of Radiologists in Ultrasound Guidelines for Detection of Malignancy in Adnexal Cysts. American Journal of Roentgenology. 2020;214(3):694-700.
11. Rashmi N, Singh S, Begum J, Sable MN. Diagnostic Performance of Ultrasound-Based International Ovarian Tumor Analysis Simple Rules and Assessment of Different NEoplasias in the adneXa Model for Predicting Malignancy in Women with Ovarian Tumors: A Prospective Cohort Study. Women's Health Reports. 2023;4(1):202-210.
12. Gareeballah A, Gameraddin M, Alshoabi SA, Alsaedi A, Elzaki M, Alsharif W, *et al*. The diagnostic performance of International Ovarian Tumor Analysis: Simple Rules for diagnosing ovarian tumors—a systematic review and meta-analysis. Front Oncol. 2025;14:1474930.

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