

Exploring the Value of Ovarian-Adnexal Imaging-Reporting-Data System in Evaluating the Malignancy of Ovarian Serous Tumors

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1. Abstract

1.1. Objective: To evaluate the application value of the Ovarian-Adnexal Imaging-Reporting-Data System (O-RADS) in the diagnosis of benign and malignant ovarian serous tumors based on pathological results.

1.2. Methods: A total of 184 patients diagnosed with ovarian serous tumors based on pathological results were included in this study. Two ultrasound physicians with more than 5 years of experience classified the ovarian tumor ultrasound images according to the O-RADS classification criteria in a blinded manner, and compared them with their pathological results. Chi-square test and ridge regression analysis were used to evaluate the ultrasound features of ovarian serous cancer, the efficacy of O-RADS in assessing the benign and malignant nature of ovarian serous tumors, and the differences in ROC curve, AUC, sensitivity, specificity, and accuracy.

1.3. Results: Among the 184 cases of ovarian serous tumors, there were 78 cases of serous cystadenoma, 94 cases of serous adenocarcinoma, and 12 cases of serous borderline tumors, which were classified as malignant. O-RADS 2-3 was considered benign and 4-5 was considered malignant. The sensitivity of O-RADS was 96.9%, specificity was 86.6%, positive predictive value was 79.5%, and negative predictive value was 98.1%. Papillary projections on the cyst wall, irregular solid masses, central blood flow signals, ascites, and/or peritoneal nodules were independent predictors of malignancy, with statistical significance (all $P < 0.01$). The malignancy diagnostic rates of O-RADS 2, 3, 4, and 5 were 0%, 5.9%, 53.1%, and 98.9%, respectively. The AUC of O-RADS ROC curve was 0.921, with a 95% CI value of 0.891-0.963. The O-RADS

classification results showed good consistency between the two ultrasound physicians, with a Kappa value of 0.911 ($P < 0.01$). Conclusion: O-RADS has good value in assessing the benign and malignant nature of ovarian serous tumors.

2. Background

Ovarian cancer is the tumor with the highest mortality rate among gynecological tumors. Its pathological classification is extremely complex, with over 90% of cases being epithelial tumors, among which high-grade serous adenocarcinoma is the most common [1]. Therefore, the risk assessment and grading management of ovarian serous tumors are particularly important, and they play an important role in clinical diagnosis and treatment as well as in improving the survival rate of patients. In 2020, the Ovarian-Adnexal Reporting and Data System (O-RADS) consensus guidelines from the American College of Radiology (ACR) provided an effective reference for the risk classification and grading management of ovarian and adnexal tumors [2]. Based on the characteristics of preoperative ultrasound images in 184 patients with pathologically confirmed ovarian serous tumors, this study explored the value of O-RADS in evaluating the benign or malignant nature of ovarian serous tumors.

3. Materials and Methods

Study Subjects: A total of 184 patients with ovarian serous tumors who were treated at the Department of Obstetrics and Gynecology, the Second Affiliated Hospital of Dalian Medical University from March 2020 to March 2022 were selected. The age of the patients ranged from 14 to 87 years old, with a mean age of 52.1 ± 15.1 years old. Among them, 102 were postmenopausal and 82 were premenopausal, and all had complete ultrasound diagnostic re-

ports, ultrasound images, and pathological results.

3.1. Exclusion criteria were as follows:

1. poor ultrasound image quality and/or incomplete image acquisition;
2. patients taking hormonal medication;
3. pregnant or lactating patients;
4. patients with ovarian tumors who had undergone radiotherapy or chemotherapy.

4. Instruments and Methods

The GE Voluson E8 ultrasound diagnostic equipment and the Mindray Resona 8 ultrasound diagnostic equipment were used with abdominal probes (frequency 3.5-7.5 MHz) and vaginal probes (frequency 2.8-8.2 MHz). Transvaginal ultrasound examination was mainly used, and transabdominal ultrasound examination was performed when necessary. Two ultrasound physicians with more than 5 years of experience blindly classified ovarian tumor ultrasound images according to the O-RADS guidelines [2].

RADS 0 is an incomplete evaluation due to technical factors such as bowel gas, large size of the lesion, location of the adnexa, or inability to tolerate endovaginal imaging.

O-RADS 1, the physiologic category that is relevant only in premenopausal patients, includes the follicle and corpus luteum.

O-RADS 2, the almost certainly benign category (<1% risk of malignancy), comprises the majority of unilocular cysts less than 10 cm. This group includes simple cysts, nonsimple unilocular cysts with smooth walls, and cysts that may be described by using classic benign lesions and their descriptors if less than 10 cm in maximal diameter.

O-RADS 3, the low-risk category (1% to <10% risk of malignancy), includes lesions in the almost certainly benign category that are larger, and other lesions where descriptors apply that denote a slightly higher risk of malignancy. This includes both simple cysts, unilocular smooth nonsimple cysts, and lesions with classic benign descriptors that are greater than or equal to 10 cm. Also included are unilocular cysts with wall irregularity, multilocular cysts less than 10 cm without solid component(s) with a color score less than 4, and avascular solid or solid-appearing lesions with a smooth external contour of any size.

O-RADS 4 refers to the intermediate-risk category (10% to <50% risk of malignancy) includes multilocular cysts that are greater than or equal to 10 cm, or have an irregular inner wall or septal irregularity (<3 mm in height), unilocular and multilocular cysts of any size with a solid component or color score up to 4, and smooth solid lesions (<80% solid) with color score of 2-3. It should be noted that a papillary projection is a type of solid component with

height greater than or equal to 3 mm that arises from the cyst wall or septation and protrudes into the cyst cavity.

O-RADS 5, the high-risk category (>50% risk of malignancy), is comprised of descriptors that are highly predictive of malignancy such as irregular solid lesions and multilocular cysts with a solid component and high color score) The presence of ascites and/or peritoneal nodules would also indicate an O-RADS 5 score except when there is ascites in association with a physiologic cyst or almost certainly benign lesion.

Statistical analysis SPSS 25.0 software was used for statistical analysis. χ^2 test and ridge regression analysis were used to draw the ROC curve based on the pathological results, and the maximum AUC index was selected, and its specificity, sensitivity, positive predictive value, negative predictive value, and diagnostic accuracy were calculated. In addition, the Kappa consistency test was performed on the O-RADS classification of the two physicians. If we obtain a p value that is less than 0.05, we would conclude that the difference is statistically significant, which means that the probability of observing such a difference by chance alone is less than 5%.

5. Results

Among the 184 cases of ovarian serous tumors, there were 78 cases of serous cystadenoma, 94 cases of serous adenocarcinoma, and 12 cases of serous borderline tumors, with the borderline tumors being classified as malignant, resulting in 78 benign cases and 106 malignant cases. According to the O-RADS classification, there were 30 cases of O-RADS 2, 34 cases of O-RADS 3, 32 cases of O-RADS 4, and 88 cases of O-RADS 5. Compared with the pathological results, the malignant diagnosis rates were 0%, 5.9%, 53.1%, and 98.9%, respectively (Table 1). Using O-RADS 2- O-RADS 3 as negative and O-RADS 4- O-RADS 5 as positive, the sensitivity of O-RADS was 96.9%, specificity was 86.6%, positive predictive value was 79.5%, and negative predictive value was 98.1%. The AUC of the ROC curve was 0.921, with a 95% confidence interval of 0.891 to 0.963 (Figure 1). Univariate analysis of malignant ultrasound features found that, except for whether the cyst wall was accompanied by papilla ($P=0.679$), the other features showed statistical differences between the benign and malignant groups (all $P<0.01$) (Table 2). Multivariate ridge regression analysis found that papillary projections on the cyst wall, irregular solid components, central blood flow signals, and ascites and/or peritoneal nodules were independent predictors of malignant tumors (all $P<0.01$) (Table 3). The Kappa consistency test was performed on the results of the participating physicians in the O-RADS classification, with a Kappa value of 0.911 and $P<0.01$, indicating good consistency among the observers (Figure 2).

Table 1: Malignancy rates in the O-RADS for adnexal masses stratified

| Category | Total no. (n = 184) | | Calculated malignancy rate (%) |
|----------|---------------------|-------------------|--------------------------------|
| | benign (n=78) | malignant (n=106) | |
| O-RADS 2 | 30 | 0 | 0% |
| O-RADS 3 | 32 | 2 | 5.90% |
| O-RADS 4 | 15 | 17 | 53.10% |
| O-RADS 5 | 1 | 87 | 98.90% |

Table 2: Descriptions were used to differentiating benign and malignant ovarian masses by One-way ANOVA

| Description | Final diagnosis | | Chi-square value | p value |
|--------------------------------------|-----------------|------------|------------------|---------|
| | benign | malignant | | |
| cyst | | | | |
| smooth wall | 72 (92.3%) | 96 (91.2%) | 0.172 | 0.679 |
| solid papillary projections | 6 (7.7%) | 10 (8.8%) | | |
| solid or predominantly solid lesions | | | | |
| regular | 78 (100%) | 28 (37.1%) | 99.631 | <0.001 |
| irregular | 0 (0%) | 78 (62.9%) | | |
| Internal blood flow | | | | |
| solid CS 1-2 | 1 (0%) | 78 (63.7%) | 92.948 | <0.001 |
| solid CS 3-4 | 77 (100%) | 28 (36.3%) | | |
| Ascites or metastases | | | | |
| Yes | 1 (0.13%) | 58 (54.0%) | 58.899 | <0.001 |
| No | 77 (99.87%) | 48 (46.0%) | | |
| the size of the tumor | | | | |
| >10cm | 14 (17.9%) | 73 (68.9%) | 46.74 | <0.001 |
| ≤ 10cm | 64 (82.1%) | 33 (31.1%) | | |

Table 3: Multifactor ridge regression analysis of ultrasound features of ovarian serous carcinoma.

| Description | Unstandardized coefficient | | Standardized coefficient | t value | P value | R ² | F |
|--|----------------------------|----------|--------------------------|---------|---------|----------------|----------------|
| | B value | SE value | Beta | | | | |
| Cyst-solid papillary projections | 0.344 | 0.07 | 0.196 | 4.933 | 0 | 0.618 | 57.703 (0.000) |
| solid or predominantly solid lesions irregular | -0.318 | 0.044 | -0.318 | -7.216 | 0 | | |
| Internal blood flow solid CS 3-4 | 0.296 | 0.044 | 0.296 | 6.662 | 0 | | |
| Ascites or metastases | 0.139 | 0.047 | 0.131 | 2.958 | 0 | | |
| the size of the tumor >10cm | 0.081 | 0.044 | 0.082 | 1.862 | 0.064 | | |

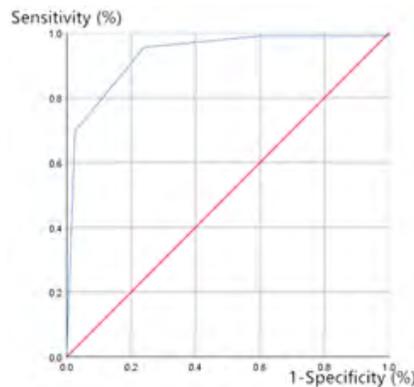


Figure 1: ROC curve of O-RADS



Figure 2: A. Sonogram of high-grade serous cystadenocarcinoma of the ovary (O-RADS 5). B. Serous borderline ovarian tumor (O-RADS 4). C. Serous cystadenoma (O-RADS 3).

6. Discussion

Ultrasound examination is the most commonly used method to evaluate adnexal masses [3], but there is variability in the subjective perception and evaluation experience of the examiner, leading to a lack of relatively objective quantification in ultrasound results. The International Ovarian Tumor Analysis (IOTA) group has proposed using ovarian pathological features as a basis for evaluating the benign or malignant nature of ovarian tumors, providing valuable reference values [4]. O-RADS has referred to the IOTA evaluation system and standardized the description of ultrasound images, reducing the ambiguity in ultrasound reports, and providing O-RADS classification management recommendations for the risk category of ovarian tumors.

The present study identified that several ultrasound features, including papillary projections on the cyst wall, irregular solid components, central blood flow signals, and the presence of ascites and/or peritoneal nodules, were independent risk predictors for ovarian serous carcinoma. These ultrasound findings were associated with an increased risk of malignancy. The malignancy grades of ovarian serous tumors in O-RADS 2, O-RADS 3, and O-RADS 5 were consistent with the recommended risk levels in the guidelines [5]. However, the malignancy rate in O-RADS 4 was higher than the guideline's risk level, and previous studies have also shown that the malignancy rates in all O-RADS are higher than the O-RADS suggested malignancy risk level [6]. In the present study, the malignancy risk in O-RADS 2 was 0%, and the ultrasound diagnosis had a high level of accuracy for distinguishing between benign and malignant tumors. A study [7] showed that the malignancy risk in O-RADS 2 tumors was less than 1%, and the malignancy risk in O-RADS 3 tumors was less than 2%. However, further studies are needed to confirm these deviations.

In this study, the O-RADS AUC was 0.921, and the O-RADS classification demonstrated high specificity and sensitivity in evaluating the malignancy of ovarian serous tumors, indicating that the O-RADS could effectively evaluate the benign and malignant

nature of ovarian serous tumors. The specificity was significantly higher than the study of Solis Cano et al [8]. A study [9] showed that the O-RADS AUC was significantly higher than that of GI-RADS and IOTA, and O-RADS had higher sensitivity, similar specificity, and reliability compared to GI-RADS and IOTA SR. Another study [10] found that the sensitivity of the O-RADS to malignancy and benignity was higher than its specificity. Therefore, O-RADS could provide a basis for choosing diagnostic and treatment options: O-RADS 0-2 classification patients may lean towards conservative treatment, while O-RADS 3-5 classification patients may be more suitable for surgical treatment.

Two ultrasound physicians referred to the O-RADS to classify images of ovarian serous tumors, and there was a high degree of consistency (Kappa value = 0.911) in this study. This is due to the detailed description of ultrasound images in O-RADS, and the clear corresponding grading of images, which makes the scoring of ultrasound physicians repeatable and consistent. However, Lan Cao [7] found that O-RADS lacks descriptions such as echogenicity, and their research found that echogenicity may be a sign of benign lesions, especially helpful in the assessment of solid tumors.

7. Conclusion

O-RADS can effectively evaluate the risk level of ovarian serous tumors with good reproducibility. In this study, O-RADS 3 or above is recommended for surgical treatment, and O-RADS 4 or above indicates extremely high risk of malignancy. Therefore, it can provide guidance for clinical decision-making and management.

8. Limitations of this Study

This study is a retrospective analysis based on surgical patient data, and the comparison of ultrasound images with surgical pathology lacks a comprehensive evaluation of other indicators of tumors, which may overestimate the risk of malignant tumors. Secondly, the study only analyzed ovarian serous tumors and lacked analysis of other pathological types of tumors, which has certain limitations.

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