

## Original Article

# The Accuracy of Risk Malignancy Index in Prediction of Malignancy in Women with Adnexal Mass in Basrah, Iraq

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### ABSTRACT

**Background:** Adnexal masses indicate a variety of gynecological and nongynecological disorders, which may be benign or malignant. Early detection of malignancy is crucial to a proper planning of treatment and improvement of survival. **Objective:** To determine the accuracy of risk of malignancy index (RMI) in prediction of malignant adnexal mass. **Subjects and Methods:** This was a prospective multicenter study which included 101 women with adnexal masses. RMI2 with cutoff value of 200 was used to discriminate between benign and malignant tumors. Histopathological examination was used to confirm the final diagnosis. **Results:** Out of the studied women, 20.8% proved to have malignant tumors. The RMI showed a sensitivity of 100%, a specificity of 96.2%, a positive predictive value of 87.5%, and a negative predictive value (NPV) of 100%. The RMI identified malignant cases more accurately than any individual criterion in diagnosing ovarian cancer. The receiver operating characteristic analysis showed that the area under the curve of the RMI, CA 125, ultrasound, and menopausal status were significantly high with values of 1.0, 0.99, 0.86, and 0.85, respectively. **Conclusion:** The RMI is a simple sensitive, practical, and reliable tool in preoperative discrimination between benign and malignant adnexal masses that can facilitate selection of cases for timely referral to oncology center.

**KEYWORDS:** Accuracy, adnexal masses, Basrah, malignancy, prediction

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## INTRODUCTION

Adnexal masses indicate a variety of disorders from gynecologic and nongynecologic causes; they may be benign or malignant. The initial detection and evaluation of an adnexal mass necessitate a thorough history, physical examination, and timely appropriate laboratory and radiographic investigations.<sup>[1,2]</sup>

The goal of evaluation of adnexal masses is to differentiate between benign or malignant conditions such as ovarian cancer. This is because early stage diagnosis leads to better planning of treatment and more acceptable prognosis.<sup>[3-7]</sup>

Ovarian malignancy is the principal cause of death from gynecologic malignancy worldwide.<sup>[8,9]</sup>

No one modality was sufficient to predict accurately the presence of an ovarian malignancy. Therefore, Jacobs *et al.*<sup>[10]</sup> established the risk of malignancy

index (RMI) which is called later RMI 1, calculated as the product of ultrasound, CA-125 (biochemical data), and menopausal status (demographic characteristic), for referral of patients with adnexal mass to gynecologic oncology centers. The RMI 1 was modified by Tingulstad *et al.*<sup>[11]</sup> in 1996 (RMI 2) and again in 1999 (RMI 3).<sup>[12]</sup> The three versions of the RMI have been confirmed retrospectively and prospectively in different clinical studies<sup>[13-15]</sup> where a cutoff value of 200 revealed the best judgment between benign and malignant pelvic masses, with high sensitivity and specificity levels (sensitivity 51%–90% and specificity 51%–97%). RMI 4 was presented by Yamamoto *et al.*<sup>[16]</sup> The main

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difference between RMI 1 and the other versions is that RMI 1 scores ultrasound finding as 0 when none of the ultrasound features were present whereas the other versions score absence of ultrasound features as 1.

The chief benefit of the four RMIs is that an unsophisticated scoring method can be pertained straightforwardly into practice for daily use without the insertion of costly or complicated procedures (such as computed tomography scan and magnetic resonance imaging). It can be useful in low-resource locations.<sup>[17]</sup>

The aim of this study was to find if the multiparametric RMI score could be used as useful tool to differentiate between benign and malignant tumors in women with adnexal masses. The prospective confirmation of the RMI is the leading step for the longstanding purpose of this study, which is to apply a risk scoring system in Basrah.

## SUBJECTS AND METHODS

The study was a prospective observational multicenter one done during January 2015–October 2015 at three major hospitals in Basrah (Basrah Maternity Hospital, Al-Mawnea Hospital, and Al-Fayhaa Hospital). Data were collected using a questionnaire form inquiring about information regarding women age and menopausal status. All women with adnexal masses, consecutively referred to the aforementioned hospitals for laparotomy during the study period, were included. The total number was 101 women, which represents the sample size. Pregnant women and known cases of ovarian cancers were excluded. The aim of the study was explained appropriately, and informed written consent was obtained from each patient before enrollment in the study.

A 2D ultrasound was performed transabdominally with a full bladder by specialized radiologists in these hospitals. Score was assigned for the following ultrasound features suggestive of malignancy: the presence of a multilocular cystic lesion, solid areas, bilateral lesions, ascites, and intra-abdominal metastases, scored as one point for each. A total ultrasound score (US) was thus calculated for each patient. Postmenopausal status was defined as  $\geq 1$  year of amenorrhea or age older than 50 years in women who had undergone hysterectomy.<sup>[18]</sup>

Serum samples were collected preoperatively, and serum CA-125 levels were measured using fluorescence enzyme immunoassay (Automated immunoassay analyzer AIA-360, Tosoh Bioscience, Japan) in accordance with the manufacturer's instructions.

RMI 2 was used because it was found to be reliable in differentiation between benign and malignant disease

by many investigators.<sup>[11,19,20]</sup> It is the product of M, CA-125, and US where M is the menopausal status, US is the ultrasound finding, and CA-125 is the serum level of CA-125.

The following five ultrasound features were sought and each one was given 1 point if present: bilaterality, multilocularity, solid areas, extraovarian tumors (evidence of metastases), and ascites. If the total of these points was 0 or 1; an ultrasound score of US = 1, whereas if the total of the points was 2 or more; a score of US = 4. For premenopausal women; M = 1, and for postmenopausal women; M = 4. The serum level of CA-125 was applied directly to the calculation.<sup>[11]</sup>

A cutoff value of 200 for RMI was used in this study because it was considered by many studies as the best discrimination value between benign and malignant pelvic masses due to its high sensitivity and specificity levels.<sup>[10,13,15,21]</sup> The histopathological diagnosis was considered as the gold standard for definite outcome.

The Ethical Committees of College of Medicine, University of Basrah, and Barah General Health Directorate approved the study.

## Statistical analysis

Statistical software SPSS (IBM Corp., Chicago, Illinois, USA) v. 20 was used for data input and analysis. Quantitative variables presented as means with standard deviations. Discrete variables were presented as numbers and percentages. Chi-square test was used to test the significance of association between discrete variables. The difference in means of normally distributed variables between 2 groups was assessed by *t*-test. Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of RMI were determined. Sensitivity was calculated as the proportion of true positives out of true positives + false negatives, specificity was calculated as the proportion of true negatives out of true negatives + false positives, PPV was calculated as the proportion of true positives out of true positives + false positives, and NPV was calculated as the proportion of true negatives out of true negatives + false negative. For all statistical analyses,  $P < 0.05$  was considered statistically significant.

## RESULTS

A total of 101 patients were enrolled in this study. According to the histopathological examination of the specimens, 21 (20.8%) were malignant and 80 (79.2%) were benign. The mean age of patients was  $41.4 \pm 13.5$  years ( $36.9 \pm 10.7$  for patients with benign tumors and  $58.4 \pm 8.4$  for patients with malignant tumors,  $P < 0.001$ ).

**Table 1: Comparison of basic characteristics of women with benign and malignant adnexal masses**

Variable	Patients with benign tumor (n=80)	Patients with malignant tumor (n=21)	Total (n=101)	P
Age, years (mean±SD)	36.9±10.7	58.4±8.4	41.4±13.5	<0.001
Menopausal status, n (%)				
Premenopausal	75 (93.8)	5 (23.8)	80 (79.2)	<0.001
Postmenopausal	5 (6.2)	16 (76.2)	21 (20.8)	
US features, n (%)				
None	28 (35.0)	0	28 (27.7)	<0.001
1	32 (40.0)	1 (4.8)	33 (32.7)	
≥2	20 (25.0)	20 (95.2)	40 (39.6)	
CA-125/IU	44.8±30.1	914.1±727.9		<0.001
RMI	42.6±30.1	6490.6±63.0		<0.001

SD=Standard deviation; US=Ultrasound score; RMI=Risk of malignancy index

**Table 2: The sensitivity, specificity, positive predictive value, and negative predictive value of the risk of malignancy index and other studied parameters**

	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
RMI ≥200	100	96.2	87.5	100
CA-125 (≥35 U/ml)	100	80	65.7	100
Postmenopausal	76.1	93.7	76.1	93.7
Ultrasound ≥2 features	95.2	75	50	98.3

PPV=Positive predictive value; NPV=Negative predictive value; RMI=Risk of malignancy index

**Table 3: The distribution of histopathological diagnosis and staging of cancers**

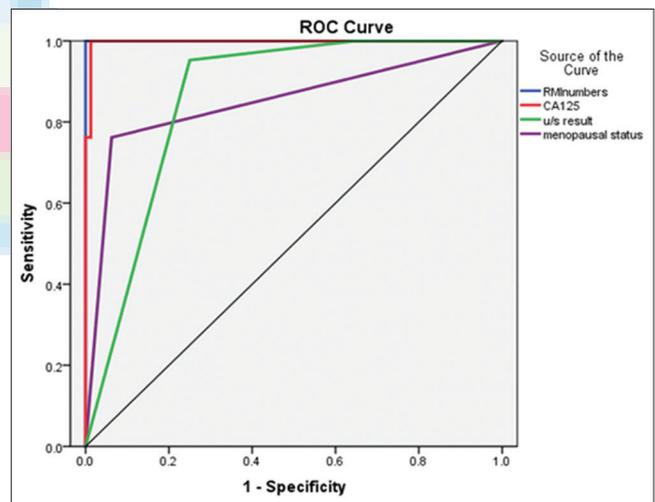
Histopathological diagnosis of malignancies	Stages of cancers	Number of the patients (%)
Mucinous adenocarcinoma	2, 4, 4, 2, 4, 4	6 (28.6)
Serous adenocarcinoma	4, 2, 4, 4, 2	5 (23.8)
Krukenberg tumor	4, 2, 3	3 (14.3)
Leiomyosarcoma	4, 4	2 (9.5)
Clear cell adenocarcinoma	2, 2	2 (9.5)
Germ cell tumor	3, 3	2 (9.5)
Endometrial adenocarcinoma	1	1 (4.8)

**Table 4: Histopathological classifications of benign tumors**

Histological diagnosis	n (%)
Dermoid cyst	23 (28.8)
Corpus luteum cyst	21 (26.2)
Simple cyst	16 (20.0)
Endometriosis	14 (17.5)
Fibroma	2 (2.5)
Paraovarian cyst	2 (2.5)
Tubo-ovarian abscess	2 (2.5)
Total	80 (100.0)

As shown in Table 1, highly significant differences were found between patients with benign and malignant tumors regarding all studied basic characteristics.

The RMI showed higher sensitivity and specificity than its components separately [Table 2].



**Figure 1:** Receiver operator curve showing the performance of risk of malignancy index, CA-125, ultrasound score, and menopausal status

As shown in Table 3, more than half of the cancers (52.4%) were either mucinous adenocarcinoma or serous adenocarcinoma. In addition, most of them were in advanced stage.

Table 4 shows the histopathological distribution of benign tumors. Dermoid cysts represent 28.8% of these tumors. While Corpus luteum and simple cysts constituted 26.2% and 20.0% of all benign tumors, respectively.

The receiver operating characteristic analysis of the RMI, CA-125, ultrasound, and menopausal status

showed that the values of area under the curve were significantly high with a value of 1.00, 0.99, 0.86, and 0.85, respectively ( $P < 0.001$ ) [Figure 1].

## DISCUSSION

Adnexal mass is one of the most frequent reasons for women to be referred to gynecological oncologist. The rate of malignancy of pelvic masses is about 24% in premenopausal women, and it increases to  $\geq 60\%$  in postmenopausal women.<sup>[6]</sup> In our study, 20.8% of the adnexal masses showed malignancy on histopathological examination (76.2% of them were in postmenopausal women). The results seem to agree with earlier reports of similar incidence rates and predominance in postmenopausal patients.<sup>[22]</sup> The mean age of the patients with adnexal masses in our study was  $41.4 \pm 13.5$  years ( $36.9 \pm 10.7$  years for women with benign tumors and  $58.4 \pm 8.4$  years for those with malignant tumors). The occurrence of ovarian cancer was reported to be rare before age of 40 years, but it increases steadily thereafter, and it reaches its peak at the age of 50–60 years.<sup>[23]</sup>

Our study showed that RMI 2 was reliable in preoperative discrimination between malignant and benign adnexal masses at cutoff value of 200. It yielded sensitivity and specificity of 100% and 96.2%, respectively, which were higher than that reported by other studies. Obeidat *et al.*<sup>[13]</sup> reported a sensitivity of 90% and specificity of 89%, while Håkansson *et al.*<sup>[24]</sup> reported sensitivity and specificity of 92% and 82%, respectively. During 2010, van den Akker *et al.*<sup>[21]</sup> reported sensitivity and specificity of 81% and 85%, respectively.

This study also revealed the superiority of RMI in detection of malignancy over the individual parameters; a result which had been found by others.<sup>[25]</sup>

The RMI is particularly sensitive to elevations of serum CA 125.<sup>[26]</sup> Elevated levels of CA 125 were found in  $>90\%$  of patients with advanced stage ovarian cancer but in only 50% of patients with Stage I disease.<sup>[27]</sup> Borderline malignancies that occur in younger women and mucinous cancers manage to have lower RMI scores compared to invasive malignancies and are consequently less detectable. The different characters, they exhibit, can clarify this. Therefore, they have low scores on both ultrasound and CA 125 levels.<sup>[17,26]</sup> While in this study, the late presentation of the patients with adnexal masses and after confirmation with histopathology, most of the malignancies showed stages two or more in which the RMI showed high scores of ultrasound and very high levels of CA 125. Hence, this may explain the high readings of RMI in our study.

A significant difference in serum level of CA 125 between patients with malignant and benign tumors was found in this study, a result that is similar to that reported by others,<sup>[8,13]</sup> with a sensitivity of 100% and specificity of 80% which are similar to that found in other studies.<sup>[28,29]</sup>

The specificity of CA 125 is expected to be lower in premenopausal patients. CA 125 levels fluctuate during the menstrual cycle, being the highest during menstruation. In addition, diseases such as endometriosis and pelvic inflammatory disease are more frequent in premenopausal women. These diseases are known to cause elevated CA 125 values.<sup>[29,30]</sup> In our study, 76.2% of the malignant tumors were in postmenopausal women, and about one-fourth (23.8%) of them were in premenopausal women.

Ultrasonography is universally regarded as good imaging technique for diagnosis of ovarian mass. In our study, an US of 4 had a sensitivity of 95.2% and NPV of 98.3% in prediction of malignancy. This result is higher than the sensitivity and NPVs reported by Aziz and Najmi<sup>[3]</sup> (78.3% and 96.1%, respectively), but Arun-Muthuvel and Jaya<sup>[31]</sup> reported higher sensitivity and specificity than our study (96.1% and 81%, respectively).

Although RMI seems to be a reliable method in discrimination between malignant and benign pelvic masses,<sup>[18,20,25]</sup> its utilization in the community depends on the inclination of clinicians to its usage and whether a considerable proportion of patients with suspected ovarian cancer will be referred to a gynecologic oncologist with appropriate expertise. To maximize its use, access of information for women and educational programs for health professionals are required.<sup>[17]</sup>

Some researchers reported that RMI is inadequate in detecting ovarian cancers in a population where nonepithelial ovarian cancer and borderline ovarian tumors are prevalent.<sup>[22,26]</sup> However, they suggest further validation of their results.

Some of the important advantages of RMI are its relative simplicity and applicability in assessment of patients with pelvic masses in nonspecialized gynecological units.<sup>[19,26]</sup> In addition to its potential role in discrimination between benign and malignant tumors, RMI provides a rational basis for referral of women with malignancy for effective surgical intervention.<sup>[32,33]</sup>

This study could be criticized for its small sample size including high proportion of patients with late stage cancer. Nevertheless, the results of our study are in line with that previously established, which suggest that

the RMI is a valuable tool and the method of choice for discrimination between malignant and benign adnexal masses particularly in developing countries.<sup>[3,34,35]</sup>

## CONCLUSION

Based on our results, we conclude that, in the absence of a definitive biomarker, the multipara metric risk of malignancy index should be reliable tool for assessment of a patient with adnexal mass before operation, and a cutoff point of 200 shows a very high sensitivity, specificity, positive, and NPVs for discriminating malignant and benign adnexal masses.

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## Conflicts of interest

There are no conflicts of interest.

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