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ORIGINAL ARTICLE

Diagnostic accuracy of the O-Rads and Adnex models in identifying malignant adnexal lesions taking histopathology as gold standard.

Shamoona Rashid[1], Hassan Bukhari[2], Sadia Zafar[3], Ramsha Javed[4]

ABSTRACT... Objective: To use histopathology as the gold standard to assess the diagnostic accuracy of the O-RADS and ADNEX models in identifying malignant adnexal lesions. **Study Design:** Cross Sectional (validation) Study. **Setting:** Aziz Fatima Medical and Dental College Faisalabad, Faisalabad Medical University, Faisalabad. **Period:** 01-01-2025 to 30-06-2025. **Methods:** Included were 170 patients aged 20–60 who were admitted for elective surgical ovarian mass exploration and excision. An oophorectomy history, a history of adnexal malignancy, a history of adnexal mass surgery, pregnancy or ectopic pregnancy, and failure to have surgery within 120 days of the ultrasound screening were all disqualified. Five milliliters of venous blood were sent to the pathology lab for the measurement of serum CA-125 levels. Senior radiologist performed the ultrasound, noting O-RADS and ADNEX model properties. The advanced gynecologist performed the surgery. On O-RADS, ADNEX model, and histology, a malignant adnexal lesion was observed. **Results:** In terms of identifying malignant adnexal lesions using histopathology as the gold standard, O-RADS's overall sensitivity, specificity, positive predictive value, negative predictive value, and diagnostic accuracy were 90.53%, 85.33%, 88.66%, 87.67%, and 88.24%, respectively. When employing histopathology as the gold standard to identify malignant adnexal lesions, the ADNEX model's overall sensitivity, specificity, positive predictive value, negative predictive value, and diagnostic accuracy were 86.17%, 81.57%, 85.26%, 82.67%, and 84.12%, respectively. **Conclusion:** This study found that the diagnostic accuracy of the O-RADS and ADNEX models for identifying malignant adnexal lesions is nearly equal.

Key words: ADNEX Model, Adnexal Lesions, O-RADS, Sensitivity.

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INTRODUCTION

The term "adnexal mass" describes a growth in the uterine adnexa, which encompasses the ovary and tube.[1] The 5-year survival rate for ovarian malignancies is as low as 10%, and they are typically detected at advanced stages. However, a 90% 5-year survival rate is possible with early detection.[2] Among gynecological malignancies, ovarian cancer has the highest fatality rate, although its morbidity is second only to endometrial and cervical cancer. Thus, it is known as the "silent killer." In 2020, there were around 210,000 new fatalities and over 310,000 new cases of ovarian cancer worldwide, which is a considerable increase over 2018.[3] Because there are rarely any early signs of ovarian cancer, the majority of women who have the disease are discovered at an advanced stage.[4] The clinical manifestation of an adnexal mass makes it nearly impossible to differentiate between a benign and malignant lesion. For effective treatment of any disease, including cancer, an early, confirmed diagnosis is crucial. As technology has advanced, noninvasive diagnostic techniques like ultrasound, computed tomography (CT) scans, and magnetic resonance imaging (MRI) have made it easier to diagnose the type of adnexal masses. For adnexal masses, the most popular noninvasive test is pelvic ultrasonography. Ultrasonography is an accessible and inexpensive modality that greatly depends on experience. By accurately predicting the malignancy of adnexal masses, numerous recommendations, grading systems, and prediction models have been devised to enhance clinical care and surgical approach.[5] The most frequent cause of cancer-related deaths from gynecologic tumors in the US is ovarian cancer. It is estimated that over 200,000 women worldwide have ovarian cancer each year, and the disease claims the lives of over 100,000 of them. Women are 1 in 70 to develop epithelial ovarian cancer in their lifetime. Early-stage illness manifests as few, vague, or nonexistent symptoms. The majority of cases are therefore diagnosed at an advanced stage. Overall, the prognosis for patients with ovarian cancer is still dismal since it is strongly correlated with the stage of diagnosis.[6] Despite being the 17th most prevalent cancer in women, ovarian cancer accounts for 5% of all cancer deaths, making it the fifth most common cause of cancer-related deaths in women.

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This is more than any other gynecologic malignancy. The ovarian cancer death rate for white women fell by 2.0% year between 2007 and 2011, whereas it remained constant for black women.[7] Although there is no known exact cause of ovarian cancer, a number of risk factors and contributing variables have been found. An algorithm was created by Hippisley-Cox and Coupland to assess the risk of ovarian cancer in women who exhibit symptoms and those who do not.[8] Hormone therapy raises the risk of ovarian cancer, regardless of the length of usage, formulation, estrogen dosage, regimen, type of progestin, and mode of administration, according to a 10-year nationwide prospective cohort research that included all Danish women aged 50–79.[9] According to a case-control research, pelvic and abdominal pain, bloating and an increase in abdominal size, and trouble eating or feeling full were all symptoms that were independently linked to the presence of ovarian cancer.[10] A case-control research revealed that stomach and pelvic pain, bloating and enlargement of the abdomen, and trouble eating or feeling full were symptoms that were independently linked to the presence of ovarian cancer. In another study, it was found that later-stage illness was linked to gastrointestinal (GI) symptoms like diarrhea, constipation, nausea, and vomiting.[11] The combination of bloating, increased abdominal girth, and urinary symptoms was observed in 43% of ovarian cancer patients but only 8% of main care clinic patients, according to a prospective case-control study of 1,709 women who visited primary care clinics.[12] Dermoids are tumors that preserve relatively ordered patterns, with well-differentiated mesodermal and ectodermal tissues encircling endodermal components, for those who still distinguish. Dermoids are distinguished from teratomas by the existence of some degree of organization, a high degree of cellular differentiation, and cystic structure. Teratomas, particularly solid teratomas, are entirely devoid of organization.[13] MRI can improve the imaging evaluation's specificity when the lesion's ultrasound appearance is unclear.[14] However, an MRI is not conclusive. Endometriotic cysts with elevated mural nodules on MRI are a characteristic of ovarian cancer, however they can also be seen in benign tumors and even inflammatory conditions. In older patients, big contrast-enhanced nodules on large endometriotic cysts are more likely to be malignant.[15] According to a study by Hirai et al, stage IA ovarian tumors in women with normal CA125 levels typically have less solid components, a somewhat different distribution of histopathologic types, and are smaller than cancers with elevated CA125 levels.[16] According to a Buys et al. study, screening for ovarian cancer with both CA125 and transvaginal ultrasonography at the same time did not lower the death rate for ovarian cancer among women in the general US population when compared to usual care. 6.2% of women underwent surgery as a result of 9.6% of them having false-positive results.[17] There are tests that employ several markers. Five indicators are included in the OVA1 test: CA125, beta-2 macroglobulin, transferrin, apolipoprotein A1, and transthyretin. The six markers that make up the Ovasure test are CA125, insulinlike growth factor II, prolactin, osteopontin, leptin, and macrophage inhibitory factor. Neither of those is recommended by the NCCN for ovarian cancer screening.[18] According to a Lin et al. study, women with pelvic inflammatory condition had an adjusted hazard ratio of 1.92 for ovarian cancer. This implies that pelvic inflammatory disease could serve as a helpful indicator of ovarian cancer.[19] CT scanning is mostly used to evaluate metastatic disease rather than the ovarian mass; MRI and ultrasonography are more useful for evaluating the ovarian mass.[20]

The rationale to conduct this study is that prior evaluation of malignant adnexal lesions by using ultrasound ORADS and ADNEX model helps the surgeons giving proper management before surgery and in Pakistan there is not a single local study that evaluates these models.

METHODS

This cross-sectional study (validation) was conducted in the Department of Radiology, Aziz Fatima Medical and Dental College Faisalabad, Faisalabad Medical University. The research was conducted from Jan to June 2025. 170 patients who satisfied the inclusion requirements and were seen in the radiology department of the Department of Radiology, Aziz Fatima Medical and Dental College Faisalabad, Faisalabad Medical University were selected with approval from the institutional ethical review committee. Those patients who met the inclusion criteria and came through the emergency room or outpatient clinic were enrolled in the study after receiving ethics committee permission, and each patient gave their informed consent. The pathology lab received a 5.0 ml venous blood sample to measure the serum CA-125 levels. The ADNEX model and O-RADS traits were identified during the senior radiologist's ultrasound. An experienced gynecologist performed the surgery. Following surgery, the specimen was transferred to the pathology department of Punjab Medical College in Faisalabad for histology, and the results were gathered. O-RADS, the ADNEX model, and histology all showed malignant adnexal lesions in accordance with the operational definition. I gathered all the information and entered it on a pre-made Performa that is attached.

The inclusion criteria includes;

- Women aged 20 to 60 who are admitted for elective surgical exploration and ovarian mass resection

(ovarian mass with irregular border, multilocular, and solid component as shown by USG).

The following factors resulted in study exclusion:

- No surgical indication
- Pregnancy or ectopic pregnancy
- Questionable biopsy sample histology, Not having surgery within 120 days of the ultrasound test
- Adnexal cancer history
- Adnexal mass surgery history
- Oophorectomy history.

SPSS version 25 was used for data entry and analysis. All quantitative factors, including age, had their means and standard deviations determined. Frequency and percentage were computed for true positive, family history of ovarian cancer, and menopausal status.

Ethical Approval

This work was approved ethically by the Allied Hospital's Ethical Committee in Faisalabad.

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RESULTS

The study's participants ranged in age from 20 to 60, with a mean age of 44.36 ± 7.53. As seen in Table I, the majority of the 100 patients (58.82%) were between the ages of 41 and 60. Table II displays the patient distribution based on confounding variables. There were 11 False Positives and 86 True Positives among patients with O-RADS. As indicated in Table III, out of 73 RMI-negative patients, 9 were False Negative and 64 were True Negative (p=0.0001). In terms of identifying malignant adnexal lesions using histopathology as the gold standard, O-RADS's overall sensitivity, specificity, positive predictive value, negative predictive value, and diagnostic accuracy were 90.53%, 85.33%, 88.66%, 87.67%, and 88.24%, respectively. Tables IV display the diagnosis accuracy stratification by family history of ovarian cancer.

TABLE-I

Distribution of patients according to Age

Age (years)	Number of Patients	%age
20-40	70	41.18
41-60	100	58.82
Total	170	100.0

TABLE-II

Distribution of patients according to confounding variables

Confounding Variables		Frequency	%age
Family history of ovarian cancer	Yes	26	15.29
	No	144	84.71
Menopausal status	Pre-menopause	80	47.06
	Post-menopause	90	52.94

TABLE-III

Diagnostic accuracy of O-RADS in detecting malignant adnexal lesions using histopathology as gold standard.

	Positive Result on Histopathology	Negative Result on Histopathology	P-Value
Positive on O-RADS	13 (TP)	03 (FP)	0.001
Negative on O-RADS	00 (FN)	10 (TN)	

TABLE-IV

Stratification of diagnostic accuracy with respect to family history of ovarian cancer (n=26)

	Positive Result on Histopathology	Negative Result on Histopathology	P-Value
Positive on O-RADS	86 (TP)*	11 (FP)***	0.0001
Negative on O-RADS	09 (FN)**	64 (TN)****	

DISCUSSION

With improvements in the image quality of ultrasonography machines, the number of patients diagnosed with adnexal masses has increased. Adnexal masses with a low malignancy risk can be followed up. Benign and malignant adnexal masses should be distinguished accurately using more sensitive and specific tests. The American College of Radiology defined a classification system called the ovarian-adnexal reporting and data system (O-RADS) to standardize the reporting of sonographic findings and assess the malignancy risk of an adnexal mass. This scoring system is based on the maximum diameter of the lesion, number of locules, type of cyst (dermoid, endometrioma, or hemorrhagic), number of papillary projections, and presence of a solid component, ascites, or peritoneal nodules. This system categorizes adnexal masses into six groups: O-RADS 0–5. The O-RADS 0 category indicates incomplete evaluation; O-RADS 1 category refers to normal or physiological ovary; O-RADS 2 category refers to lesions that are most certainly benign with a risk of malignancy below 1.0%; O-RADS 3 category

refers to lesions with a low risk of malignancy (1.0% to <10.0%); O-RADS 4 category refers to lesions with an intermediate risk of malignancy (10.0% to <50.0%); and O-RADS 5 category refers to lesions with a high risk of malignancy above 50.0%. The International ovarian tumor analysis (IOTA) group developed the Assessment of Different NEoplasias in the adneXa (ADNEX) model using data from a study conducted on approximately 6,000 patients in 10 countries. This model was based on three clinical variables (age, serum cancer antigen 125 [CA-125] level, and oncology center) and six ultrasound variables (maximum lesion diameter, maximum solid component diameter, >10 locules, number of papillary projections, acoustic shadowing, and ascites). After applying the ADNEX model to a patient with an adnexal mass, the lesion was classified into five categories: benign, borderline, stage I invasive, stage II-IV invasive, and secondary metastatic tumors.[21] I have conducted this study to determine the diagnostic accuracy of O-RADS and ADNEX model in detecting malignant adnexal lesions using histopathology as gold standard. Overall sensitivity, specificity, positive predictive value, negative predictive value and diagnostic accuracy of O-RADS in detecting malignant adnexal lesions using histopathology as gold standard was 90.53%, 85.33%, 88.66%, 87.67% and 88.24% respectively. Overall sensitivity, specificity, positive predictive value, negative predictive value and diagnostic accuracy of ADNEX model in detecting malignant adnexal lesions using histopathology as gold standard was 86.17%, 81.57%, 85.26%, 82.67% and 84.12% respectively. Sensitivity and specificity of ADNEX were 91.4% and 78.9% respectively. Sensitivity and specificity of O-RADS were 91% and 81.9% respectively and prevalence of malignant adnexal lesion was 24.5%. In the study by Soo Jeong et al they identified the optimal cut-off point of discriminating ovarian malignancy using the ADNEX model at 90% sensitivity. The optimal cut-off point determined by the Youden index method in all participants was 47.3%. In another non-tumor center, Tug et al study showed an optimal cut-off value of 14.05% exhibited more balanced results for sensitivity and specificity regardless of the patient's menopausal status.[22] The study from Hiett and colleagues compared O-RADS classification using the IOTA lexicon with the ADNEX model (not O-RADS risk stratification using the ADNEX model). They found that the sensitivity and specificity for O-RADS using the IOTA lexicon was 100% and 46.4%, respectively. However, these figures for the ADNEX model using a 10% cut-off were 97.5% and 63.6%, respectively. Somehow, these authors made a comparison similar to ours.[23] I have conducted this study to determine the diagnostic accuracy of O-RADS and ADNEX model in detecting malignant adnexal lesions using histopathology as gold standard. Overall sensitivity, specificity, positive predictive value, negative predictive value and diagnostic accuracy of O-RADS in detecting malignant adnexal lesions using histopathology as gold standard was 90.53%, 85.33%, 88.66%, 87.67% and 88.24% respectively. Overall sensitivity, specificity, positive predictive value, negative predictive value and diagnostic accuracy of ADNEX model in detecting malignant adnexal lesions using histopathology as gold standard was 86.17%, 81.57%, 85.26%, 82.67% and 84.12% respectively. Sensitivity and specificity of ADNEX were 91.4% and 78.9% respectively. Sensitivity and specificity of O-RADS were 91% and 81.9% respectively and prevalence of malignant adnexal lesion was 24.5%.[24] Although O-RADS and the ADNEX model all demonstrated high diagnostic performance, in clinical practice, subjective assessment of pelvic ultrasound images by clinicians with considerable experience in gynecologic ultrasound has demonstrated a high degree of accuracy in differentiating between benign and malignant pelvic lesions. In fact, subjective assessment appears to be the best method to predict the likelihood of a pelvic malignancy. However, clinicians with this level of expertise may not be universally available, presenting a challenge to accurate diagnosis and patient management. Transferring the expertise of experienced ultrasound examiners to less experienced ones poses a significant challenge in the field of gynecologic US. While scoring systems and risk calculation models can potentially assist less experienced examiners in characterizing pelvic lesions, there are valid criticisms regarding the complexity of US information required by some ultrasound-based risk calculation models, particularly outside of specialist centers. One of the primary criticisms of these models is their reliance on sophisticated ultrasonic features and measurements that may be challenging to obtain consistently and accurately by less experienced examiners. Moreover, the interpretation of ultrasound findings can be subjective and may vary among examiners, leading to potential discrepancies in risk assessment and diagnostic accuracy. Considering the low incidence but high mortality rate, risk stratification of adnexal masses is a trade-off between sensitivity and specificity, which should take into consideration a number of factors such as risk tolerance for missing cancer and surgery risk.[25] Therefore, the physician and the patient have to contemplate the risks and benefits of any procedure and determine the individual cutoff in specific circumstances in which the adnexal mass is evaluated.

CONCLUSION

This study found that the O-RADS and ADNEX models for identifying malignant adnexal lesions have nearly equal diagnostic accuracy. Our ability to distinguish between benign and malignant adnexal lesions before surgery has

significantly increased, and it also aids surgeons in making the right decisions. Therefore, we advise routinely using these straightforward and readily accessible techniques in all suspected cases of malignant adnexal lesions prior to surgery and choosing the appropriate surgical strategy.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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AUTHORSHIP AND CONTRIBUTION DECLARATION	
1	**Shamoona Rashid:** Study design.
2	**Hassan Bukhari:** Data analysis.
3	**Sadia Zafar:** Data entry.
4	**Ramsha Javed:** Data collection.