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Evaluation of Risk Malignancy Index and Its Diagnostic Value in Patients with Ovarian Mass: A Prospective Study

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Keywords

RMI, Ovarian Malignancy, CA 125, Ultrasound Score

Abstract

Introduction: Discrimination between benign and malignant ovarian tumors is essential before planning their management. Risk malignancy index is a combined parameter based on CA 125 level, USG score and menopausal status Aim: The objective is to examine the demographic characteristics of ovarian tumors and evaluate the effectiveness of the RMI 2 cutoff in distinguishing between malignant and benign ovarian tumors. Methods: A prospective study was carried out at two government hospitals in Chennai, namely the Institute of Obstetrics and Gynecology Hospital in Egmore and the ISO Kasthurba Gandhi Hospital. Patient records were used to obtain demographic profiles. RMI is computed based on CA 125, USG score, and menopausal status, and the study involved determining the sensitivity, specificity, positive predictive value, and negative predictive value of RMI 2 using different cut-off values. Results: The study compared RMI values at various cut-off points, and the findings indicated that using an RMI cut-off value of 200 provided higher accuracy in predicting malignancy, with a sensitivity of 84%, specificity of 95%, positive predictive value of 84%, and negative predictive value of 95.7%. Conclusion: In our study, we found that the ideal cut-off point for distinguishing between benign and malignant ovarian masses is 200. Therefore, RMI proved to be a useful tool for distinguishing between benign and malignant ovarian masses. RMI is simple easy to calculate and helps selection of patients for referral to tertiary center

1. Introduction

"Ovarian cancer is the seventh cause of cancer deaths among women globally"[1]. Most of the patients are diagnosed at an advanced stage, which leads to poor outcomes. It is very essential to discriminate between benign and malignant tumors for accurate management

About 30% of ovarian tumors in postmenopausal women are malignant while only 7% of ovarian epithelial tumors in premenopausal women are malignant.

A thorough pelvic examination, ultrasound assessment and tumor markers are used in preoperative evaluation of ovarian mass. None of these methods individually are effective in diagnosing the disease.

"A combined scoring system was developed by Jacob et al"[(2)] in 1990, Risk Malignancy Index using CA 125, USG score and menopausal score. This was called RMI 1. "Later it was modified by Tingulstad et al[(3)] and was named RMI 2".

The purpose of this study is to study the demographic profile of ovarian tumors and thereby study the risk factors of ovarian malignancy. Assess the sensitivity and specificity of RMI 2 to discriminate benign and malignant ovarian masses

2. Materials And Methods

Between October 2020 and October 2021, this study was carried out at the Madras Medical College's Institute of Obstetrics and Gynecology and ISO KGH in Chennai

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Study design: Prospective study

Study population: 120 Patients with ovarian masses who were admitted to our hospital are included in the study.

Inclusion criteria:

Patients with ovarian mass planned for surgical intervention

Exclusion criteria:

- Age <15yrs
- Pregnancy with adnexal mass
- Patients not willing for surgery
- Non operable ovarian mass.

Following clearance from the institutional ethical committee, the study was carried out. The study's participants were given a thorough explanation of its purpose, and their written agreement was acquired.

At admission, detailed history elicited. General, physical,systemic, pelvic examination was performed.

An ultrasound examination was performed on the patient using a 3.5 MHz abdominal convex transducer when their bladder was full. Conversely, a 7.5 MHz vaginal probe was used for the exam when their bladder was empty. The following characteristics received an ultrasound score:

1. Bilaterality
2. Multi Loculations
3. Solid areas
4. Ascites
5. Metastasis

ULTRASOUND FEATURES	SCORING SYSTEM(U)
0 or 1 abnormality.	1
2 or more abnormality	4

5 ml of venous blood were drawn for the measurement of serum CA 125. Serum concentrations > 35U/ml of CA125 are considered abnormal in postmenopausal women. Radioimmunoassay was used to measure CA 125.

M = 1 denotes premenopausal status, whereas M = 4 denotes postmenopausal status. CA 125 levels will be substituted as such in the formula.

Once all parameters assessed RMI calculated using the formula

RMI : U * M * CA125

The RMI is computed, with histopathological diagnosis serving as the reference standard for defining the outcome. The sensitivity, specificity, positive predictive value, and negative predictive value of RMI will be assessed in relation to the actual existence of a benign or malignant tumor.

STATISTICAL ANALYSIS:

Chi-square tests were used to assess the data. Demographic information was summarized using descriptive statistics like mean with standard deviation or frequency with percentage. The Student's t-test was used in univariate studies to examine the connection between each parameter.

Afterwards, logistic regression was utilized to identify the independent correlation. The diagnostic performances of each test, in terms of sensitivity, specificity, positive predictive value, and negative predictive value, were provided along with a 95% confidence interval.

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3. Results

The study participants were then analyzed under the following headings:

1.Baseline characteristics of the study participants

2.Based on the ovarian marker classification 3.Based of RMI

First the study participants were classified into two study groups based on their histopathological classification:

TABLE 1: Distribution According to the Nature of Tumor in Hpe

Types of ovarian tumor	Number	Percentage
Benign	95	79.2%
Malignant	25	20.8%

About 21% had malignant lesions while majority 79% had benign pathology in our study

TABLE 2: Distribution of Age Among the Study Participants

Age category	Benign	Malignant	P value
21-30	18(18.9%)	1(4%)	<0.00001
31-40	51(53.7%)	2(8%)	
41-50	25(26.3%)	9(36%)	
51-60	1(1.1%)	13(52%)	
Total	95(100%)	25(100%)	

Age distributions in benign and malignant groupings differ from one another. It is determined that the difference is statistically significant.

TABLE 3: Body Mass Index Distribution of the Study Participants

Body Mass Index	Benign	Malignant	P value
Underweight	1(1.1%)	0	0.27
Normal	52(54.7%)	12(48%)	
Overweight	36(37.9%)	10(40%)	
Obese class	6(6.3%)	3(12%)	
Total	95(100%)	25(100%)	

In benign type both underweight 1(1.2%) and obese class 6(6.3%) were there in the study participants whereas in

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malignant only overweight 10(40%) and obese class 3(12%) were present. There is a difference between the body mass distribution but it is not statistically significant.

TABLE 4: Menopausal Status of the Study Participants

Menopausal status	**Benign**	**Malignant**	**P value**
Premenopausal	80(84.2%)	5(20%)	<0.0001
Postmenopausal	15(15.8%)	25(80%)	
Total	95(100%)	25(100%)	

The current study has revealed a noteworthy distinction between menopausal condition and the incidence of both benign and malignant illnesses.

TABLE 5: Usg Score of the Study Participants

USG Score	**Benign**	**Malignant**	**P value**
USG Score 1	76(80%)	6(24%)	<0.0001
USG Score 4	19(20%)	19(76%)	
Total	95(100%)	25(100%)	

The USG score of the benign and malignant groups differ from one another, and this difference is shown to be statistically significant.

TABLE 6: CA 125 CUT OFF OF THE STUDY PARTICIPANTS

CA125	Benign	Malignant	P Value
<35	59(62.1%)	2(8%)	<0.0001
>35	36(37.9%)	23(92%)	
Total	95(100%)	25(100%)	

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Between the benign and malignant groups, there is a difference in the distribution of the CA125 marker, and this difference is shown to be statistically significant.

TABLE 7: Comparison of Risk Malignancy Index for Index For Various Cut Offs

RMI	SENSITIVITY	SPECIFICITY	PPV	NPV
100	92%	82%	57.5%	98.7%
150	84%	87%	63.6%	95.4%
200	84%	95%	84%	95.7%
250	76%	97%	90.4%	94%

The discrimination of benign and malignant tumors was high with cut off 200.The specificity was highest with cut off 200. As the cut off of RMI increases the sensitivity also increases. The positive predictive value was found to be highest in cut off 200 and negative predictive value increases gradually as RMI cut off increases.

TABLE 8: Comparison of Different Parameters in Rmi

	SENSITIVITY	SPECIFICITY	PPV	NPV
Menopause	84.21%	84%	95.2%	84%
USG Score	80%	76%	92.6%	50%
CA125	62.1%	92%	96.7%	38.9%
Total	84%	95%	84%	95.7%

The RMI has both high negative and positive predictive values and great sensitivity. In both the USG score and the menopausal score, the sensitivity and specificity have reduced.

TABLE 9: Illustrates A Comparison Between and Previous Study

STUDY	SENSITIVITY	SPECIFICITY	PPV	NPV
Jacob et al	85%	97%	-	-

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Tingulstad 1996	71%	96%	89%	88%
Tingulstad 1999	71%	92%	69%	92%
Morgante et al(4)	58%	95%	78%	87%
Obeidat et al(5)	90%	89%	96%	78%
Manjunath et al(6)	73%	91%	93%	67%
Our study	84%	95%	84%	95%

4. Discussion

The aim of this study is to evaluate the role of RMI 2 in distinguishing malignant from benign ovarian mass. This was a prospective study conducted on 120 patients admitted with ovarian mass over a period of one year. 95 patients in the current study had benign pathology, while 25 patients had malignant pathology. This conveys 79% benign and 21 % malignant lesions. In our study, the incidence of malignancy peaked between the ages of 51 and 60, when 52% of participants had malignancy. Among the benign tumors, the peak age group was at 31 to 40yrs with 53.7%. Suggesting that the risk of malignancy increases with increased age. Old age is associated with advanced stage and low survival.84% of the post-menopausal women had malignancy while 16% of the premenopausal had malignancy.

Zhen liu et al(7) stated that the relationship between obesity and risk of ovarian cancer is related to menopausal status. Obesity before menopause had increased risk of malignancy .Leizman et al reported that obesity has increased risk of ovarian cancer and increased mortality for those affected. In our study, 12 % of the obese and 40% of overweight had malignancy.

Though ultrasound has high potential in discerning against malignant and benign tumors. But they are non specific if there is no volume , morphological features and are subject to the examiner's expertise. The outcomes of our research indicated that the Ultrasonographic score demonstrated a sensitivity of 76% and specificity of 80%, along with a positive predictive value of 50% and a negative predictive value of 92%. Difference in proportion of benign and malignant patients having USG score 4 (20% vs 90%) was statistically significant.

CA 125 with cut off 35 had a Sensitivity: 92% Specificity : 62% PPV : 50% NPV : 92.6%. These findings were similar to those of Rachmasari's studies, which reported a sensitivity of 81%, specificity of 60%, positive predictive value of 48%, and negative predictive value of 88%. The high false positive rate of ultrasound in premenopausal women is indicated as the limiting factor. CA 125 is unreliable in differentiating malignant from benign mass due to its high false positive rate and low specificity.

RMI translated the morphological features of ovarian mass into numerical data thereby reducing examiner bias. For each of the 120 patients included in the

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study, the RMI was computed using the formula. Among the 120 patients, with a RMI cutoff value of 200, 95 had benign tumors and 25 had malignant tumors. One of the aims of our study was to determine RMI cut off for discriminating malignancy for our population. To evaluate its efficacy, the sensitivity, specificity, positive predictive value, and negative predictive value of RMI were assessed for various cutoff levels (100, 150, 200, and 250). The RMI exhibited the highest sensitivity (92%) and negative predictive value (98.7%) at a cutoff level of 100. However, its specificity (82%) and positive predictive value (57.5%) were found to be low. With an increase in cutoff levels, the sensitivity of RMI decreases while its specificity increases. At a cutoff value of 250, RMI exhibited the highest specificity (97%) and positive predictive value (90.4%). "The sensitivity of the RMI was only 76%, which is considered low based on previous studies that have established a cut off value of 200" (7,8). However, our study found that the RMI performed significantly better at this cut off value, with a sensitivity of 84%, specificity of 95%, positive predictive value of 84%, and negative predictive value of 95.7%.

5. Conclusion

The differentiation between a benign and malignant ovarian tumor is a crucial aspect of the preoperative assessment of an ovarian mass. When a definitive biomarker is unavailable, the Risk of Malignancy Index (RMI) can provide a more accurate estimate for the diagnosis of ovarian masses and facilitate early referral to a gynecologic oncologist. RMI is a composite parameter that takes into account the patient's menopausal status, ultrasound score, and CA 125 level. In the current study, the ideal threshold value that effectively distinguishes between benign and malignant ovarian masses using the Risk of Malignancy Index (RMI) is 200.

Reference

[1] ParkinDM,BrayF,FerlayJ,PisaniP.Globalcancerstatistics,2002.CACancer Clin2005;55:74108

[2] Jacobs I, Oram D, Fairbanks J, Turner J, Frost C, Grudzinskas JG Br J Obstet

[3] Gynaecol. 1990 Oct; 97(10):922-9.

[4] The risk-of-malignancy index to evaluate potential ovarian cancers in local hospitals. Tingulstad S, Hagen B, Skjeldestad FE, Halvorsen T, Nustad K, Onsrud M Obstet Gynecol. 1999 Mar; 93(3):448-52.

[5] Morgante G, Marca AI, Ditto A, et al. Comparison of two malignancy risk indices based on serum CA-125, ultrasound score and menopausal status in the diagnosis of ovarian masses. Br J Obstet Gynecol. 1999;1999(106):524–527. doi: 10.1111/j.1471-0528.1999.tb08318.x

[6] Obeidat BR, Amarin ZO, Latimer JA, Crawford RA. Risk of malignancy index in the preoperative evaluation of pelvic masses. Int J Gynaecol Obstet. 2004;85(3):255–8

[7] A.P. Manjunath, K. Sujatha, and R. Vani, "Comparison of three risk of malignancy indices in evaluation of pelvic masses," Gynecologic Oncology, vol. 81, no. 2, pp. 225–229, 2001

[8] Ulusoy et al The risk of malignancy index in discrimination of adnexal masses, International J GynaecolObstet 2007 Mar,96(3)

[9] Sharadha, T.A. Sridevietal Ovarian masses changing clinicopathological trends J ObstetGynaecol India.2015 Feb ;65(1)34-38