DOI: https://doi.org/10.53350/pjmhs2023171666

ORIGINAL ARTICLE

Diagnostic Accuracy of Risk of Malignancy Index RMI in Patients with Adnexal Mass

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ABSTRACT

Background: Gynecological cancers often begin in the ovaries. Malignant pelvic masses may often be predicted using the Risk of Malignancy Index (RMI).

Objective: To evaluate the RMI for its ability to differentiate between benign and malignant adnexal masses.

Methods: A cross-sectional study in a gynecology and obstetrics OPD of Saidu Group Of teaching hospital,swat was carried out. 55 women who were hypothesized to have adnexal masses were included after informed consent. Each patient menopausal status, ultrasonography (USG) score and blood CA-125 level was measured. For every participant, the RMI was determined.

Results: Thirty-five of the recruited women had noncancerous adnexal mass, whereas twenty had cancerous ones. Benign adnexal mass was seen in 19 premenopausal women and 16 postmenopausal women, and in malignant adnexal mass there were 13 premenopausal women and 7 postmenopausal women. Participants' mean ages were 44 years for benign adnexal mass and 40 years for malignant adnexal mass. USG score and CA-125 have significant variation between the benign and malignant adnexal masses, with p value of 0.000. High sensitivity (80%) and specificity (71.3%), as well as positive (77.3%) and negative (74.7%) predictive values, were found for the RMI at a cut-off of <200 when used to differentiate between benign and malignant adnexal masses.

Conclusion: In conclusion, the RMI seems to be a trustworthy, easy, and cost-effective technique for clinical distinction between benign and malignant adnexal masses.

Keywords: adnexal mass, USG score, ovarian cancer, ovary malignancies

INTRODUCTION

There is a high incidence of ovarian cancer, making it a major health concern for women. Differentiating between benign and malignant tumors is an important part of any medical diagnosis. Ovarian cancer progresses asymptomatically, therefore the majority of women are detected when it is too late (1). There is a strong correlation between the quality of initial cytoreductive surgery and patient survival. Many women go to a doctor who performs poor surgery when treating advanced ovarian cancer (2). Twenty-five percent of gynecological cancers are caused by the ovary malignancies, and 50% of cancer-related deaths in women, occur in the female genital tract. Malignant ovarian tumors account for up to 60% of ovarian tumors in women who have passed menopause, and up to 24% of ovarian tumors in women who have not yet reached menopause (3, 4). Unfortunately, modern diagnostic methods are not always able to determine if a tumor is cancerous before surgery (5). Since the diagnosis of pelvic masses, such as ovarian cancer, by various techniques remained imprecise and ambiguous, Jacob et al. established an indicator termed risk of malignancy index [RMI] in 1990 based on serum level of CA125, menopausal state, and ultrasound findings. Before surgery, the RMI may be used to assess pelvic mass, and it has shown to be an accurate measure. A better ability to distinguish between benign and malignant pelvic tumors has been linked to the use of RMI in earlier research. Because of its high sensitivity and specificity, the RMI cut-off value of 200 is widely agreed upon as the best discriminator between benign and malignant pelvic mass (6, 7). Through combining serum CA-l25 levels, ultrasound morphology, and menopausal state, a "risk of malignancy index" has been shown to detect the chance of cancer in ovarian mass. RMI has been shown to be highly effective in the diagnosis of ovarian masses, with a sensitivity of 91.3% and specificity of 76.9%, in previous study (8). It is not always possible to tell before surgery whether a tumor is cancerous or benign using just existing diagnostic techniques, such as ultrasonography and serum levels. Because of this, RMI can be a fast, improved, specific, and sensitive approach for identifying ovarian tumors (9). Direct clinical use of this straightforward grading system is possible. The RMI is a grading system based on blood CA125, ultrasonographic characteristics of the ovarian mass, and menopausal state. Using the formula, we can determine RMI = Menopause x Ultrasound Characteristics x CA125 (10). The purpose of this research is to ascertain whether or not the Risk of Malignancy Index (RMI) is an effective and cost-efficient tool for making a preliminary diagnosis of malignancy in women presenting with ovarian masses prior to referring them to specialist centers for further therapy.

METHODOLOGY

It is a crossectional study carried out after the approval of ethical committee. Subjects were recruited from the outpatient Gynecology clinic Saidu Group Of teaching Hospital,swat , where they had been diagnosed with adnexal tumors during January 2020 to January 2022. Patients' written permission was first sought, and then a thorough medical and gynecological checkup was conducted thereafter. After that, either a transvaginal or transabdominal ultrasound was performed on the subjects. Sonographic morphological criteria, including bilaterality, solid regions, multilocularity, ascites, and metastases, were used to assess adnexal masses. If none or one of the ultrasound requirements were met, a score of U = 1 was given, whereas a score of U = 3 was given if two or more ultrasound criteria were met. Then the total score was calculated. The Serum Ca 125 level was determined from 5 ml of venous blood. Serum concentrations of CA-125 that are more than 35 U/ml are considered abnormal. The onset of menopause was recorded. If a woman hasn't had menstruation for a year or more, or if she's had a hysterectomy, she's considered to be in menopause. Premenopausal women were given a menopause score of M = 1, while postmenopausal women were given a score of M = 3. Tingulstad et al. 's Risk of Malignancy Index 1 (RMI 1) was used for this analysis (11). The RMI 1 was determined by multiplying U by M by CA 125. To distinguish between benign and malignant tumors, a cutoff threshold of 200 was established. Patients who did not meet the inclusion criteria were those who showed evidence of metastasis to the liver, spleen, or lungs.

The demographic and clinical was recorded in an Excel spreadsheet. Population characteristics, biochemical profiles, and ultrasound images were compared between those with benign and malignant adnexal masses using the t test for means and the Chi square test. The diagnostic accuracy of RMI was determined by

determining if it was able to distinguish between a malignant and benign adnexal mass. Predictive value of RMI was determined using ROC plots with cutoffs ranging from 25 to 1,000. SPSS version 26 utilized for the statistical analysis with p value ≤0.05 was considered significant.

RESULTS

Among the recruited participants 35 women had benign and 20 women had malignant adnexal mass. The classes of participants by age, menstrual status, USG score are presented in Table 1. 19 premenopausal and 16 postmenopausal women had benign adnexal mass, while 13 premenopausal and 7 postmenopausal women had benign adnexal mass. Mean ± SD of participants age in benign and malignant adnexal mass was 44±14.94 and 40.45±12.48, respectively, both masses have statistically significant (p=0.001) variation in the participants age (Table 2). Mean ± SD of participants menstrual status in benign and malignant adnexal mass was 1.91±1.01and 1.7±0.98, respectively, both masses have statistically significant (p=0.010) variation in the participants menstrual status (Table 2). Mean ± SD of participants USG score in benign and malignant adnexal mass was 1.68±1.28 and 3.4±1.32, respectively, both masses have statistically significant (p=0.000) variation in the participants USG score (Table 2). Mean ± SD of participants CA-125 in benign and malignant adnexal mass was 46.28±25.63 and 254.25±174.95, respectively, both masses have statistically significant (p=0.000) variation in the participants CA-125 levels (Table 2). Mean ± SD of participants RMI score in benign and malignant adnexal mass was 208.42±307.84 and 1763.6±2036.73, respectively, both masses have statistically significant (p=0.001) variation in the participants RMI score (Table 2). Different RMI cutoff values were utilized to generate the ROC curve shown in Fig. 3. High sensitivity (80%) and specificity (71.3%), as well as positive (77.3%) and negative (74.7%) predictive values, were found for the RMI at a cut-off of >200 when used to differentiate between benign and malignant adnexal masses. Further analysis revealed that an RMI cutoff of >200 was the most effective criteria for identifying ovarian malignant tumor in women with adnexal masses, and that the area under the curve (AUC) was high (0.86, 95% CI, 0.7399 to 0.9715) (Figure 1).

Table 1: Demographic and Clinical parameters of enrolled participants

Parameters	Benign (n=35)	Malignant (n=20)
Age		
<30	8(22.8%)	5(25%)
31-44	10 (28.5%)	7(35%)
45-54	7 (20%)	6(30%)
>55	10 (28.5%)	2 (10%)
Menstrual Status		
Premenopausal	19 (54.2%)	13(65%)
Postmenopausal	16(45.8%)	7(35%)
USG Score		
1	27(77%)	4(20%)
3	4(23%)	16(80%)

Table 2: Mean±S.D of participant's age, menstrual status, USG score, CA-125 and RMI score

	Benign	Malignant	P Value
Age			
Mean	44	40.45	
S. D	14.94	12.48	
Median	44	41.5	0.001**
Min	17	19	
Max	69	61	
Menstrual Status			
Mean	1.91	1.7	
S. D	1.01	0.98	
Median	1	1	0.010*
Min	1	1	
Max	3	3	
USG Score			
Mean	1.68	3.4	0.000****
S. D	1.28	1.23	
Median	1	4	
Min	1	1	
Max	4	4	
CA125			
Mean	46.28	254.25	
S. D	25.63	174.95	
Median	43	259	0.000****
Min	2	5	
Max	99	678	
RMI Score			
Mean	208.42	1763.6	
S. D	307.84	2036.73	
Median	76	1160	0.001***
Min	2	5	
Max	1188	8136	

DISCUSSION

Because it is usually detected at a late stage, ovarian cancer has the poorest prognosis of all gynecologic cancers. Ovarian cancer can only be diagnosed conclusively during a laparotomy. Ovarian tumors account for around 10% of all exploratory laparotomies performed on women (12, 13). Several methods, such as a single cutoff CA-125 level, a USG score, and Doppler USG parameters, have been explored and shown to be ineffective in detecting ovarian cancer at an early stage. Adnexal masses are still often diagnosed preoperatively using clinical impression and USG investigations. Nonetheless, gynecologists are frequently forced to do unscheduled procedures after discovering an unexpected discovery during an operation. Most doctors will employ a technique called RMI before operating to determine whether an adnexal growth is benign or cancerous (14).

The purpose of this research was to examine the diagnostic utility of the RMI in assessing and distinguishing benign and malignant adnexal masses in females. The RMI was employed as an index, determined from the US characteristics, menopausal state, and blood CA-125 values, for this study.

Numerous crucial and relevant insights have been gleaned from the current research, all of which point to the usefulness of the RMI evaluation in participants. However, the current research has several limitations due to the small size of the cohort, making comparisons with other studies challenging. On average, patients with malignant diseases were 40.5 years old, whereas those with benign diseases were 44 years old. Patients older than 50 years old constituted a significant proportion of those diagnosed with adnexal masses, according to previous research (14, 15). For women, the chance of OC increased with age, perhaps because more accumulated damage in cells with time leads to cancer (16).

In the current investigation, 64% of adnexal masses were found to be benign. Consistent with previous research on OMs, which found that 70-90% of OMs were benign and 12-20% malignant, our findings support the former (17, 18). Benign OMs were reported to be more prevalent than malignant OMs. For many years, ultrasound has been the go-to imaging method for defining and characterizing adnexal masses. When adnexal masses were found, vaginal ultrasound was often the most effective and primary imaging modality (19, 20). Malignant characteristics were seen in several adnexal, including a solid region, multilocularity, papillary characteristics, and irregular internal septations. According to data from the extensive international experience indicated that ultrasound adnexal masses evaluation accuracy was 90% (21). Multiple studies looked at the usefulness of US in analyzing adnexal masses to determine the likelihood of malignancy, and they all found that US had a high sensitivity, specificity, and positive predictive value (22). In light of this, the technique was advocated for use as the primary screening for determining whether or not patients with adnexal masses should undergo further evaluation for the possibility of cancer. Of note, the current investigation concluded that the US score for majority malignant patients was 4 (P=0.000). These results are similar with the findings of previous research (19, 20).

Patients with adnexal masses might benefit from using CA-125 as a biological marker for differential diagnosis and monitoring. CA-125 has been the subject of a plethora of research on its potential use in determining malignancy risk in women with adnexal masses. CA-125 readings seemed to be erroneous in early-stage ovarian cancer, with almost half of stage I patients having normal CA-125 values. Even in benign diseases, an abnormally high CA-125 level is possible (23). In addition, when used alone, CA-125 is useless for screening for early adnexal masses because to its poor sensitivity and specificity. However, CA-125 remains a popular biological tumor marker for the diagnosis of adnexal masses. The specificity of CA-125 alone is questionable, however it is much improved when combined with the RMI. This research found that 95% of patients with malignant ovarian tumors and 54.2% of individuals with benign adnexal masses had high levels of CA-125 expression (35 U/ml). This agreed with findings from similar investigations (24).

The predictive usefulness of the RMI at various cut-off values for the development of malignancy was evaluated in the current research. The optimal combination of sensitivity (80%), specificity (71.3), positive predictive value (77.31%), and negative predictive value (74.47%) was achieved by setting the threshold at <200. The current findings jibe with those of several other research, which have similarly shown that an RMI cutoff of <200 may serve as a quantitative criterion for classifying individuals with adnexal masses into two groups (benign vs. malignant) based on malignancy risk (25).

CONCLUSION

In conclusion, determining the RMI is the most effective means of determining the following diagnostic, treatment, and therapeutic methods for benign and malignant adnexal masses. Nonetheless, further investigation is needed because of the limited sample size in the current study.

REFERENCES

1. Mohammed ABF, Ahuga VK, Taha M. Validation of the Risk of Malignancy Index in primary evaluation of ovarian masses. Middle East Fertility Society Journal. 2014;19(4):324-8.
2. Rafii A, Halabi NM, Malek JA. High-prevalence and broad spectrum of Cell Adhesion and Extracellular Matrix gene pathway mutations in epithelial ovarian cancer. Journal of clinical bioinformatics. 2012;2(1):1-5.
3. Arun-Muthuvel V, Jaya V. Pre-operative evaluation of ovarian tumors by risk of malignancy index, CA125 and ultrasound. Asian Pacific Journal of Cancer Prevention. 2014;15(6):2929-32.
4. Jelovac D, Armstrong DK. Recent progress in the diagnosis and treatment of ovarian cancer. CA: a cancer journal for clinicians. 2011;61(3):183-203.
5. Aktürk E, Karaca RE, Alanbay İ, Dede M, Karaşahin E, Yenen MC, et al. Comparison of four malignancy risk indices in the detection of malignant ovarian masses. Journal of gynecologic oncology. 2011;22(3):177-82.
6. van den Akker PA, Aalders AL, Snijders MP, Kluivers KB, Samlal RA, Vollebergh JH, et al. Evaluation of the risk of malignancy index in daily clinical management of adnexal masses. Gynecologic oncology. 2010;116(3):384-8.
7. Bouzari Z, Yazdani S, Kelagar ZS, Abbaszadeh N. Risk of malignancy index as an evaluation of preoperative pelvic mass. Caspian journal of internal medicine. 2011;2(4):331.
8. Irshad F, Irshad M, Naz M, Asim Ikram M. Accuracy of "risk of malignancy index" in the preoperative diagnosis of Zovarian malignancy in post menopausal women. Rawal Med J. 2013;38:266-70.
9. Liaqat B. Diagnostic Accuracy of Risk of Malignancy Index (RMI) in Pre-Operative Evaluation of Ovarian Masses. Saudi J Med. 2021;6(10):343-7.
10. Disasa FA, Olika AK. Diagnostic Accuracy and Appropriate Cut Off Value of Risk of Malignancy Index in Preoperative Discrimination Between Malignant and Benign Ovarian Tumors: Prospective Cross-sectional Study. 2021.
11. Tingulstad S, Hagen B, Skjeldestad FE, Halvorsen T, Nustad K, Onsrud M. The risk-of-malignancy index to evaluate potential ovarian cancers in local hospitals. Obstetrics & Gynecology. 1999;93(3):448-52.
12. Jacobs IJ, Rivera H, Oram DH, Bast Jr RC. Differential diagnosis of ovarian cancer with tumour markers CA 125, CA 15-3 and TAG 72.3. BJOG: An International Journal of Obstetrics & Gynaecology. 1993;100(12):1120-4.
13. Ramya Krishnan R. A Prospective study to Evaluate the Risk Malignancy Index and Its Diagnostic Implications in Patients with Suspected Ovarian Mass: Madras Medical College, Chennai; 2022.
14. No G-tG. Management of suspected ovarian masses in premenopausal women. 2011.
15. Jha R, Karki S. Histological pattern of ovarian tumors and their age distribution. Nepal Med Coll J. 2008;10(2):81-5.
16. Hoffman BL, Schorge J, Schaffer J, Halvorson L, Bradshaw K, Cunningham F, et al. Endometrial cancer. Williams Gynecology. 2012;826.
17. McGuire V, Hartge P, Liao LM, Sinha R, Bernstein L, Canchola AJ, et al. Parity and Oral Contraceptive Use in Relation to Ovarian Cancer Risk in Older WomenParity, OC Use, and Ovarian Cancer Risk in Older Women. Cancer Epidemiology, Biomarkers & Prevention. 2016;25(7):1059-63.
18. Al-Musalhi K, Al-Kindi M, Ramadhan F, Al-Rawahi T, Al-Hatali K, Mula-Abed W-A. Validity of cancer antigen-125 (CA-125) and risk of malignancy index (RMI) in the diagnosis of ovarian cancer. Oman Medical Journal. 2015;30(6):428.
19. Liu J, Xu Y, Wang J. Ultrasonography, computed tomography and magnetic resonance imaging for diagnosis of ovarian carcinoma. European journal of radiology. 2007;62(3):328-34.
20. Valentin L, Ameye L, Jurkovic D, Metzger U, Lécuru F, Van Huffel S, et al. Which extrauterine pelvic masses are difficult to correctly classify as benign or malignant on the basis of ultrasound findings and is there a way of making a correct diagnosis? Ultrasound in Obstetrics and Gynecology: The Official Journal of the International Society of Ultrasound in Obstetrics and Gynecology. 2006;27(4):438-44.
21. Patel MD. Practical approach to the adnexal mass. Radiologic Clinics. 2006;44(6):879-99.
22. Rein BJ, Gupta S, Dada R, Safi J, Michener C, Agarwal A. Potential markers for detection and monitoring of ovarian cancer. Journal of Oncology. 2011;2011.
23. Nazneen T, Begum S, Mahmud T, Khatoon F, Islam F, Amatullah M. Preoperative Analysis of CA-I25 and its Relation with Histopathological Study in Ovarian Tumours. Mymensingh Medical Journal: MMJ. 2021;30(2):402-9.
24. Liao X-Y, Huang G-J, Gao C, Wang G-H. A meta-analysis of serum cancer antigen 125 array for diagnosis of ovarian cancer in Chinese. Journal of cancer research and therapeutics. 2014;10(7):222.
25. Chia YN, Marsden DE, Robertson G, Hacker NF. Triage of ovarian masses. Australian and New Zealand Journal of Obstetrics and Gynaecology. 2008;48(3):322-8.