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Original Research Article

# Assessment of risk of malignancy index scoring and histopathological correlation in the diagnosis and management of adnexal mass

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ABSTRACT

**Introduction**: Pathologies of adnexal masses are commonly benign. The malignant lesions of adnexa carries a very low five-year survival rate, and hence the early recognition need to be done. There is no single gold standard investigation for the diagnosis of the malignancy of the adnexa. Risk of Malignancy Index (RMI) scoring system, combines the Serum CA 125(U/ML), Ultrasound score (U) and the menopausal status(M).

**Objectives**: To assess the efficiency of Risk of Malignancy Index-3 (RMI-3) scoring system in discriminating benign and malignant adnexal mass, for early detection and management of malignant ovarian mass.

**Materials and Methods**: This is a prospective, observational study, among 50 female patients above the age of 25 years, diagnosed with adnexal mass under the Department of obstetrics and gynaecology, Government Rajaji Hospital, affiliated to Madurai Medical College, Madurai.

All the study participants were subjected to detailed history taking, thorough clinical examination, ultrasonogram of abdomen and pelvis, and markers such as CA 125. Risk of Malignancy Index was calculated and correlated with the histopathological (HPE) findings of the excised tumours.

**Results**: When the cut off of RMI score for predicting malignancy is 149.2 which had a sensitivity of 79.2%, specificity of 92.3%, positive predictive value of 90.47%, negative predictive value of 82.78% and a diagnostic accuracy of 86.01%.

**Conclusion**: Risk of Malignancy Index score is a simple tool, with a good diagnostic accuracy, hence it can be used as good screening tool for identification of the malignant lesions from the adnexal mass.



## 1. Introduction

Adnexa is the area next to the uterus containing ligaments, vessels, fallopian tubes, ovaries.[1] Adnexal masses are the growth near the uterus, usually in the ovary or fallopian tube. Adnexal masses includes commonly the ovarian cysts, ectopic (tubal) pregnancies, and tumours (benign or malignant).[2]

Adnexal masses are the fourth most common gynaecological cause for hospitalisation and 90% have benign characteristics.

Risk of malignancy found to be 13% in premenopausal women and 45% in postmenopausal women.[3,4] Adnexal masses represent a spectrum of conditions from gynaecological and non-gynaecological sources. They may be benign or malignant. The initial detection and evaluation of an adnexal mass requires a high index of suspicion. Appropriate lab and radiographic studies are required.[5]

The most common symptoms reported are abdominal pain, abdomen distension, bloating, urinary urgency, incontinence, weight loss. This requires further evaluation

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if it persists for more than 2 weeks or failure to respond to appropriate therapy.

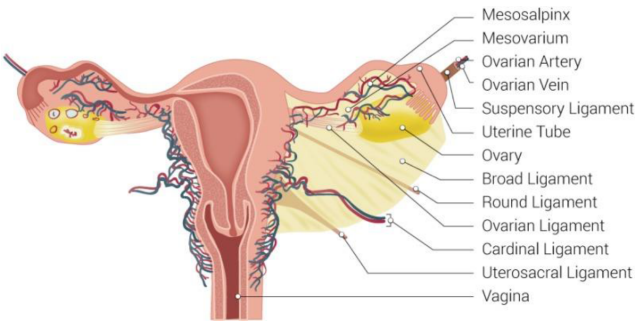


**Fig. 1:** Anatomy of the adnexa. Citation: "Gross Anatomy of the Female Reproductive System.". Lecturio.., .Web. 5 Dec. 2022 (https://app.lecturio.com/#/article/3847)

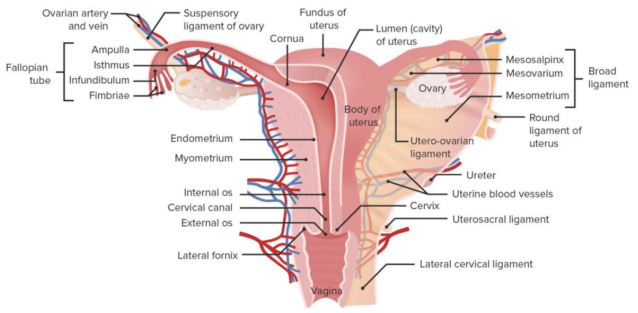


**Fig. 2:** Posterior view of the adnexa and the related structures. Citation: Gross Anatomy of the Female Reproductive System." Lecturio.., .Web. 5 Dec. 2022. (https://app.lecturio.com/#/article/3847)

The risk increases with age, with greater risks after menopause. Most of the patients present in an advanced stage for which 5 year survival rate remains very low. Hence, it is important to discriminate between benign and malignant nature of the adnexal mass at an earlier stage.[6,7]

Non-malignant adnexal masses can be managed, however prepubertal and postmenopausal women with adnexal masses should be evaluated earlier for a better prognosis. Hence, the goal is to differentiate between benign and malignant masses. CA-125 is a used as a screening tool for ovarian malignancy, elevated in almost 80% of ovarian cancer.[8]

CA-125 is a non-specific marker for ovarian malignancy, also elevated in other malignancies (endometrial cancer, germ cell tumour, cervical cancer, breast cancer, colon cancer, pancreatic cancer), pregnancy, pelvic inflammatory diseases, adenomyosis etc., It is found to be elevated in 1% of normal females.CA-125 levels less than 35 are considered to be within the normal limit.[8]

The sensitivity of CA 125 value is low. Not all malignant ovarian cancer was associated with elevated CA 125. It is useful for predicting the recurrence of ovarian tumour at earliest and in predicting the treatment effectiveness of patients undergoing chemotherapy for ovarian cancer.

Risk of malignancy index (RMI) is a parameter which is simple, easy to use, practical and highly sensitive, and more specific.

Risk of Malignancy Index is calculated from the three parameters by the following formula, "RMI=U * M *CA 125"

Risk of Malignancy Index (RMI) scoring system, combines the Serum CA 125(U/ML), Ultrasound score (U) and the menopausal status (M).

**Table 1:**

| **Parameters** | RMI 1 | RMI 2 | RMI 3 | RMI 4 |
|---|---|---|---|---|
| USG Criteria | | | | |
| No feature | 0 | 1 | 1 | 1 |
| 1 Feature | 1 | 1 | 1 | 1 |
| >2 Feature | 3 | 4 | 3 | 4 |
| Premenopausal | 1 | 1 | 1 | 1 |
| Postmenopausal | 3 | 4 | 3 | 4 |
| CA125 | - | - | - | - |
| Tumour size<7cm | - | - | - | 1 |
| Tumour size>7cm | - | - | - | 2 |

## 2. Aim and Objectives

To assess the efficiency of Risk of Malignancy Index-3 (RMI-3) scoring system in discriminating benign and malignant adnexal mass, and to compare the RMI 1 and RMI 4 Scoring for early detection and management of malignant ovarian mass.

### *2.1. Primary objectives*

To assess the efficiency of Risk of Malignancy Index-3 (RMI-3) scoring system in discriminating benign and malignant adnexal mass compared to the histopathological results.

### *2.2. Secondary objectives*

To study the usefulness of the RMI-3 Scoring for early detection and management of malignant ovarian mass.

Currently, the risk of malignancy index is a scoring system developed to improve the diagnostic accuracy of malignant ovarian tumour. Risk of Malignancy Index is based on Ultrasound score, Menopausal status and CA 125 level as follows, RMI score = Ultrasound score x Menopausal score x CA - 125 concentration.

**USG score**

Features of malignancy on ultrasound comprise of,

1. Irregular solid or multi-loculated cystic mass
2. Solid components on cyst wall

3. High-Doppler flow in solid components
4. Ascites, peritoneal-nodules, or other evidence of metastases

0 = no features of malignancy on ultrasound
1 = one feature of malignancy on ultrasound
3 = two or more features of malignancy on ultrasound
M score
1 = premenopausal
3 = postmenopausal

**Interpretation of RMI scores**

<25 - Low Risk - Repeat clinical assessment, with MRI if ultrasound features are borderline.

25 to 200 - Moderateor Intermediate Risk - MRI recommended.

>200 - High Risk - Referral to specialist gynaecological cancer service, and staging CT. [18,37]

## 3. Materials and Methods

### *3.1. Study subjects*

50 female patients above the age of 25 years, diagnosed with adnexal mass under the department of obstetrics and gynaecology, Government Rajaji Hospital, affiliated to Madurai Medical College, Madurai.

### *3.2. Study design*

Prospective, observational study.

### *3.3. Study period*

Data collection –1 year (2020 December to 2022 January).

### *3.4. Study setting*

Department of obstetrics andgynaecology, Government Rajaji Hospital, affiliated to Madurai Medical College, Madurai.

### *3.5. Sampling procedure*

Convenient sampling.

### *3.6. Inclusion criteria*

1. Female patients age above 25 years.
2. Both premenopausal and post-menopausal women.
3. All symptomatic individual diagnosed to have adnexal mass.

### *3.7. Exclusion criteria*

1. Age less than 25
2. Pregnant women
3. Patient on peritoneal dialysis
4. Patient who are not willing to give informed consent
5. Asymptomatic individuals.

### *3.8. Sample size*

The total sample size for the study is 50.

### *3.9. Ethical consideration*

Institutional Ethical Committee approval, from Madurai Medical College, Madurai, was obtained before the start of the study. Informed written consent was obtained.

### *3.10. Study procedure*

After obtaining the IEC approval, the patients who meet the inclusion criteria, were included in the study. Informed and written consent was obtained from each of the study participants. All the study participants were subjected to detailed history taking, thorough clinical examination, ultrasonogram of abdomen and pelvis, and markers such as CA 125. After pre-op evaluation, patients were taken up for surgery. Other investigations, such as complete blood count, Random blood sugar, renal function test, liver function test and histopathology were done.

Menopausal statuses were assessed. M=1 if premenopausal M=3 if postmenopausal.

Serum CA-125 and Ultrasound examination were performed.

A total ultrasound score U was calculated for each patients after assessing all 5 parameters. Ultrasound score was assigned U=1 if 0 or 1 criteria fulfilled and ultrasound score U=3 if 2 or more criteria fulfilled. RMI was calculated for all the patients.

Preoperative assessment was done for all patients. After a thorough preoperative evaluation and aesthetic fitness an informed written consent was obtained and the patients were taken up for laparotomy. After surgery, histopathological (HPE) findings of the excised tumours were analysed in order to determine the final diagnosis. Post-operative follow up were done at 3/6/12 month.

### *3.11. Budget*

Self. (No added investigation or intervention)

### *3.12. Statistical methods*

#### *3.12.1. Descriptive statistics*

1. Numerical variables like Age, CA-125 values, Blood investigation values etc, are represented in mean, SD, median, and mode. Histograms are used wherever necessary.
2. Categorical variables like benign/malignant nature of lesion on histopathology, RMI scoring, etc., are represented in frequencies and percentages. Pie-charts and bar diagrams are used as appropriate.

3. Data was entered in MS excel sheet and analysed using SPSS software version 16.

### *3.13. Inferential statistics*

1. Prediction of benign/malignant nature of the lesion by RMI scoring is compared with the presence of benign/malignant nature of lesion by histopathology, by the sensitivity, specificity, positive predictive value and negative predictive values. ROC curves were plot and diagnostic accuracy were represented.
2. P-values less than 0 05 were considered statistically significant.

## 4. Results

Results of the study, on efficiency of Risk of Malignancy Index (RMI) scoring system in discriminating benign and malignant adnexal mass compared to the histopathological results, is discussed.

**Table 2:** The mean age (years) among the subjects was 48.76 (± 13.06) years ranging from 23 to 72 years.

| **Age (years)** | |
|---|---|
| Mean | 48.76 |
| Median | 50 |
| Std. Deviation | 13.06 |
| Range | 49 |
| Minimum | 23 |
| Maximum | 72 |

**Table 3:** Among the subjects, 14 (28%) had <= 40 years followed by 14 (28%) had <= 40 years and least 10 (20%) had > 60 years

| **Age group** | **Frequency** | **Percent** |
|---|---|---|
| <= 40 years | 14 | 28.00 |
| 41 - 50 years | 12 | 24.00 |
| 51 - 60 years | 14 | 28.00 |
| > 60 years | 10 | 20.00 |
| Total | 50 | 100.00 |

**Table 4:** Menopausal score-among the subjects, 25 (50%) had score 1 and 25 (50%) had score 3

| **Menopausal Score** | **Frequency** | **Percent** |
|---|---|---|
| 1 | 25 | 50.00 |
| 3 | 25 | 50.00 |
| Total | 50 | 100.00 |

## 5. Discussion

This is a prospective, observational study, among 50 female patients above the age of 25 years, diagnosed with adnexal mass under the department of obstetrics and gynaecology, Government Rajaji Hospital, affiliated to Madurai Medical

**Table 5:** USG score-among the subjects, 27 (54%) had score 3 and 23 (46%) had score 1

| **USG score** | **Frequency** | **Percent** |
|---|---|---|
| 1 | 23 | 46.00 |
| 3 | 27 | 54.00 |
| Total | 50 | 100.00 |

**Table 6:** CA 125- The mean CA-125 level among the subjects was 77.81 (± 95.44) ranging from 4.5 to 350 U/m

| **CA-125 level (U/ml)** | |
|---|---|
| **Mean** | 77.81 |
| **Median** | 32 |
| **Std. Deviation** | 95.44 |
| **Range** | 345.5 |
| **Minimum** | 4.5 |
| **Maximum** | 350 |

**Table 7:** RMI Score- The mean RMI score among the subjects was 487.43 (± 793.37) ranging from 4.5 to 315

| **RMI score** | |
|---|---|
| **Mean** | 487.43 |
| **Median** | 117.5 |
| **Std. Deviation** | 793.37 |
| **Range** | 3145.5 |
| **Minimum** | 4.5 |
| **Maximum** | 3150 |

**Table 8:** Among the subjects, 14 (28%) had Serous Cystadenoma Carcinoma followed by 7 (14%) had Benign Serous Cystadenoma and least 1 (2%) had Clearcell Tumour

| **Histopathological diagnosis** | **Frequency** | **Percent** |
|---|---|---|
| **Benign Serous Cystadenoma** | 7 | 14.00 |
| **Clear cell Tumour** | 1 | 2.00 |
| **Dermoid Cyst** | 3 | 6.00 |
| **Endometrioid Adeno Carcinoma** | 3 | 6.00 |
| **Endometrioma** | 1 | 2.00 |
| **Fibroma** | 1 | 2.00 |
| **Fibrothecoma** | 2 | 4.00 |
| **Follicular Cyst** | 4 | 8.00 |
| **Granulosa Cell Tumour** | 1 | 2.00 |
| **Mature Cystic Teratoma** | 2 | 4.00 |
| **Mucinous Cystadenoma** | 5 | 10.00 |
| **Mucinous Cystadenoma Carcinoma** | 4 | 8.00 |
| **Serous Cystadenoma** | 2 | 4.00 |
| **Serous Cystadenoma Carcinoma** | 14 | 28.00 |
| **Total** | 50 | 100.00 |

**Table 9:** Among the subjects, 26 (52%) had Benign and 24 (48%) had Malignant tumours

| Tumour type | Frequency | Percent |
|---|---|---|
| Malignant | 24 | 48.00 |
| Benign | 26 | 52.00 |
| **Total** | 50 | 100.00 |

**Table 10:** Comparison of age group with the tumour type

| Age group | Tumour type | | Total | Fisher exact p value |
|---|---|---|---|---|
| | Malignant | Benign | | |
| **<= 40 years** | 3 (21.42%) | 11 (78.57%) | 14 (100%) | |
| **41 - 50 years** | 7 (58.33%) | 5 (41.66%) | 12 (100%) | 0.01 |
| **51 - 60 years** | 7 (50%) | 7 (50%) | 14 (100%) | |
| **> 60 years** | 7 (70%) | 3 (30%) | 10 (100%) | |
| **Total** | 24 (48%) | 26 (52%) | 50 (100%) | |

**Table 11:** The mean RMI score among Malignant was 953.52 (± 949.17) which is higher by 896.33 and statistically significant compared to 57.19 (± 61.56) in Benign

| | Tumour type | N | Mean | Std. dev. | Mean diff. | p value by 't' test |
|---|---|---|---|---|---|---|
| **RMI score** | **Malignant** | 24 | 953.52 | 949.17 | 896.330 | 0.001 |
| | **Benign** | 26 | 57.19 | 61.56 | | |

**Table 12:**

| Test Result Variable(s) | Cut off | Sensitivity | Specificity | PPV | NPV | Accuracy |
|---|---|---|---|---|---|---|
| **RMI score** | 241.50 | 75.% | 100.00% | 100.00% | 81.25% | 88% |
| | 149.20 | 79.20% | 92.30% | 90.47% | 82.78% | 86.01% |
| | 111.50 | 83.30% | 76.90% | 76.90% | 83.30% | 79.97% |

College, Madurai. All the study participants were subjected to detailed history taking, thorough clinical examination, ultrasonogram of abdomen and pelvis, and markers such as CA 125.

Risk of Malignancy Index was calculated and correlated with the histopathological (HPE) findings of the excised tumours.

The main objective of the study is to assess the efficiency of Risk of Malignancy Index-3 (RMI-3) scoring system in discriminating benign and malignant adnexal mass, for early detection and management of malignant ovarian mass.

The mean RMI score observed among the Malignant lesions was 953.52 (± 949.17) which is higher by 896.33 and statistically significant compared to 57.19 (± 61.56) in Benign lesions.

## 6. Results

The study population comprise of 50 female patients above the age of 25 years, diagnosed with adnexal mass under the Department of obstetrics and gynaecology, Government Rajaji Hospital, affiliated to Madurai Medical College.

### *6.1. Risk of malignancy parameters and diagnosis*

1. **Menopausal Score:** Among the subjects, 25 (50%) had score 1 and 25 (50%) had score 3.
2. **USG score:** Among the subjects, 27 (54%) had score 3 and 23 (46%) had score 1.
3. **CA-125 level:** The mean CA-125 level among the subjects was 77.81 (±95.44) ranging from 4.5 to 350 U/ml.
4. **RMI score:** The mean RMI score among the subjects was 487.43 (± 793.37) ranging from 4.5 to 3150.
5. **Histopathological diagnosis:** Among the subjects, 26 (52%) had Benign and 24 (48%) had Malignant tumours. Among the subjects, 14 (28%) had Serous Cystadenoma Carcinoma followed by 7 (14%) had Benign Serous Cystadenoma and least 1 (2%) had Clear cell Tumour.

### *6.2. Comparision of RMI score and its parameters with the tumour type*

1. **Comparision of menopausal Score with the tumour type:** 32% of the subjects with score 1 were malignant type which is lower compared to subjects with score 3 of whom 64% were malignant type and the difference was statistically significant ($p < 0.05$).
2. **Comparision of USG score with the tumour type:** 17.39% of the subjects with score 1 were malignant type which is lower compared to subjects with score 3 of whom 74.07% were malignant type and the difference was statistically significant ($p < 0.05$).
3. **RMI score with tumour type:** The mean RMI score among Malignant lesions, which was 953.52 (± 949.17) which is higher by 896.33 and statistically significant compared to 57.19 (± 61.56) in Benign lesions.

### *6.3. Accuracy of predicting malignancy using RMI score*

The area under the curve for RMI score in predicting malignancy is 0.905(0.819 - 0.991).

When the cut off of RMI score for predicting malignancy is 241.5 which had a sensitivity of 75%, specificity of 100%, positive predictive value of 100%, negative predictive value of 81.25% and a diagnostic accuracy of 88%.

When the cut off of RMI score for predicting malignancy is 111.5 which had a sensitivity of 83.3%, specificity of 76.9%, positive predictive value of 76.9%, negative predictive value of 83.3% and a diagnostic accuracy of 79.97%.

When the cut off of RMI score for predicting malignancy is 149.2 which had a sensitivity of 79.2%, specificity of 92.3%, positive predictive value of 90.47%, negative predictive value of 82.78% and a diagnostic accuracy of 86.01%.

By using Binomial regression, for each unit increase in RMI score, the odds of getting malignancy increases by 1.01 times which is statistically significant.

## 7. Conclusion

The mean RMI score among Malignant lesions, which was 953.52 (± 949.17) significantly higher, compared to 57.19 (± 61.56) in Benign lesions. The area under the ROC curve for RMI score in predicting malignancy is 0.905 (0.819-0.991). When the cut off of RMI score for predicting malignancy is 149.2 which had a sensitivity of 79.2%, specificity of 92.3%, positive predictive value of 90.47%, negative predictive value of 82.78% and a diagnostic accuracy of 86.01%.

Risk of Malignancy Index score is a simple tool, with a good diagnostic accuracy, hence it can be used as good screening tool for identification of the malignant lesions from the adnexal mass.

## 8. Source of Funding

None declared.

## 9. Conflict of Interest

None declared.

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