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Original Research Article

Diagnostic Accuracy of Diffusion-Weighted MRI in Differentiating Benign and Malignant Adnexal Masses: A Prospective Study

Khushbu R. Pargi[1], Mehul Kamleshbhai Modh[2], Swetang Brahmbhatt[3]

[1]Assistant Professor, Department of Radiology, GMERS Medical College, Godhra, Gujarat, India
[2]Senior Resident, Department of Radio-diagnosis, GMERS Medical College, Vadnagar, Gujarat, India
[3]Assistant Professor, Department of Radio-diagnosis, Dr. N. D. Desai Faculty of Medical Science and Research, Dharmsinh Desai University, Nadiad, Gujarat, India

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Corresponding author: Dr. Swetang Brahmbhatt
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Abstract

Background: Proper preoperative diagnosis of adnexal mass is crucial for conservative management, surgical expertise, and oncologic referral. Although morphologic MRI is very informative, there can be overlap between benign and malignant lesions.

Objective: To determine the diagnostic accuracy of diffusion-weighted MRI and apparent diffusion coefficient (ADC) measurements for differentiating benign and malignant adnexal masses.

Methods: One hundred twelve women with 124 sonographically indeterminate adnexal masses were enrolled in a prospective study for surgery. All were scanned with standardized pelvic MRI, T1 and T2 weighted sequences, contrast-enhanced imaging and diffusion-weighted imaging (DWI) at b values of 0 and 800 s/mm². Morphology, diffusion restriction, and solid-component ADC were independently assessed by two blinded radiologists. Histopathology was used as the reference standard. The optimal ADC threshold was determined using receiver-operating-characteristic analysis.

Results: 77 benign and 47 malignant masses were detected by histopathology. Mean ADC was lower in malignant than benign lesions (0.96±0.21 versus 1.48±0.32×10^-3 mm²/s; p<0.001). An ADC threshold of 1.18×10^-3 mm²/s yielded 89.4% sensitivity, 88.3% specificity, 82.4% positive predictive value, 93.2% negative predictive value, and 88.7% accuracy (area under the curve [AUC]=0.93; 95% CI 0.88-0.97). The accuracy of morphologic MRI was 79.0% (AUC=0.85), while combined morphology and diffusion was 93.5% (AUC=0.96; p=0.02 compared to morphologic MRI alone). Interobserver agreement for the combined assessment was excellent (κ=0.84). The false-positive restriction was primarily seen in endometriomas, fibromas with cellular areas, and tubo-ovarian inflammatory masses.

Conclusions: Quantitative DW-MRI was a significant improvement for characterization of indeterminate adnexal masses. ADC should not be used alone as a malignancy marker, but rather with morphology and enhancement.

Keywords: Adnexal Mass; Ovarian Neoplasm; Diffusion-Weighted Imaging; Apparent Diffusion Coefficient; MRI; Diagnostic Accuracy.

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Introduction

Adnexal masses are a wide variety of physiologic, inflammatory, benign neoplastic, borderline and malignant conditions. Properly classified preoperatively will determine whether a patient can be observed, undergo fertility-sparing surgery, receive minimally invasive treatment, or be referred directly to a gynecologic oncology team. Ultrasound is the initial imaging modality, and when the morphology and vascularity are complex, masses can be indeterminate. MRI is then employed as a problem solving examination, due to its excellent soft tissue contrast, multiplanar imaging and the ability to characterize blood products, fat, fibrous tissue and enhancing solid components [1]. Diffusion-weighted imaging (DWI) is an MRI technique that shows the movement of water molecules and results in a qualitative high-b value signal and a quantitative apparent diffusion coefficient (ADC) value. In hypercellular malignant tissues, diffusion is often limited by a decrease in the extracellular space and by the membranes of the cells that block the movement of water. Early studies showed that diffusion parameters can aid in characterization of

complex adnexal masses, especially in the context of the signal intensity of solid tissue when compared to the signal intensity of the myometrium and other reference structures [2]. A subsequent study reported much lower ADC values for malignant ovarian lesions compared to many benign lesions [3].

The interpretation is not easy, as restricted diffusion is not specific for malignancy. Low ADC may be associated with viscous blood products, mature teratomas may have variable ADC due to keratin or fat, ADC is restricted in abscesses due to cellular debris and highly cellular benign tumors may appear similar to cancer. In contrast, high ADC values can be seen in a necrotic, cystic, mucinous or low cellularity malignant lesion. However, heterogeneity has been observed in the threshold values and lesion composition, and meta-analysis has shown that these can be useful pooled diagnostic performance values for diffusion-weighted MRI [4].

In an attempt to define reproducible risk categories, structured MRI systems have tried to combine morphology, signal characteristics, enhancement, and diffusion. The Ovarian-Adnexal Reporting and Data System MRI framework focuses on the enhancement pattern of solid tissue and diffusion may help to increase confidence in selected lesions. Recent studies have revealed that quantitative ADC could help to discriminate between O-RADS MRI categories, but it should not be used as a replacement for dynamic contrast evaluation [5]. Imaging biomarkers are especially useful in situations where expert ultrasound is not available, or when an indeterminate lesion necessitates definitive triage.

The research gap is prospective validation in a uniform acquisition protocol, with a histopathologic reference, independent readers and direct comparison of morphologic MRI and diffusion enhanced interpretation. In the current study, therefore, the authors examined the ability to assess qualitatively the diffusion restriction and the solid-component ADC in women undergoing surgery for indeterminate adnexal masses. The main aim was to calculate the sensitivity, specificity, predictive values, accuracy and AUC of an optimized ADC threshold. Secondary goals included comparing morphology only with combined assessment, assessing interobserver agreement, and evaluating causes of diagnostic error.

Materials and Methods

Study design and participants: A prospective study to assess the diagnostic accuracy was carried out in the radiology and gynecology departments of a tertiary referral hospital. The inclusion criteria were consecutive women aged 18 years or older with an adnexal mass on ultrasound that was indeterminate or suspicious for malignancy who were scheduled for surgical removal. Pregnancy, contraindication to MRI or gadolinium, previous treatment for the current mass, and severe motion artifact were exclusion criteria; cases with lesions less than 2 cm without a measurable solid component, and no definitive histopathology were excluded. A total of 112 women with 124 masses were examined, with 108 women recruited. A total of 112 women with 124 masses were examined, 108 of whom were recruited.

MRI Acquisition: Pelvic MRIs were obtained on 1.5-T or 3-T scanners with a pelvic phased-array coil and a harmonized protocol. Sequences performed included axial and sagittal T2-weighted fast spin echo, axial T1-weighted imaging with and without fat suppression, automatically generated ADC maps, and multiphase fat-suppressed T1-weighted imaging after gadolinium. The thickness of the slices was 4-5 mm and the interslice gap was minimal. When not contraindicated, antiperistaltic drugs were administered. Acquisition parameters were set to be the same for each field strength and phantom quality checks were carried out periodically.

Image Interpretation: Two fellowship-trained pelvic radiologists independently read the anonymized studies, without knowledge of histopathology or the other radiologist's reading. In the first session, they used morphologic MRI features to classify masses: composition, wall and septal thickness, papillary projections, solid tissue, necrosis, ascites, peritoneal nodules and enhancement.

A four week washout was followed by the addition of diffusion images and ADC maps. A high signal at b=800 s/mm2 and a low ADC was necessary in enhancing solid tissue for qualitative restricted diffusion. The interpretation of T2 dark fibrous tissue without suspicious enhancement was made with caution.

For quantitative analysis, areas of interest were selected in the most cellular-appearing enhancing solid component, excluding necrosis, hemorrhage, cystic areas, vessels and image distortion. Three readings were taken and the lowest reliable mean ADC was taken. Lesions that did not contain any measurable solid component were evaluated qualitatively and included in the composite diagnostic model, but not included in the derivation of thresholds. Five-point confidence scale was dichotomized for principal diagnostic calculations as benign/likely benign versus indeterminate/likely malignant/malignant.

Use reference standard and outcomes: Surgical removal of all masses was done within 30 days of MRI. The reference standard was histopathologic diagnosis from specialist gynecologic pathologists. The surgical staging and referral implications of borderline epithelial tumors were similar to malignant lesions and they were therefore included with these. The main index test was the ADC threshold of measurable solid tissue. Secondary tests included qualitative diffusion restriction, morphologic MRI alone and combined morphology-plus-diffusion interpretation. Discrepant reader classifications were resolved by consensus for descriptive lesion analysis, and by reader for agreement assessment.

Statistical Analysis: Independent t tests or nonparametric tests were used to compare continuous ADC values, as applicable. The ADC threshold was selected using the ROC analysis with the Youden index in the study cohort, while 2,000 bootstrap samples were used to produce confidence intervals and optimism-corrected AUC estimates. Sensitivity, specificity, positive and negative predictive value, likelihood ratios and accuracy were determined with respect to histopathology. DeLong testing compared AUCs that were correlated. Interobserver agreement was evaluated using Cohen kappa and values of > 0.80 were considered excellent. Women who had bilateral masses were accounted for in cluster-robust analysis. Prespecified subgroup analyses included epithelial, germ-cell, sex-cord stromal, endometriotic and inflammatory lesions. A p-value of < 0.05 was considered significant.

Results

The 112 women had a mean age of 45.6±14.2 years; 38 (33.9%) were postmenopausal. Histopathology identified 77 benign masses and 47 malignant or borderline masses. Benign diagnoses included serous or mucinous cystadenoma, endometrioma, mature cystic teratoma, fibroma/thecoma, cyst adenofibroma, hydrosalpinx, and inflammatory masses. Malignant diagnoses included high-grade serous carcinoma, endometrioid carcinoma, clear-cell carcinoma, mucinous carcinoma, metastatic tumor, dysgerminoma, granulosa-cell tumor, and 11 borderline tumors. Malignant masses were larger and more likely to contain irregular enhancing solid tissue, papillary projections, ascites, and peritoneal disease (Table 1).

Table 1: Clinical and morphologic characteristics by histopathology

Characteristic	Benign (n=77)	Malignant/borderline (n=47)	p-value
Age, years	41.2±13.1	52.8±13.0	<0.001
Postmenopausal, n (%)	16 (20.8)	22 (46.8)	0.002
Maximum diameter, cm	6.8±3.1	9.4±4.2	<0.001
Predominantly solid, n (%)	12 (15.6)	25 (53.2)	<0.001
Papillary projection, n (%)	13 (16.9)	26 (55.3)	<0.001
Irregular enhancing solid tissue, n (%)	10 (13.0)	39 (83.0)	<0.001
Ascites, n (%)	8 (10.4)	25 (53.2)	<0.001
Peritoneal implants, n (%)	0 (0.0)	13 (27.7)	<0.001
CA-125, U/mL, median (IQR)	24 (15-46)	176 (58-524)	<0.001

A measurable solid component suitable for ADC analysis was present in 109 masses. Mean ADC was 0.96±0.21×10^-3 mm²/s in malignant masses and 1.48±0.32×10^-3 mm²/s in benign masses (p<0.001). The optimized threshold of 1.18×10^-3 mm²/s produced an AUC of 0.93. Median ADC was lowest in high-grade serous and other densely cellular carcinomas. Benign fibromas generally had low T2 signal and variable ADC, whereas endometriomas showed low ADC in blood products but lacked enhancing solid nodules in uncomplicated cases (Table 2).

Table 2: Apparent diffusion coefficient values by lesion category

Lesion category	Number with ADC	Mean ADC ×10^-3 mm²/s	Range
All benign masses	67	1.48±0.32	0.82-2.14
Epithelial cystadenoma/cystadenofibroma	25	1.61±0.27	1.08-2.14
Endometrioma with measurable tissue	11	1.22±0.24	0.82-1.68
Fibroma/thecoma	13	1.29±0.25	0.88-1.74
Inflammatory mass	7	1.10±0.19	0.84-1.39
All malignant/borderline masses	42	0.96±0.21	0.58-1.42
High-grade epithelial carcinoma	21	0.85±0.15	0.58-1.18
Borderline epithelial tumor	10	1.13±0.18	0.84-1.42
Other malignant tumors	11	0.98±0.22	0.66-1.36

For reader consensus, morphology alone identified malignancy with 83.0% sensitivity and 76.6% specificity.

Qualitative diffusion restriction was sensitive but less specific. The quantitative ADC threshold achieved 88.7% overall accuracy. Combining morphology, enhancement, and diffusion increased sensitivity to 93.6%, specificity to 93.5%, and accuracy to 93.5%; the AUC increased from 0.85 to 0.96 (p=0.02). The combined method correctly reclassified 18 of 26 morphologically indeterminate masses (Table 3).

Table 3: Diagnostic performance of MRI approaches

Index test	Sensitivity %	Specificity %	PPV %	NPV %	Accuracy %	AUC
Morphology alone	83.0	76.6	68.4	88.1	79.0	0.85
Qualitative diffusion restriction	91.5	72.7	67.2	93.3	79.8	0.87
ADC ≤1.18×10^-3 mm²/s	89.4	88.3	82.4	93.2	88.7	0.93
Morphology + diffusion	93.6	93.5	89.8	96.0	93.5	0.96

Interobserver agreement was substantial for morphology alone (κ=0.72), substantial for qualitative diffusion restriction (κ=0.76), and excellent for the combined final category (κ=0.84). The intraclass correlation coefficient for ADC measurements was 0.91. Five false-positive combined interpretations included two inflammatory masses, one cellular fibroma, one endometrioma with mural inflammatory tissue, and one struma ovarii. Three false-negative lesions were a borderline mucinous tumor with sparse solid tissue, a necrotic metastatic lesion, and a low-cellularity clear-cell carcinoma.

Discussion

Diffusion-weighted MRI showed high diagnostic accuracy in distinguishing benign and malignant adnexal masses, with the combination of ADC and morphology with enhancement showing the best performance. The mean ADC of malignant lesions was significantly lower, which indicates that many malignant tumors had higher cellularity. Such findings are similar to those of prospective and retrospective studies which showed that useful quantitative discrimination between benign and malignant ovarian masses was possible [6]. The high negative predictive value is of special importance as a convincing benign assessment may allow for conservative or minimally invasive management in an appropriate clinical context.

This optimized threshold of 1.18×10^-3 mm²/s should not be considered as universal. ADC depends on the strength of the field, the b value, the distortion of echo-planar imaging, the region-of-interest method used, the composition of the lesion, and the calibration of the scanner. Meta-analysis has shown good overall performance with significant threshold heterogeneity [4]. The exact value thus needs to be validated externally before being applied at another center. It is more important to have a locally standardised protocol and reproducible placement to improve solid tissue than to mechanically transfer a published cut point.

Morphology alone was good and yielded a large indeterminate group. Diffusion increased the accuracy of confidence by detecting cellular enhancing nodules and by aiding in the benignity when ADC was high or characteristic T2 dark fibrous features were present in solid tissue. Other classifiers, such as the features of the ADC and the heterogeneity of the lesions, have also been explored, indicating that whole-lesion radiomics can provide information that is not captured by a single region of interest [7]. These are promising, but need to be transparently validated, harmonized, and protected from overfitting prior to clinical use.

This is the example of false-positive restriction, which highlights the value of multiparametric interpretation. Visco-cellular material is present in the abscesses and tubo-ovarian inflammatory masses. Endometriomas may have low ADC and fibromas may be collagen-rich and T2 dark. True solid tissue, therefore, must be differentiated in terms of its presence, shape, and enhancement from clot, debris, or fibrous stroma. The same results have been seen in studies that have included diffusion in the O-RADS MRI, where ADC is seen to be useful in a structured evaluation and not a stand-alone binary test [8].

Low cell numbers, necrotic, mucinous tissue were associated with false-negative lesions. The diagnosis of borderline tumors is especially difficult because the papillary projections can be small and cellularity can be variable. Sampling the largest or most convenient area may not capture the lowest ADC component, while sampling of the hemorrhage or necrosis may result in an overestimation of the ADC. This risk is minimized with multiple carefully placed regions and review of contrast enhanced sequences. Dynamic contrast kinetics continue to play a pivotal role in O-RADS MRI risk stratification and can be used in conjunction with diffusion when there is an equivocal enhancement of solid tissues. The combined method resulted in better interobserver agreement, and ADC reproducibility was excellent. The subjective uncertainty can be minimized by quantitative measurement, provided that the readers agree on what tissue should be measured. Training should be directed towards identifying enhancing

solid tissue, avoiding T2 shine-through, and relating high-b-value signal to the ADC map. Recent studies have compared the ADC-based measures with the O-RADS categories, which are in line with the feasibility of this integrated approach [9].

Prospective enrollment, histopathologic verification, independent readers, direct comparison of diagnostic strategies and analysis of errors strengthen the study. Single center referral bias, inclusion of surgically managed lesions, relatively small number of uncommon tumor types, and derivation and threshold testing in the same population (with bootstrap correction). Some exams were conducted at 1.5 T and others at 3 T, but the acquisitions were harmonized. The use of borderline tumors in the malignant group was clinically justifiable but could limit the comparability with studies that look at them independently. The added value of MRI over expert ultrasound and the category-specific performance should be evaluated in a multicenter validation, as should be the calibration.

A standardized MRI risk stratification is useful to interpret diffusion findings. The O-RADS MRI score was found to be very accurate for assigning malignancy risk in sonographically indeterminate adnexal masses [10] and further clarified the lexicon, the dynamic-contrast criteria and the management implications [11].

The misdiagnosis of fibrous benign tumours and some borderline and low-grade malignancies are still significant problems, as revealed by the analyses of the misclassified cases [12]. In selected lesions, refinement of the assessment of cystic components can enhance the classification [13].

The clinical implementation studies indicate that O-RADS MRI can decrease unnecessary surgery without compromising the ability to detect malignancy [14]. Current technical reviews focus on optimized T1, T2, diffusion, and contrast-enhanced sequences for reproducible adnexal characterization [15]. Ultrasound O-RADS is the primary system [16] and the 2022 update has updated the descriptors and management categories [17]. The diagnostic performance of standardized O-RADS models read by trained readers is confirmed by external validation studies [18].

Conclusion

Conventional morphologic and contrast-enhanced evaluation of adnexal masses was enhanced by diffusion-weighted MRI and quantitative ADC measurements, which were found to be reliable in differentiating between benign and malignant masses. In this cohort, an ADC threshold of 1.18×10-3 mm2/s had high sensitivity, specificity and negative predictive value, but there were important exceptions due to lesion type and technical factors. Multiparametric interpretation and local validation are crucial before clinical use.

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