

# A Prospective Observational Study Comparing IOTA Simple Ultrasound Rules and RMI-2 Scoring System in Correlation with Histopathological Examination in Diagnosing Adnexal Masses at a Tertiary Care Centre

## Research Article

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### Abstract

**Background:** Adnexal masses are frequently encountered in gynecological practice and often present a diagnostic challenge in differentiating benign from malignant lesions before surgery. Accurate preoperative assessment is essential for appropriate referral, surgical planning, and improving patient outcomes. The International Ovarian Tumor Analysis (IOTA) Simple Ultrasound Rules and Risk of Malignancy Index-2 (RMI-2) are commonly used tools for this purpose.

**Objectives:** To compare the diagnostic accuracy of IOTA Simple Ultrasound Rules and RMI-2 scoring system in differentiating benign and malignant adnexal masses, using histopathological examination as the gold standard.

**Methods:** This prospective study included 50 women with adnexal masses at a tertiary care centre. Patients underwent clinical evaluation, ultrasonography, serum CA-125 testing, and assessment by IOTA Simple Rules and RMI-2, with final diagnosis confirmed by histopathology. Diagnostic performance was compared using sensitivity, specificity, PPV, and NPV.

**Results:** IOTA Simple Rules demonstrated 100% sensitivity, 96.8% specificity, 93.75% PPV, and 100% NPV. RMI-2 showed 81.25% sensitivity, 79.4% specificity, 65% PPV, and 90% NPV. IOTA Simple Rules showed superior diagnostic performance compared to RMI-2 in differentiating benign from malignant adnexal masses.

**Conclusion:** IOTA Simple Ultrasound Rules are more accurate than RMI-2 in the preoperative evaluation of adnexal masses and can be used as a simple, reliable, and effective screening tool in routine gynecological practice.

**Keywords:** Adnexal mass; IOTA; RMI-2; Ovarian malignancy; Ultrasonography; Histopathology; CA-125

## Introduction

Adnexal masses are common and range from benign cysts to malignant tumors, making accurate preoperative diagnosis essential as management varies by lesion type. These lesions may arise from the ovaries, fallopian tubes, or surrounding structures and may present with symptoms such as pelvic pain, abdominal distension, or may be incidentally detected during imaging for unrelated conditions. Accurate preoperative differentiation between benign and malignant adnexal masses is essential for appropriate clinical management, as it directly influences surgical planning, the extent of intervention, and the need for referral to oncologic centers. Misclassification may result in unnecessary extensive surgery for benign lesions or delayed treatment in malignant cases, adversely affecting patient outcomes

Although less common, ovarian malignancies have high morbidity and mortality due to late presentation, with vague symptoms like abdominal pain, distension, bloating, urinary issues, and menstrual irregularities hindering early diagnosis. Most cases are diagnosed after the disease has spread beyond the pelvis, resulting in poor survival outcomes, with a five-year survival rate of less than 45%. This highlights the urgent need for reliable, accessible, and cost-effective diagnostic methods for early detection and risk stratification of adnexal masses. Given that these masses occur across all age groups, from reproductive to postmenopausal women, an effective and standardized approach to evaluation is critical

To improve preoperative diagnosis, several models and scoring systems have been developed. The Risk of Malignancy Index (RMI) is a widely used composite score based on menopausal status, ultrasonographic findings, and serum CA-125 levels. The IOTA Simple Ultrasound Rules, on the other hand, are based on standardized sonographic morphological features and classify masses as benign, malignant, or inconclusive.

The performance of these tools may vary by patient and tumor factors; thus, this study compared the diagnostic accuracy of IOTA Simple Rules and RMI-2 in adnexal masses, with correlation to histopathology.

## Aims and Objectives

### Primary Objective

To compare the diagnostic accuracy of IOTA Simple Ultrasound Rules and RMI-2 scoring system in differentiating benign and malignant adnexal masses.

### Secondary Objective

To correlate the findings of both scoring systems with histopathological examination, considered the gold standard.

## Materials and Methods

### Study Design and Setting

This was a prospective observational study conducted in Department of Obstetrics and Gynaecology GMCS, GUJARAT among women diagnosed with adnexal masses and planned for surgical management.

### Study Population

A total of **50 patients** with adnexal masses were included in the study.

#### Inclusion Criteria

- Women diagnosed with adnexal masses on clinical and/or ultrasonographic evaluation
- Patients admitted for operative management
- Patients willing to participate in the study

#### Exclusion Criteria

- Patients managed conservatively
- Patients with incomplete investigations or unavailable histopathological diagnosis
- Patients unwilling to participate
- Ectopic pregnancy

#### Study Procedure

After obtaining informed consent, all eligible patients underwent:

- Detailed clinical history and physical examination
- Routine laboratory investigations
- Serum CA-125 estimation
- Ultrasonographic evaluation of adnexal mass
- Application of:
  - IOTA Simple Ultrasound Rules
  - RMI-2 scoring system

The final diagnosis in all cases was established by **histopathological examination**, which was considered the reference standard.

### IOTA Simple Rules

The IOTA Simple Rules were applied using predefined sonographic benign features (B-features) and malignant features (M-features). Lesions were categorized as:

- **Benign**
- **Malignant**
- **Inconclusive**

### RMI-2 Scoring

The Risk of Malignancy Index-2 (RMI-2) was calculated using the formula:

$$\text{RMI-2} = \text{U} \times \text{M} \times \text{CA-125}$$

Where:

- U = Ultrasound score
- M = Menopausal score
- CA-125 = Serum CA-125 level (U/mL)

**Outcome Measures**

The diagnostic performance of both methods was assessed by:

- Sensitivity
- Specificity
- Positive Predictive Value (PPV)
- Negative Predictive Value (NPV)

**Statistical Analysis**

Data were entered into a Microsoft Excel spreadsheet and analyzed using appropriate descriptive and inferential statistical methods. Histopathological examination was taken as the gold standard for comparison.

**Results**

**Demographic Characteristics**

Among the 50 study participants, the majority belonged to the 26-40 years age group (58%), followed by 41-55 years (24%). Most patients were premenopausal (70%), while 30% were postmenopausal. Nulliparous women constituted the largest parity group.

**Clinical Presentation**

The most common presenting complaint was abdominal pain (74%), followed by abdominal distension (24%) and mass per abdomen (16%). Other symptoms included bloating, menstrual disturbances, bowel/bladder complaints, and vaginal bleeding/discharge.

**Histopathological Findings**

Histopathology showed most adnexal masses were benign, with fewer malignant cases. Benign lesions included non-neoplastic and benign neoplastic masses (e.g., serous and mucinous adenomas), while malignant lesions included serous and mucinous cystadenocarcinoma, endometrioid carcinoma, dysgerminoma, and granulosa cell tumor.

**IOTA Classification**

According to IOTA Simple Rules:

- 31 cases (62%) were classified as benign
- 16 cases (32%) were classified as malignant
- 3 cases (6%) were classified as inconclusive

**Diagnostic Accuracy**

HPE distribution of study subjects and comparison of RMI-2 with IOTA Simple USG Rules among the 50 study subjects. 14 cases of non-neoplastic lesions of adnexa are identified. In the Epithelial tumors of ovary: 9 Benign forms are presented as Serous adenoma and Mucinous adenoma [6]; 7 Malignant cases are presented as Serous cystadenocarcinoma [5], Mucinous cystadenocarcinoma [1] and Endometrioid cancer [1]. Among Germ cell tumors, 5 Malignant cases are presented as Dysgerminoma (4), Mixed Germ cell tumor [1]; 3 Benign cases are identified as Mature teratoma. In the Sex cord stromal tumor, 2 Malignant cases are identified: Granulosa cell tumor [1], Signet ring type [1] and 1 Benign Fibroma case is presented.

One [1] Metastatic tumor is identified which is GIST from stomach and One [1] Fallopian tumor is identified. Other- [2] Pedunculated fibroids are identified.

IOTA correctly identified all malignant lesions and showed excellent specificity in excluding benign lesions. In contrast, RMI-2 showed lower sensitivity and specificity, with more false positive and false negative results.

RMI-2 correctly identified 13 malignant cases, falsely classified 7 benign cases as malignant, and missed 3 malignant cases, thereby showing lower overall predictive performance than IOTA.

**Discussion**

Preoperative evaluation of adnexal masses is crucial for proper triage, as management depends on distinguishing benign from malignant lesions. This study found IOTA Simple Ultrasound Rules performed significantly better than RMI-2.

Most patients were of reproductive age and had benign lesions, consistent with epidemiological trends where benign masses are common in younger women and malignancies in postmenopausal women.

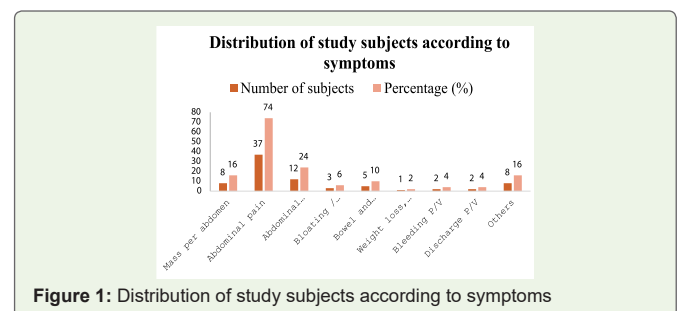


Figure 1: Distribution of study subjects according to symptoms

Table 1: Distribution of benign and malignant study subjects according to age, obstetric history and menopausal status. (N=50)

S. No	Factor	Benign (n=34)	Malignant (n=16)
		Number (%)	Number (%)
1.	Age (Yrs)		
	11-25 yrs (n=6)	3 (8.82)	3 (18.75)
	26-40 yrs (n=29)	25 (73.52)	4 (25)
	41-55 yrs (n=12)	6 (17.64)	6 (37.5)
	> 55yrs (n=3)	0	3 (18.75)
2.	Obstetric History		
	Nullipara (n=26)	17 (50%)	9 (56.25%)
	Primipara (n=14)	12 (35.29%)	2 (12.5%)
	Multipara (n=10)	5 (14.70%)	5 (31.25%)
3.	Menopausal Status		
	Premenopausal (n=35)	30 (88.23%)	5 (31.25%)
	Postmenopausal (n=15)	4 (11.76%)	11 (68.75%)

Table 2: Diagnostic performance of IOTA Simple Rules and RMI-2

Parameter	IOTA Simple Rules	RMI-2
Sensitivity (%)	100	81.25
Specificity (%)	96.8	79.4
Positive Predictive Value (%)	93.75	65
Negative Predictive Value (%)	100	90

**Table 3:** HPE Distribution of study subjects and comparison of RMI 2 with IOTA Simple USG Rules

Sr. No	HPE Diagnosis	Number of Subjects	Number of subjects correctly identified by IOTA	Number of Subjects correctly identified by RMI 2
1.	Non-neoplastic lesions of adnexa	14	13	11
2.	Epithelial tumors	17	14	9
2a.	Benign	9	7	2
2b.	Malignant	7	7	7
2c.	Borderline	1	0	0
3.	Germ cell tumors	8	8	5
3a.	Benign	3	3	1
3b.	Malignant	5	5	4
4.	Sex cord stromal tumors	3	2	1
4a.	Benign	1	1	1
4b.	Malignant	2	1	0
5.	Metastatic tumors	1	1	1
6.	Inflammatory / infective lesions	4	4	4
7.	Fallopian tube tumors	1	1	1
8.	Others (Pedunculated fibroid)	2	2	2

Abdominal pain was the most common symptom, followed by distension and lump, aligning with literature that adnexal masses often present with nonspecific symptoms that can delay diagnosis.

In the current study, IOTA Simple Rules achieved 100% sensitivity and 96.8% specificity, with PPV 93.75% and NPV 100%. These findings indicate that IOTA is highly effective in both detecting malignancy and ruling out benign lesions. The high negative predictive value is particularly important in clinical practice, as it can help avoid unnecessary radical surgical intervention in benign conditions.

By contrast, RMI-2 demonstrated 81.25% sensitivity and 79.4% specificity, with a lower PPV of 65% and NPV of 90%. This comparatively reduced performance may be due to the dependence of RMI-2 on CA-125, which is known to be elevated in a variety of benign gynecological and inflammatory conditions such as endometriosis, pelvic inflammatory disease, fibroids, and even menstruation, thereby reducing specificity.

IOTA performed better in this study likely due to its detailed ultrasound assessment of lesion features, such as architecture, papillary projections, multilocularity, acoustic shadows, solid areas, and ascites, making it more reflective of tumor biology than composite scores.

Similar results have been reported in several studies. Bamniya et al. concluded that IOTA Simple Rules outperform the RMI-2 scoring system in terms of diagnostic accuracy and reliability. Likewise, Pandey et al. compared IOTA with RMI-3 and reported that IOTA showed better predictive ability in evaluating adnexal masses among both premenopausal and postmenopausal women. Samal et al. also demonstrated that IOTA models provide improved diagnostic performance compared with RMI in predicting ovarian malignancy.

These findings align with previous studies showing IOTA models

outperform RMI in evaluating adnexal masses, supporting IOTA Simple Rules as a more reliable first-line preoperative tool.

Clinically, IOTA Simple Rules are particularly useful in tertiary care and settings requiring early malignancy detection and timely referral to gynecologic oncology.

## Conclusion

The present study concludes that both IOTA Simple Ultrasound Rules and RMI-2 are useful tools for the preoperative assessment of adnexal masses. However, IOTA Simple Rules demonstrated superior diagnostic accuracy when compared with RMI-2, using histopathological examination as the gold standard.

IOTA showed:

- Higher sensitivity
- Higher specificity
- Better positive predictive value
- Excellent negative predictive value

Therefore, IOTA Simple Ultrasound Rules can be recommended as a more accurate, simple, and reliable method for differentiating benign and malignant adnexal masses in routine gynecological practice.

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