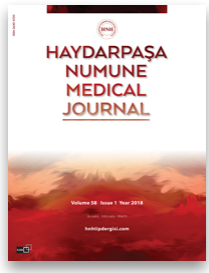
HAYDARPAŞA NUMUNE MEDICAL JOURNAL

DOI: 10.14744/hnhj.2024.70456
Haydarpasa Numune Med J 2024;64(4):472–478



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ORIGINAL ARTICLE

Predictive Value of Inflammatory Markers, Ca-125 Measurement, and Malignancy Risk Index Calculations in the Diagnosis of Endometrioma

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Abstract

Introduction: Adnexal mass is a frequently encountered problem in gynecology practice. Although ultrasonography is our main tool in distinguishing endometrioma cases, there is a need for methods that will provide preoperative prediction, especially in rare cases. For this reason, we aimed to investigate the predictive value of CA-125 level, inflammatory markers, and malignancy index calculations in the diagnosis of endometrioma.

Methods: In this study, 679 cases who were operated on, and diagnosed with an adnexal mass, at the Health Sciences University Haydarpaşa Numune Training and Research Hospital, Gynecology and Obstetrics Clinic, between 01.01.2010 and 30.06.2016, were retrospectively examined. The predictive value of CA-125, RMI, and inflammatory markers was investigated among these groups, which were divided into three groups: benign and malignant adnexal mass endometrioma patients.

Results: In the comparison of the three groups, CA-125 value, malignancy risk index calculations, and some hematological markers were found to be statistically significantly higher. In the subgroup analysis for CA-125; It was found in the comparison of endometrioma and benign masses (p=0.000), in the comparison of benign and malignant masses (p=0.000), and the distinction between endometrioma and malignant masses (p=0.004).

In the subgroup analysis for inflammatory markers, the NLR value was found to be significantly different in malignant and benign cases (p=0.000). The neutrophil count was significantly different in malignant and benign cases (p=0.005).

Discussion and Conclusion: CA125 levels were found to be sensitive but not specific in the diagnosis of endometrioma. There is a need for studies on modeling in which new algorithms are developed in which TV-USG findings are combined with hematological markers.

Keywords: Adnex; endometriosis; RMI; CA-125.

Adnexal masses are a commonly encountered issue in gynecological practice. Determining the malignancy risk of these masses and distinguishing between benign and malignant cases are essential, especially in evaluating patients with premenopausal endometriomas who desire fertility and need malignancy to be ruled out. Endometriosis is defined as the presence of endometrial glands and stroma outside the uterine cavity. Endometrioma, in contrast, is the accumulation of chocolate-like fluid within a pseudocyst resulting from the invagination of an endometriotic focus

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Submitted Date: 03.04.2024 **Revised Date:** 20.05.2024 **Accepted Date:** 26.05.2024
Haydarpaşa Numune Medical Journal

located in the ovarian cortex [1]. It is seen in approximately 10% of women of reproductive age [2]. Symptoms can vary widely, depending on the location of the endometriotic focus, and may include infertility, chronic pelvic pain, dysmenorrhea, dyspareunia, dyschezia, hematuria, or may present asymptomatically [3-5]. Endometriosis remains a chronic inflammatory, progressive, and insidious disease with a still debated etiopathogenesis [6]. Early diagnosis of the disease is crucial. In diagnosis, clinical history and physical examination are followed by imaging methods to confirm suspicion. Developing diagnostic procedures that can improve our preoperative predictions could allow for the early detection of this progressive disease in its initial stages.

Cancer Antigen-125 (CA-125) is an important parameter among tumor markers for differentiating between benign and malignant masses, as well as for diagnosing endometriosis. While the increase is more pronounced in malignant epithelial ovarian tumors, serum levels can also rise in various other physiological, inflammatory, and benign pathologies. Proper assessment of patients with premenopausal subfertile endometriomas who wish to preserve fertility and the exclusion of malignancy in these patients are crucial. Due to the low specificity of CA-125, Jacobs et al. developed a scoring system called the Risk of Malignancy Index (RMI) in 1990 by scoring patients' ultrasound findings, menopausal status, and CA-125 values [7]. Subsequently, Tingulstad et al. developed the RMI-2 and RMI-3 scoring systems [8,9]. RMI-4 was created by adding tumor size to the parameters [10]. In 2011, the Pelvic Mass Score (PMS) was defined by incorporating the vascularity status and resistance index of the adnexal mass into the parameters [11].

Although ultrasonography is our primary tool in differentiating endometrioma cases, there is a need for methods that can provide preoperative insights, especially in borderline cases. Therefore, we aimed to investigate the predictive value of CA-125 levels, inflammatory markers, and malignancy index calculations (RMI 1, 2, 3, 4) in the diagnosis of endometrioma.

Materials and Methods

This study retrospectively included 679 cases diagnosed with adnexal masses and operated on between January 1, 2010, and June 30, 2016, at the Department of Obstetrics and Gynecology, University of Health Sciences Haydarpaşa Numune Training and Research Hospital. Among these patients, 4 cases were excluded due to being under 18 years of age, and 6 cases were excluded because they were operated on under emergency conditions and lacked sufficient data. As a result, the study was conducted with 669 patients who underwent surgery for adnexal masses and for whom histopathological results were available. Patients with incomplete computer or hospital record data, those with a history of prior ovarian surgery, or those with known malignancy were excluded during the screening. Additionally, patients with known chronic illnesses, connective tissue diseases, hematological diseases, hemorrhagic cysts, ectopic pregnancies, tubo-ovarian abscesses, torsioned ovarian cysts, those under 18, patients with acute infections of adnexal masses, and those with a postoperative pathology report indicating non-gynecological causes were excluded from the study.

The age, parity, presenting complaints, ultrasound findings, preoperative diagnosis, tumor markers, and hemogram parameters of all cases were recorded. Menopausal status was defined as postmenopausal if one year had passed since the patient's last menstrual period.

Ultrasonographic imaging was performed using a Mindray DC7 ultrasound device with 5 MHz convex abdominal and 8 MHz vaginal probes. Malignancy risk index calculations were made based on ultrasound findings, the patient's CA-125 level, and menopausal status. Accordingly, the formula U x M x CA-125 was used to calculate RMI 1, 2, and 3 [7-9], where M represents menopausal status and U represents the ultrasound appearance. The CA-125 value was directly included in the calculation. In the RMI 4 calculation, tumor diameter was added to the formula (U x M x CA-125 x S) [10].

RMI-1 = (U x M x CA-125). Here, U = 0 (no ultrasound findings), U = 1 (one finding on ultrasound), U = 3 (two or more findings on ultrasound). M (premenopausal: 1 point, postmenopausal: 3 points).

RMI-2 = (U x M x CA-125). Here, U = 1 point (no ultrasound findings), U = 4 points (two or more findings). M = (premenopausal patient: 1 point, postmenopausal patient: 4 points).

RMI-3 = (U x M x CA-125). Here, U = 1 point (no ultrasound findings or only one finding), U = 3 points (two or more findings). M = (premenopausal patient: 1 point, postmenopausal patient: 3 points).

RMI-4 = (U x M x CA-125 x S), where the RMI-2 calculation is multiplied by the S factor (S = 1 if the tumor size is less than 7 cm, and S = 2 if greater than 7 cm).

For hemogram parameters (hemoglobin, hematocrit, lymphocyte, neutrophil, leukocyte, red cell distribution

width (RDW), mean platelet volume (MPV)), 2 ml of whole blood was collected in EDTA tubes. Complete blood counts taken within one week before surgery were included in the study. The NLR ratio was manually calculated by taking the neutrophil-to-lymphocyte ratio.

For CA-125, the venous blood sample was centrifuged at 4000 rpm for 3 minutes, and the resulting serum was analyzed using the Chemiluminescent Microparticle Immunoassay (CMIA) method on the Architect Abbott c 2000i Immunological Analyzer system.

Statistical Analysis: In this study, statistical analyses were performed using the SPSS (Statistical Package for Social Sciences) for Windows 21.0 software package. Continuous data were expressed as mean±standard deviation / median (minimum-maximum), and categorical variables were presented as frequency and percentage. The Kruskal-Wallis test was used for comparing more than two continuous variables, and the Dunn test was applied for post hoc analyses. ROC analysis was conducted to investigate the diagnostic value of RMI calculations and CA-125 levels for endometrioma cases. Sensitivity indicates the percentage of positive test results among the cases investigated, while specificity represents the percentage of negative test results among the cases investigated. Results were evaluated at a 95% confidence interval, with significance considered at $p<0.05$.

Ethics Committee approval was obtained on 12.12.2016 with decision number HNEAH-KAEK2016/116 (HNEAH-KAEK 2016/KK/116). Our study was conducted in accordance with the Declaration of Helsinki.

Results

The age range of patients included in the study was 14-87 years, with a mean age of 43.9±14.4 years. Of the cases, 18% had malignant adnexal masses (n=120), 21% had endometriomas (n=140), and 61% (n=406) had benign adnexal masses (Fig. 1). The presenting complaints of patients diagnosed with adnexal masses (n=679) were pelvic pain in 58% (n=398), routine check-ups in 11% (n=78), and vaginal bleeding in 10% (n=73). The demographic characteristics of the patients included in the study are presented in Table 1.

Among the cases, 30% (n=206) were in the postmenopausal period, while 69% (n=473) were in the premenopausal period. Examining the distribution of adnexal mass cases by menopausal status, the rate of malignant masses was 37% (n=77) in postmenopausal patients, compared to 9% (n=43) in premenopausal patients (Table 2).

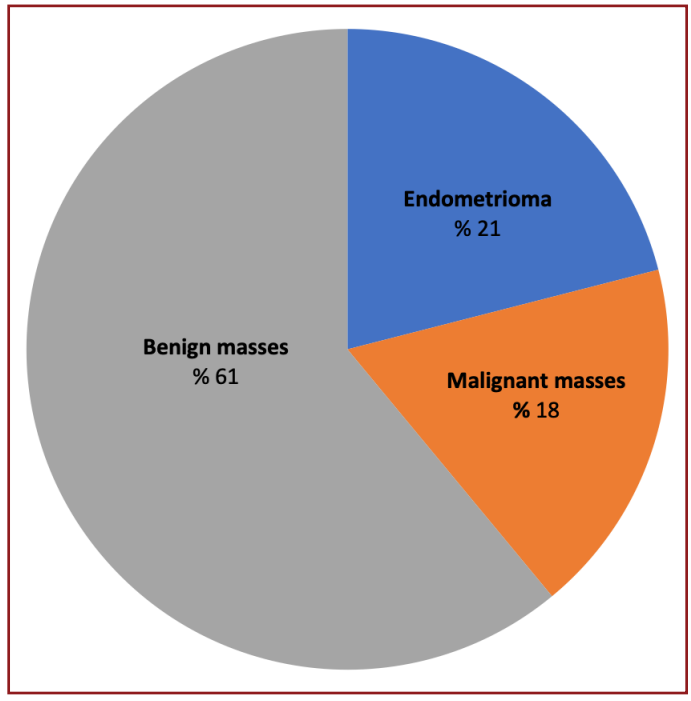


Figure 1. Distribution of Adnexal Masses Based on Pathology Results Included in the Study.

Table 1. Descriptive Characteristics of Patients Included in the Study

	n	Percentage (%)
Gravidity		
0	143	21.1
1	54	8.0
2 or more	482	71.0
Parity		
0	168	24.7
1	65	9.6
2 or more	446	65.7
Total	679	100.0
Spontaneous Abortion		
0	546	80.4
1	87	12.8
2 or more	46	6.8
Elective Curettage		
0	496	73.0
1	105	15.5
2 or more	78	11.5
Total	679	100.0
Menopausal Status		
Menopausal	206	30.3
Premenopausal	473	69.7

All cases were divided into three groups: benign, malignant, and endometrioma. The groups were compared in terms of CA-125 levels, malignancy risk index calculations (RMI 1, 2, 3, 4), and hematologic inflammatory markers. The

Table 2. Pathology of Adnexal Masses by Menopausal Status

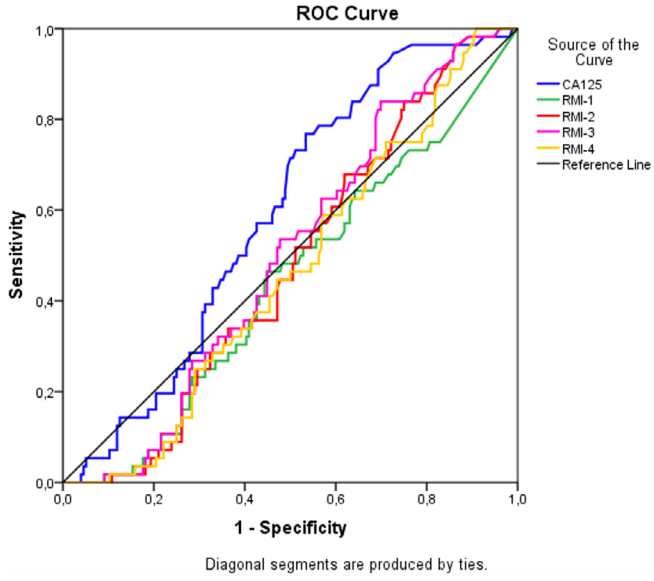
	Premenopausal Group	Postmenopausal Group	Total
Endometrioma	129	11	140
Malignant masses	43	77	120
Benign masses	290	116	406
Total	462	204	666

inflammatory markers compared included erythrocyte sedimentation rate, CRP, mean platelet volume (MPV), white blood cell count (WBC), platelet count, and neutrophil-to-lymphocyte ratio (NLR) (Table 3).

In the comparison of the three groups, CA-125 levels, malignancy risk index calculations (RMI 1, 2, 3, 4), and certain hematological markers (neutrophil count, platelet count, and NLR) were found to be significantly higher. Subsequent subgroup analysis was performed for the significant parameters. In the subgroup analysis for CA-125, significant differences were observed between endometrioma and benign masses (p=0.000), benign and malignant masses (p=0.000), and endometrioma and malignant masses (p=0.004).

In the subgroup analysis for inflammatory markers, the NLR value was significantly different between malignant and benign cases (p=0.000); however, no significant difference was found when comparing endometrioma cases with benign and malignant cases (p>0.05). Neutrophil count was significantly different between malignant and benign cases (p=0.005), but no statistical significance was observed when comparing endometrioma cases with benign and malignant cases (p>0.05). Platelet count was significantly different in comparisons between benign cases and both endometrioma cases (p=0.025) and malignant cases (p=0.000). However, there was no significant difference in platelet count between endometrioma and malignant cases (p>0.05).

In all RMI calculations (RMI 1, 2, 3, 4), differences were found



Parameter	AUC	Sensitivity	Specificity	p
CA-125 (U/ml)	0.59	0.76	0.46	0.039
RMI-1	0.44	0.46	0.55	0.190
RMI-2	0.47	0.96	0.13	0.587
RMI-3	0.49	0.83	0.30	0.975
RMI-4	0.46	1.00	0.09	0.394

Figure 2. ROC Analysis Results of RMI Calculations and CA-125 Values in Diagnosing Endometrioma.

Table 3. Comparison of Biochemical, Hematological, and RMI Values in Benign, Malignant, and Endometrioma Cases

	Benign Adnexal Mass (Mean±SD)	Endometrioma (Mean±SD)	Malignant Adnexal Mass (Mean±SD)	p
CA-125	95.2±126.7	311.4±642.8	1183.4±2408.4	0.000
Malignancy Risk Index				
RMI 1	178.1±326.2	178.1±326.2	6053.2±18060.9	0.000
RMI 2	327.8±506.5	327.8±506.5	10362.4±32086.2	0.000
RMI 3	219.0±363.6	219.0±363.6	6122.9±18149.8	0.000
RMI 4	464.2±674.8	464.2±674.8	18441.0±62685.6	0.000
Hematological Parameters				
Neutrophil count	4.9±1.71	4.9±1.7	98.6±701.8	0.006
Lymphocyte count	2.0±0.00	2.0±0.00	2.0±0.718	0.102
Platelet count	300846.1±66147.3	300846.1±66147.3	313884.1±97407	0.000
White blood cell count	8008.4±2287.5	7995.2±284.9	8289.5±2803.8	0.157
MPV (Mean Platelet Volume)	7.9±1.6	8.6±1.5	8.4±1.6	0.205
NLR (Neutrophil-to-Lymphocyte Ratio)	9.4±133.83	14.39±136.08	49.58±350.90	0.000
RDW (Red Cell Distribution Width)	18.2±8.2	18.2±8.2	18.1±7.5	0.277

in the comparisons between the malignant-endometrioma and malignant-benign groups (p=0.000). However, when comparing benign adnexal masses with endometrioma groups, no statistically significant difference was observed in RMI 1 and RMI 4 (p>0.05). In RMI 2 and RMI 3, significant differences were found in the comparison of all three groups (p<0.05).

A ROC analysis was performed to evaluate the diagnostic ability of RMI calculations and CA-125 levels for identifying endometrioma cases (Fig. 2). The AUC (Area Under the Curve) values for RMI calculations in diagnosing endometrioma were found to be very low: RMI 2 (AUC: 0.47, 96% sensitivity, 13% specificity), RMI 3 (AUC: 0.49, 83% sensitivity, 30% specificity). The CA-125 value showed an AUC of 0.59, with 76% sensitivity and 49% specificity.

Discussion

The preoperative differentiation of benign and malignant adnexal masses, which are frequently encountered in gynecological practice, is crucial for planning the surgical approach and referring the patient to appropriate centers when necessary. Specifically, the ability to predict endometrioma is essential for managing reproductive-age women who desire fertility preservation. This has led to the development of various diagnostic methods and algorithms in addition to ultrasonography. A review of the literature reveals that many researchers have utilized various sonographic variables, including Doppler analysis, to predict malignancy [11-13]. In a 2019 study, RMI-3 and the Pelvic Mass Score (PMS) were compared, and PMS was found to be statistically more valuable in detecting malignancy [14].

In this study, we investigated certain hematologic markers, various RMI types, and CA-125 levels to determine if they could help distinguish endometrioma cases from other benign and malignant adnexal masses. While hematologic inflammatory markers proved insufficient in differentiating endometrioma cases, a statistically significant difference was found when comparing CA-125 levels and RMI 2 and RMI 3 values between endometrioma cases and the benign and malignant groups. ROC analysis revealed low AUC values for the RMI 2 and RMI 3 models in predicting endometrioma: RMI 2 (AUC: 0.47, 96% sensitivity, 13% specificity) and RMI 3 (AUC: 0.49, 83% sensitivity, 30% specificity). Given that the RMI models were developed to differentiate malignant cases, there is a need for new models and algorithms specifically designed to distinguish endometrioma.

Although the ground-glass appearance in endometriomas or the focal or diffuse hyperechoic appearance in mature cystic teratomas are considered classic patterns, there are studies showing that subjective assessments in transvaginal ultrasonography (TV-USG) may yield false-negative results in the diagnosis of adnexal masses [15]. CA-125 levels, which increase in epithelial ovarian cancers, are also elevated in various non-malignant conditions, including endometriosis, uterine myomas, pelvic inflammatory disease, cirrhosis, obesity, tuberculosis, and cancers of the breast, endometrium, lung, and pancreas. Although it is not used as a standalone screening test in malignant cases, CA-125 is applied as an adjunct test and in patient monitoring. Similarly, CA-125 has been used for years in the diagnosis and monitoring of endometriosis. Kitawaki et al. reported that 10.6% of patients with endometriosis and 15.6% of patients with moderate to severe endometriosis had normal CA-125 serum levels [13]. In our study, CA-125 levels were statistically significantly different when comparing the malignant (1183.4±2408.4), benign (95.2±126.7), and endometrioma (311.4±64.8) groups. Subgroup analysis revealed that this significance was present across all groups. According to these findings, CA-125 levels in endometrioma cases were higher than in benign cases but lower than in malignant cases. A ROC analysis was performed to evaluate the predictive value of CA-125 levels for preoperative diagnosis of endometrioma, yielding an AUC of 0.59, with 76% sensitivity and 49% specificity. These results suggest that while CA-125 is a sensitive test for diagnosing endometrioma, it lacks specificity when used alone.

The neutrophil-to-lymphocyte ratio (NLR) and platelet-to-lymphocyte ratio (PLR) are parameters used to detect the presence of infection. Some studies have shown that NLR is a prognostic factor in colorectal and ovarian cancers [16,17]. In a study by Si-Hyun Cho et al. evaluating NLR as an adjunct to CA-125 in the diagnosis of endometriosis, NLR was found to be elevated in endometriosis patients, and sensitivity increased when assessed alongside CA-125 [18]. Consistent with the literature, our study also showed an increase in inflammatory markers in malignancy. In a study by Ali Yavuzcan et al., MPV, NLR, and PLR values were found to be unhelpful for identifying severe inflammation in advanced-stage endometriosis patients with proven cellular or molecular-level inflammation [19].

In our study, MPV values did not differ between groups, whereas NLR ratios were different. Endometrioma cases

had NLR levels lower than those in malignant cases but higher than those in benign masses. Subgroup analysis revealed that the increase in NLR was only significantly higher in malignant cases compared to benign cases, and there was no significant difference in distinguishing endometrioma cases from benign and malignant masses. While NLR appears to increase with malignancy as a reliable inflammatory marker, consistent with the literature, it does not serve as a distinguishing marker for endometrioma diagnosis.

Conclusion

An ideal diagnostic test should be both sensitive and specific. In light of current knowledge, there is no ideal preoperative predictive test available for diagnosing endometriosis. TV-USG and Magnetic Resonance Imaging (MRI) are currently the best diagnostic tools we have. However, due to the high cost and limited availability of MRI, there is an increasing need for supplementary methods that enhance the predictive value of TV-USG [20].

In conclusion, further studies are needed on models that combine TV-USG findings with hematologic markers to develop new algorithms for improved diagnostic accuracy.

Ethics Committee Approval: Ethics Committee approval was obtained on 12.12.2016 with decision number HNEAH-KAEK 2016/116 (HNEAH-KAEK 2016/KK/116). Our study was conducted in accordance with the Declaration of Helsinki.

Peer-review: Externally peer-reviewed.

Use of AI for Writing Assistance: Not declared.

Authorship Contributions: Concept: F.V., C.S.; Design: F.V., C.S.; Supervision: F.V.; Materials: C.S.; Data Collection or Processing: H.S., C.S.; Analysis or Interpretation: F.V., C.S., H.S.; Literature Search: C.S., H.S.; Writing: H.S.; Critical Review: F.V.

Conflict of Interest: None declared.

Financial Disclosure: The authors declared that this study received no financial support.

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