Risk stratification of sonographically indeterminate adnexal mass or masses into benignity and malignancy, using Ovarian-Adnexal Reporting and Data System Magnetic Resonance Imaging (O-RADS MRI) score – A cross-sectional study at tertiary care center

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Abstract

Background: A woman presenting with an adnexal mass is a common clinical problem. Correct characterization of the mass is a key to selecting optimal management strategies so as to report with reasonable certainty, those lesions which are benign appearing and may be excluded from surgical management while also reporting malignant appearing lesions with accuracy, to allow for its early surgical intervention. According to IOTA (International Ovarian and Tumor Analysis) Simple Rules on ultrasound examination, between 18 and 31% of adnexal masses are classified as indeterminate. So, Ovarian-Adnexal Reporting And Data System Magnetic Resonance Imaging (O-RADS MRI) score helped distinguish between benign and malignant tumors that were considered indeterminate on ultrasonography.

Objective: To study the risk stratification of the sonographically indeterminate adnexal masses into benign and malignant lesions using O-RADS MRI Score, taking histopathology and/or clinical radiological follow up for 6 months as gold standard.

Materials and methods: Hospital based prospective cross-sectional study was done enrolling 60 patients who presented with sonographically indeterminate adnexal masses in gynecology OPD.

Results: We found that an O-RADS MRI score of ≥4 was associated with malignancy of an adnexal mass, with a sensitivity of 100%, specificity of 85.29% and accuracy of 91.67% in our study. Hence, O-RADS MRI score provides a robust scoring system in differentiating sonographically indeterminate adnexal mass into benign and malignant.

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Conclusion: In our study, we concluded that O-RADS MRI risk scoring system, provides a stratification system for assigning the probability of malignancy to adnexal lesions, especially those considered indeterminate on ultrasound, which will improve communication between radiologists, referring physician and in patient management, so that benign adnexal lesions can avoid unnecessary surgery while those with potential malignancies can be expeditiously referred for oncologic surgical evaluation.

Keywords : Ovarian and Adnexal masses, MRI, USG, ORADS MRI score.

Introduction

A woman presenting with an adnexal mass is a common clinical problem. Correct characterization of the mass is a key to selecting optimal management strategies. The prime goal is to report with reasonable certainty, those lesions which are benign appearing and may be excluded from surgical management, while also reporting malignant appearing lesions with precision and accuracy, to allow for its early surgical intervention, as it is associated with better survival outcomes.[1]

The term 'ad-nexus' means appendage and is described as the region adjacent to the uterus which includes the ovary, fallopian tube, and other associated structures. Adnexal masses are frequently ovarian masses or cysts, but they can also include non-ovarian masses such as para-tubal cysts, hydrosalpinx, peritoneal inclusion cysts, etc. Despite being widespread among women of all ages, they are more frequently found in those who are in the reproductive stage of life.[2]

The possibility of upstaging a limited early-stage ovarian cancer or the chance of sample error, which could lead to a missed cancer diagnosis, make percutaneous biopsy of a suspected adnexal mass contraindicated. Because of this, a considerable percentage of women with benign but sonographically indeterminate adnexal masses endure potentially pointless or overly extensive surgical treatments, despite the low rate of malignant adnexal masses identified at ultrasonography (i.e., 8%–20%)[3,4]. This raises the danger of morbidity and reproductive loss.[4,5]

According to IOTA (International Ovarian and Tumour Analysis) Simple Rules on ultrasound examination [6], between 18 and 31% of adnexal masses are classified as indeterminate, however one estimate from South India by **Shetty et al. in 2019** found a small proportion of 10.7%.[7] Further analysis of the true nature of these indeterminate masses is necessary because histological characterization of them is not achievable which will ensure limited non-cancer surgery and suboptimal cytoreduction and help reduce surgical intervention in cases that ultimately turn out to be benign. [8]

The risk stratification algorithm separated adnexal masses into six fundamental categories (O-RADS 0-5) in accordance with the ORADS MRI lexicon, with risk categories created by the committee based on IOTA data, and helped distinguish between benign and malignant tumors that were deemed ambiguous on ultrasonography using O-RADS MRI score ≥4 associated with increased risk of malignancy. [9]

To assess the validity and accuracy of the O-RADS MRI score, **Aslan et al in 2021**[10] studied 237 masses found indeterminate on ultrasonography. O-RADS MRI score ≥4 showed 96.3% sensitivity, 95.2% specificity, and 95.3% accuracy in predicting malignancy. They concluded that the O-RADS MRI score had high accuracy and validity in distinguishing benign from malignant sonographically indeterminate adnexal masses. A similar study into the diagnostic accuracy of O-RADS MRI score was performed by **Pereira et al in 2022**[11] on 287 adnexal masses They observed a sensitivity of

91.11%, specificity of 94.92%, and overall accuracy of 93.73% for a score of ≥ 4, further supporting the role of O-RADS MRI score for evaluating adnexal masses, especially indeterminate adnexal masses.

Table 1: The five-point classification of O-RADS MRI score consists of the following-

O-RADS MRI Score	Descriptors	Estimated risk of Malignancy
0	Incomplete evaluation (non-applicable)	N/A
1	No ovarian lesion Physiologic findings including follicles, hemorrhagic cysts and corpora lutea ≤3 cm in premenopausal women	N/A
2	Unilocular ovarian cyst containing any type of fluid; no wall enhancement, no enhancing solid tissue. Unilocular ovarian cyst containing simple or endometriotic fluid; smooth enhancing wall, no enhancing tissue. Para-ovarian cysts containing any type of fluid; no enhancing tissue. Simple hydrosalpinx Cyst with lipid content (mature teratoma) and no enhancing solid tissue Smooth solid mass with low signal at T2WI and DWI	<0.5% Almost certainly benign
3	Unilocular smooth-walled ovarian cysts containing proteinaceous, haemorrhagic, or mucinous fluid; no enhancing solid tissue. Hydrosalpinx with non-simple fluid or mural thickening Multilocular cyst with smooth walls and septations Solid tissue components (excluding T2 dark/DWI dark), low-risk DCE curve	~5% Low risk
4	Solid tissue components (excluding T2 dark/DWI dark) with intermediate-risk DCE curve OR enhancement less than or equal to myometrium at 30–40 s (if no DCE) Lesion with lipid content and large volume enhancing tissue	~50% Intermediate risk
5	Solid tissue components (excluding T2 dark/DWI dark) with high-risk DCE curve OR enhancement greater than myometrium at 30–40 s (if no DCE) Peritoneal findings (ascites or nodules)	~90% High risk

Materials and methods

Study type: Qualitative study.

Study Design: Hospital based Prospective cross-sectional study.

Study universe: All patients attending gynaecology OPD in SMS medical college and attached group of hospitals with clinically suspected ovarian and adnexal lesion.

Sampling technique: Every eligible case was included in the study.

Study population: The study included all patients above 18 years of age with clinically suspected ovarian and adnexal lesions.

Study area: Department of Radiodiagnosis, SMS hospital, Jaipur, Rajasthan, India .

Study duration: Data collection for study was started after approval from the institutional research and review board from April 2022 to September 2022.

Sample size: 60 cases were enrolled for the study who met the inclusion criteria.

Equipment : Philips Affinity 70G Ultrasound Machine

3.0 T GE Signa Architect 64 channel MRI machine

Inclusion criteria : Study participants included those, who were more than 18 years of age, willing to give informed consent and considered sonographically indeterminate as per IOTA simple rules, having at-least one from both B (Benign) and M (Malignant) feature or having neither of the B (Benign) or M (Malignant) features.

B (Benign)

1. Unilocular cyst.

2. Presence of solid components with largest diameter <7 mm.

3. Presence of acoustic shadow.

4. Smooth multilocular tumor with largest diameter <100 mm.

5. No blood flow on colour Doppler. (CS=1)

 M (Malignant)

1. Irregular solid tumor

2. Presence of ascites

3. At-least 4 papillary structures.

4. Irregular multilocular-solid tumor with largest diameter >100 mm.

5. Very strong blood flow (CS=4)

Exclusion Criteria: Patients who were unfit or contraindicated for MRI or MR contrast agents were excluded from the study.

Results and Discussion

60 patients having adnexal mass (or masses) on ultrasonography categorized as indeterminate as per IOTA simple rules were included in the study. MRI was done for all patients. The final diagnosis was established with histopathological findings in 39 cases (65%) and findings on clinical-radiological follow up in 21 cases (35%).

The present study was undertaken to score sonographically indeterminate adnexal mass O-RADS MRI score. The study comprised of 60 patients labelled as indeterminate by IOTA Simple Rules on initial ultrasonographic examination, were taken up for the study, confirmed by histopathological findings in 39 cases and clinico-radiological follow up in 21 cases.

In our study, benign adnexal lesions accounted for 56.7% of total lesions, while malignant lesions accounted for 43.3% of total lesions. These rates of malignancy are similar to those obtained by Pereira et al (47.3%)[60], but higher than those obtained by Aslan et al (11.9%)[59] likely due to our institution being a tertiary care center and our stringent inclusion criteria of IOTA indeterminate adnexal masses.

Score wise analysis of adnexal masses

29 out of 60 lesions were categorized as O-RADS MRI 1-3, all of which were confirmed as benign on follow up. (i.e., observed malignancy rate=zero).

31 out of 60 lesions were categorized as O-RADS MRI 4-5, of which all O-RADS MRI 4 lesions (**9** out of 60) were malignant on follow up. **22** out of 60 lesions were scored as O-RADS MRI 5, out of which, **5** lesions were found to be benign i.e., false positive; remaining **17**

lesions were found to be malignant. (i.e., observed malignancy rate= 77.2%).

The five lesions which were misclassified as malignant were two patient each of tubo-ovarian mass & chronic pyogenic tubo-ovarian mass and one patient of chronic ectopic pregnancy.

Diagnostic accuracy of O-RADS MRI.

Using O-RADS Score ≥4 for diagnosing malignant lesions in our study, we obtained sensitivity of 100%, specificity of 85.29%, and accuracy of 91.67%.

To assess the validity and accuracy of the O-RADS MRI score, **Aslan et al in 2021**[10] studied 237 masses found indeterminate on ultrasonography. O-RADS MRI score ≥4 showed 96.3% sensitivity, 95.2% specificity, and 95.3% accuracy in predicting malignancy. They concluded that the O-RADS MRI score had high accuracy and validity in distinguishing benign from malignant sonographically indeterminate adnexal masses.

A similar study into the diagnostic accuracy of O-RADS MRI score was performed by **Pereira et al in 2022**[11] on 287 adnexal masses They observed a sensitivity of 91.11%, specificity of 94.92%, and overall accuracy of 93.73% for a score of ≥ 4, further supporting the role of O-RADS MRI score for evaluating adnexal masses, especially indeterminate adnexal masses.

Our study achieved the highest sensitivity compared to other authors.

Conclusion

In our study, we concluded that O-RADS MRI risk scoring system (using O-RADS MRI score of ≥4 was associated with malignancy), provides a robust stratification system for assigning the probability of malignancy to adnexal lesions, especially those considered indeterminate on ultrasound, based on MRI features, which will improve communication between radiologists and referring physician and in patient management, so that women with benign adnexal lesions can avoid unnecessary surgery while those with potential malignancies can be expeditiously referred for oncologic surgical evaluation.

Limitations of the study:

1. There was a smaller and single center study, larger and multicenter studies are required for better correlation of our findings.

2. Our institute being a tertiary care center, resulted into higher number of malignant lesions.

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Legend Tables and Figures

Table 1: Distribution of lesions according to final diagnosis (n=60 lesions)

	Final diagnosis	No. of patients (60)	Percentage of total cases (%)
BENIGN (n=34)	Serous cystadenoma	4	6.7
	Mucinous cystadenoma	3	5
	Tubercular tubo-ovarian mass	4	6.7
	Chronic pyogenic tubo-ovarian mass	2	3.3
	Endometrioma	3	5
	Peritoneal inclusion cyst with haemorrhage	2	3.3
	Chronic ectopic pregnancy	3	5
	Adnexal torsion	2	3.3
	Mature teratoma	4	6.7
	Fibroma	2	3.3

	Ruptured haemorrhagic cyst	5	8.3
MALIGNANT (n=26)	Serous cystadenocarcinoma	6	10
	Mucinous cystadenocarcinoma	5	8.3
	Immature teratoma	5	8.3
	Granulosa cell tumour	3	5
	Krukenberg tumour	2	3.3
	Primary fallopian tube cancer	1	1.7
	Low grade serous papillary cancer	4	6.7
TOTAL		60	100
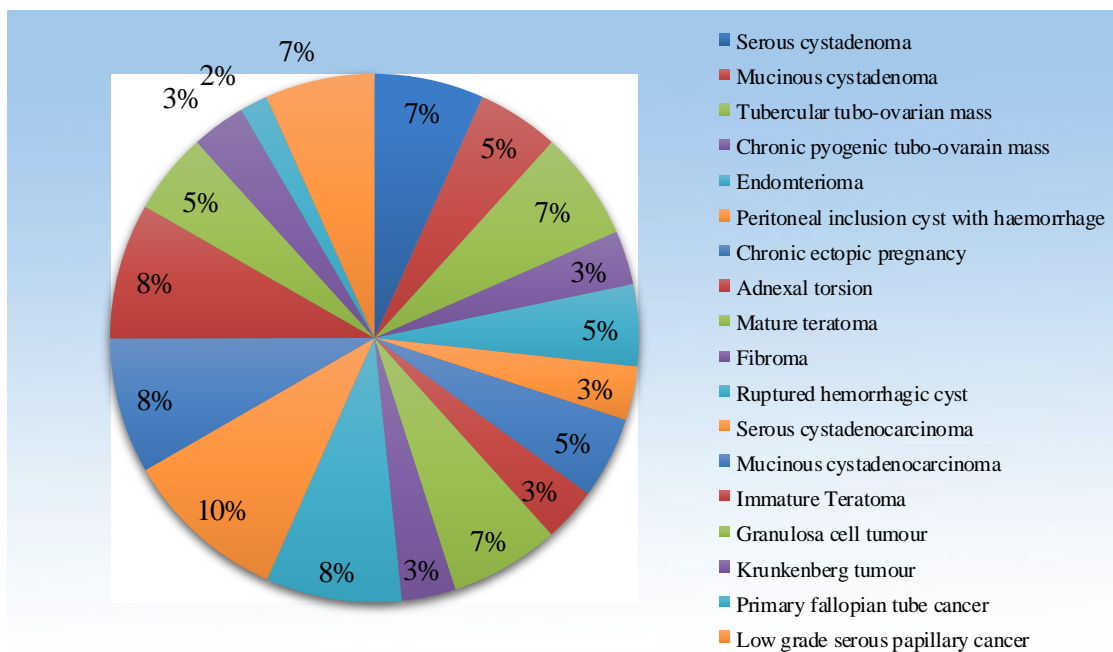
Table 2: Details of adnexal masses erroneously categorized with the O-RADS MRI score (false negatives).

False Negative	Interpretation
Chronic pyogenic tubo-ovarian mass (2)	Showed TIC type 3 curve
Tubercular tubo-ovarian mass (2)	Showed TIC type 3 curve
Chronic ectopic pregnancy	Showed TIC type 3 curve

In our study, no lesions were categorized as false positives i.e. all benign appearing lesions (O-RADS MRI 1-3) were confirmed benign on follow up examination.

Table 3: Dichotomized O-RADS MRI score for benign and malignant masses (n=60)

O-RADS MRI score	Disease status according to reference standard	
	Malignant	Benign
Malignant (4-5)	26	5
Benign (1-3)	0	29

Table 4: Comparison of diagnostic performance of O-RADS MRI score ≥4 for detecting malignancy in our study.

Parameter	Current study
Sensitivity	100.00%
Specificity	85.29%
Accuracy	91.67%

Case Illustrations :

A 49-year-old premenopausal woman, presented with loss of appetite & weight and lower abdominal pain.
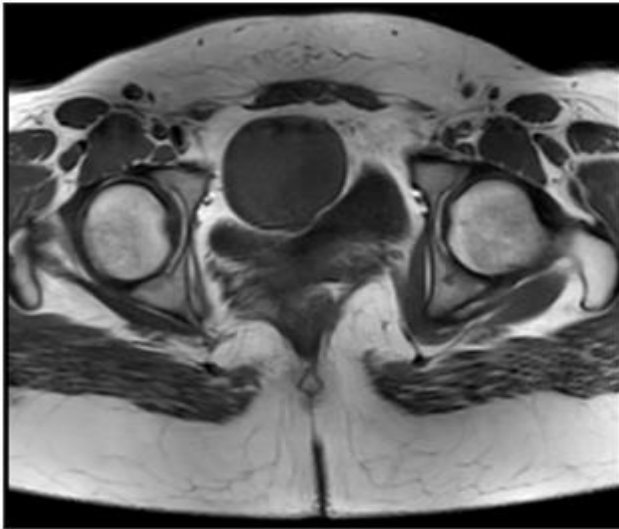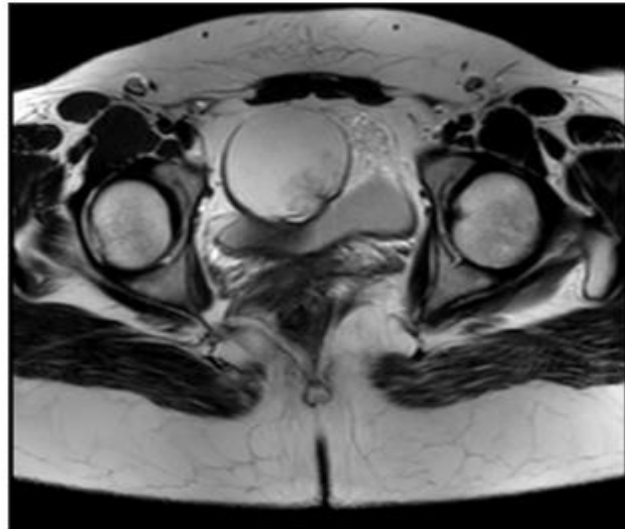
Figure (A): Axial T1
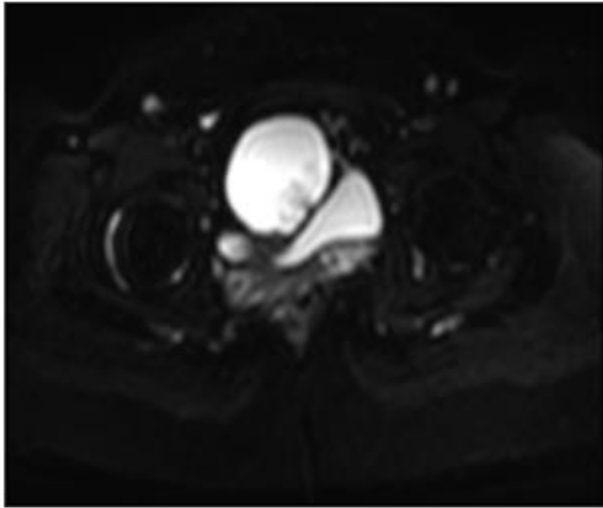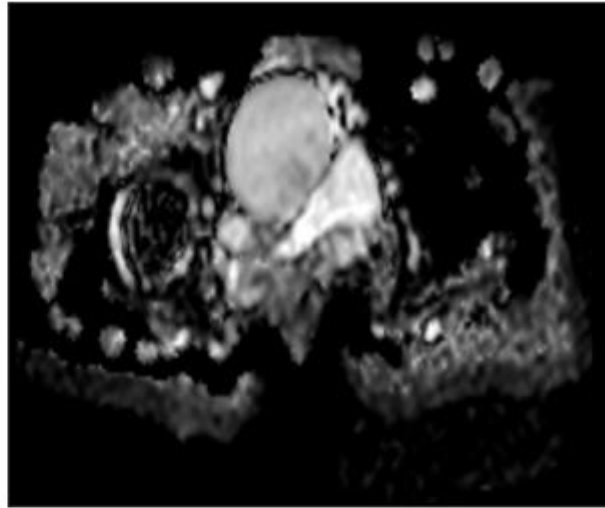
Figure (B): Axial T2
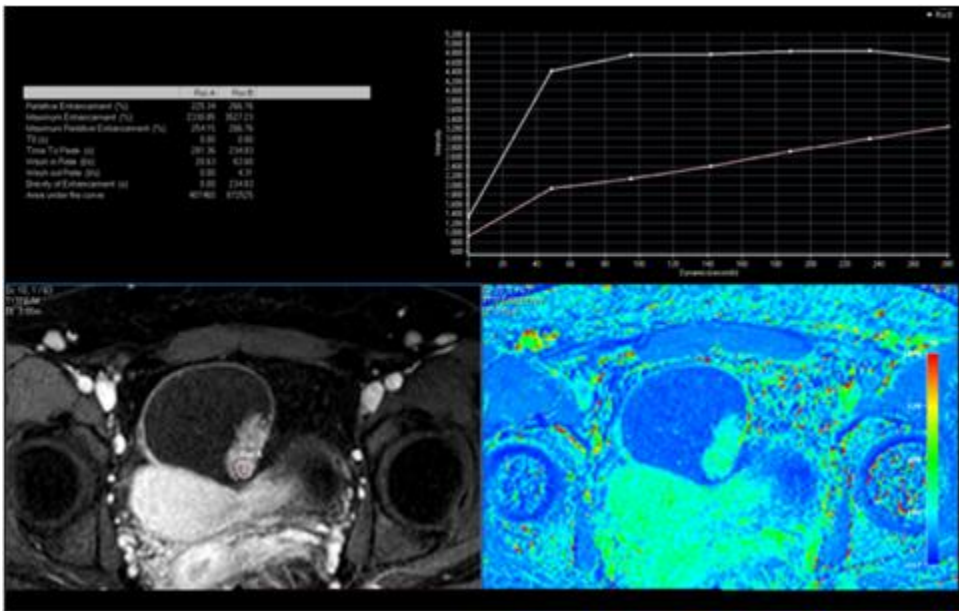
Figure (C): Axial DWI

Figure (D): Axial ADC

Figure (E): Dynamic contrast scan with TIC curve

Figure (A) - (E): On MRI, a well-defined unilocular cystic lesion appearing homogenously hypointense on T1 and hyperintense on T2 was seen in right adnexa, right ovary was not visualized. The lesion showed few irregular solid tissues (papillary projections) within it, appearing homogeneously hypointense on T1 and heterogeneously hyperintense on T2, with patchy areas of diffusion restriction on DWI-ADC images. The solid tissue showed significant contrast enhancement, and on DCE-MRI showed TIC type 2 (Intermediate curve).

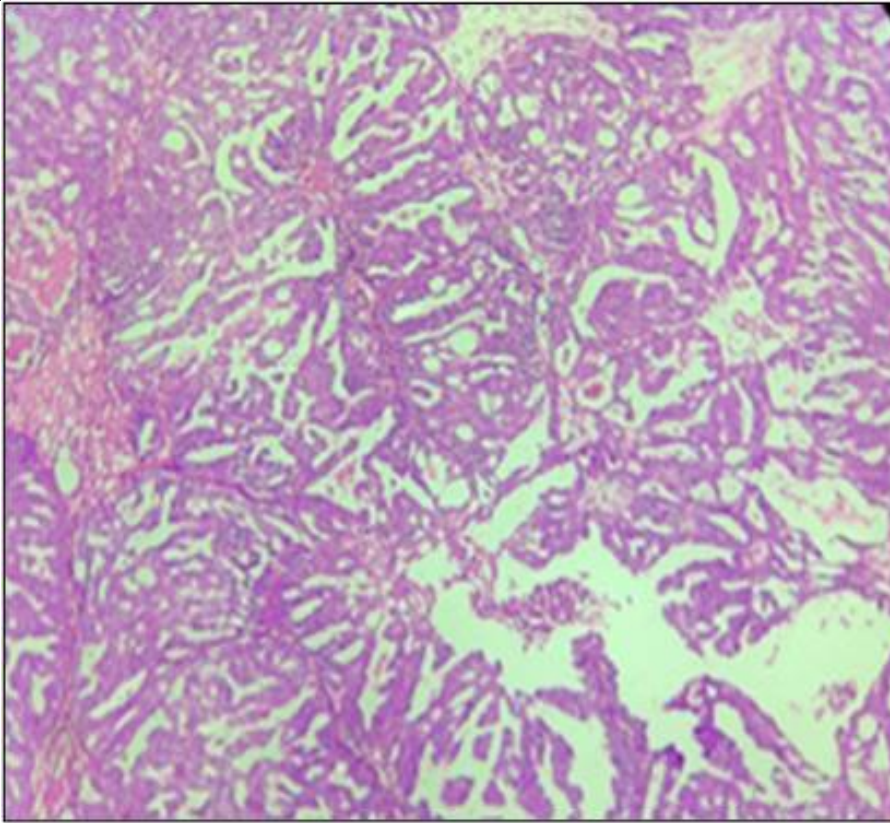According to O-RADS MRI Score: The lesion was categorized as O-RADS MRI: 4 (Suggestive of malignant etiology).

Figure (H): Histopathology: Histopathology confirmed the diagnosis of low grade serous papillary cystadenocarcinoma.